ISO/TS 16949:2009 Checklist – QWBT issue

Ref.	Question *(author comments are in italic, 16949 shalls are marked with arrow (>))*	Yes/ No	Comments *[evidence - data - collection plan]*
Advice	1. This is a yes/no checklist question for each 'shall' requirement of the standard. 2. This type of checklist is excellent for verification of conformity to requirements but should not be used for interview questions. 3. This checklist is good tool for management system audits and conformity assessments. 4. The ISO/TS 16949 requirements are **marked with an arrow or greater-than symbol** '**>**' 5. If ISO/TS 16949 and ISO 9001 conflict, ISO/TS 16949 requirements must be followed. 6. Author comments and advice are in italic print.		
4	**Quality management system** *[These are the overall system requirements as indicated by the title of the clause and will be verified as a result of the system audit.]*		
4.1	**General requirements**		
1	Does the established, documented, implemented, and maintained, quality management system meet the requirements of the standard?		
2	Has the organization... • Determine the processes • Determined the sequence & interaction of processes • Determined criteria and methods to ensure effectiveness • Ensured the availability of resources and information • Determined the measuring (where applicable), monitoring and analyzing of these processes • Implemented actions to achieve planned results and continual improvement. [*The requirements will be verified during the audit. Verify that the sequence and interaction of processes was determined in some manner.*]		
3	Are the processes managed in accordance with the requirements of the international standard?		
4	Does the organization control outsourced processes that affect product conformity to requirements?		
5	Is type of extent of control of outsourced processes needed for the QMS defined within the quality management system?		
4.1.1>	**General requirements - Supplemental**		
1>	Is the organization still responsible for conformity to all customer requirements even though there is control over outsourced processes? *[This could have been a note instead of a requirement, but you need to interview management and evaluate data to determine if the organization has attempted to absolve itself from responsibility of customer requirements just because they have outsourced the process.]*		

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4.2	**Documentation requirements**		
4.2.1	**General**		
1	Does the QMS documentation include: a) quality policy and objectives b) a quality manual c) documented procedures and records as required by this standard d) documents and records required by the organization for effective planning operation and control *[ISO 9001 requires six documented procedures for 6 QMS controls, but there may be more than or less than 6 documented procedures to address the requirements.]*		
4.2.2	**Quality Manual**		
1	Is there a quality manual that includes the scope of the QMS, justification for exclusions, and describes the interaction between the processes? *The manual must be documented, but no medium is specified.*		
2	Does the manual contain documented procedures or are they referenced?		
4.2.3	**Control of documents**		
1	Are required QMS documents controlled? *[Identified in 4.2.1. Documents required by the organization need to be identified in some manner.]*		
2	Are there written procedures to control all documents (electronic or hard copy media) required for operating the quality management system? Are they being used?		
3	Are documents approved for adequacy prior to release. *[There may be a need for both content approval and approval for authority to deploy, which may or may not be the same.]*		
4	Are documents reviewed, updated as necessary, and then re-approved?		
5	Is there a method that identifies the current version status of documents?		
6	Are documents (*procedures, instructions*) available at points of use (*locations where quality activities are performed*)?		
7	Are documents legible and readily identifiable?		
8	Are external origin documents necessary for the planning and operation of the QMS identified and distribution controlled?		

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9	Are obsolete documents (*retained for legal and/or knowledge purposes*) suitably identified to prevent unintended use.		

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4.2.3.1>	**Engineering specifications**		
1>	Does the organization have a process to assure the timely review, distribution and implementation of all customer engineering standards/specifications and changes based on customer-required schedule?		
2>	Is the review (*of customer engineering standards/specifications and changes*) conducted within two working weeks?		
3>	Is there a record of the date on which each change is implemented in production?		
4>	Does implementation of changes include updated (*changed*) documents? 16949 NOTE: A change in these standards/specifications requires an updated record of customer production part approval when these specifications are referenced on the design record or if they affect documents of production part approval process, such as a control plan, FMEAs, etc.		
4.2.4	**Control of records** >16949 NOTE: “Records” also include customer-specified records		
1	Are there documented procedures for identifying, storing, retrieval, protection, retention, and disposition of records? Are they being used? >16949 NOTE “Disposition” above includes disposal.		
2	Are records legible, readily identifiable, and retrievable?		
3	Are required records established and controlled?		
4.2.4.1>	**Record Retention**		
1>	Do records control satisfy regulatory and customer requirements?		
	List of required records		

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	Do the following records exist: >Date changes implemented in production (4.2.3.1) Management review (5.6.1) >Achievement of quality objectives and customer satisfaction of product supplied (5.6.1.1) Personnel training (6.2.2) Conformity of processes and products (7.1) Review of customer requirements (7.2.2) Design and development inputs (7.3.2) Design reviews (7.3.4) Design verification (7.3.5) Record of validation results (7.3.6) Review of design changes and actions (7.3.7) Supplier evaluations (7.4.1) Process validation (qualification) (7.5.2) Product identification where traceability is required (7.5.3) Unsuitable customer product (7.5.4) Results of calibration (7.6) Record of non-standard calibration (7.6) Validity of previous results (7.6) >Calibration/verification activities to provide evidence of conformity of product (7.6.2) Results of internal audits (8.2.2) >Significant process events, i.e. repairs (8.2.3.1) >Effective dates of process changes (8.2.3.1) Verification that product passed tests (8.2.4) Record of nonconforming product and actions (8.3) >Customer waiver expiration date and quantity (8.3.4) Results and corrective action taken (8.5.2) >Analysis of parts rejected (8.5.2.4) Results and preventive action taken (8.5.3)		

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5	**Management Responsibility**		
5.1	**Management commitment**		
1	Is there evidence of top management commitment by: a) Communicating the importance of meeting customer and regulatory requirements; b) Establishing a quality policy c) Ensuring there are quality objectives; d) Conducting management reviews; and e) Ensuring availability of resources. *[Verify a through e. See quality policy, verify management reviews taking place and top management involved. a) is linked to 5.5.2 c)]*		
5.1.1>	**Process efficiency**		
1>	Does top management review the product realization processes and the support processes to assure their effectiveness and efficiency?		
5.2	**Customer focus**		
1	Does top management ensure customer requirements are determined and met, with an aim to enhancing customer satisfaction? *[This requirement is linked to 7.2. If there is a 7.2 nonconformity, there may be 5.2 nonconformity. If the organization is not measuring 'customer satisfaction' (8.2.1), or if there is no aim (goal) for enhancing customer satisfaction, there could be a nonconformity.]*		
5.3	**Quality policy**		
1	Has top management ensured there is a quality policy		
2	Is the policy appropriate for the purpose of the organization?		
3	Does the policy include commitment to meeting requirements and continual improvement?		
4	Does the policy statement include provision for: - providing a framework for establishing/ reviewing objectives? - reviewing for continuing suitability of the policy? *[Note: Reviewing should link with management review (5.6) of the suitability of the quality system.]*		
5	Has the quality policy been communicated, understood and implemented within of the organization? *[Note it does not say memorized, although that's one way of demonstrating that it's been communicated, A paraphrased answer may be better because it would demonstrate understanding. Interviewees can also be asked to explain what it means to them.]*		

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5.4	**Planning**		
5.4.1	**Quality objectives**		
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.]*		
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.]*		
5.4.1.1>	**Quality objectives — Supplemental**		
1>	Does top management define quality objectives and measurements? >16949 NOTE: Quality objectives should address customer expectations and be achievable within a defined time period**.**		
2>	Are quality objectives and measurements included in the business plan and used to deploy the quality policy?		
5.4.2	**Quality management system planning**		
1	Does top management ensure QMS planning is carried out to meet quality objectives and requirements in clause 4.1?		
2	When organizational changes are planned and implemented, is the integrity of the management system maintained during the change? *[Note: How does management ensure integrity is maintained? Is there a method or records of actions?]*		
5.5	**Responsibility, authority, and communication**		
5.5.1	**Responsibility and authority**		
1	Have functions responsibility and authority, been defined and communicated? *[May be defined in job descriptions & communicated via organization charts, outline, and so on.]*		
5.5.1.1>	**Responsibility for quality**		
1>	Are managers with responsibility and authority for corrective action promptly informed of products or processes which do not conform to requirements? *[Auditors can identify a situation when a process does not conform and then ask the manager if they were informed. A record such as an e-mail or note would verify the communications.]*		

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2>	Do personnel responsible for product quality have the authority to stop production to correct quality problems?		
3>	Are all production operating shifts staffed with personnel in charge of, or delegated responsibility for,ensuring product quality?		
5.5.2	**Management representative**		
1	Has top management appointed a member within the organization's management with defined authority and responsibility to ensure quality management requirements are established, implemented and maintained? *[A note allows the management representative to be the liaison with external parties. The management representative may be any individual from management.]*		
2	Does the appointed member have authority to report performance to management for review and improvement of the quality management system?		
3	Does the appointed member have authority for ensuring the promotion of awareness of customer requirements throughout the organization? *[Linked to 5.1 a.)]*		
5.5.2.1>	**Customer representative**		
1>	Has top management designated personnel with responsibility and authority to ensure that customer requirements are addressed? Does this include selection of special characteristics, setting quality objectives and related training, corrective and preventive actions, product design and development?		
5.5.3	**Internal communications**		
1	Are there communication processes that communicate the effectiveness of the QMS? *[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**		
1	Are management reviews conducted at planned intervals? *[Look for a schedule or specified intervals in a document or communication of some type.]*		
2	Does top management review the quality system to ensure its continuing suitability, adequacy, and effectiveness?		
3	Are needed changes and opportunities for improvement to the quality management system (policy, objectives) assessed?		

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4	Are there records of management reviews?		
5.6.1.1>	**Quality management system performance**		
1>	Do the reviews include **all** requirements of the quality management system and its performance trends as an essential part of the continual improvement process? *[Are there linkages between reviews and improvement?]*		
2>	Are quality objectives monitored and is the cost of poor quality reported and evaluated? (See 8.4.1 and 8.5.1).		
3>	Is there a record of achievement of 1) quality objectives specified in the business plan, and 2) customer satisfaction with product supplied?		
5.6.2	**Review Input**		
1	Does the review include information about: audit results, customer feedback, process performance and product conformance, status of corrective and preventive actions, follow-up from prior reviews, changes that could effect the QMS, and recommendations for improvement. *[This is also connected to 8.2.1 for customer satisfaction and internal audit performance, 8.2.2.]*		
5.6.2.1>	**Review Input - Supplemental**		
1>	Are actual and potential field failures analyzed for their impact on quality, safety or the environment?		
5.6.3	**Review output**		
1	Do output of reviews relate to either: - Improvement of the QMS and its processes, - Improvement of product related customer requirements - Resource needs?		

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6	**Resource management**		
6.1	**Provision of resources**		
1	Are the resources needed to establish and maintain the QMS determined and provided? Are the resources used to implement, maintain and improve the QMS and enhance customer satisfaction? *[Linked to quality planning at 5.4 and 7.1 planning requirements. A nonconformity would indicate a system-wide breakdown in providing necessary resources.]*		
6.2	**Human resources**		
6.2.1	**General**		
1	Are competent personnel performing work effecting product/ service conformity to requirements, assigned to QMS activities? Is competency based on education, training, skills, and experience?		
6.2.2	**Competence, awareness and training**		
1	Does the organization - Determine competency needs for those affecting conformity to requirements? - Achieve the necessary competency by providing training or other actions? - Evaluate effectiveness of training or other actions? - Ensure employees are aware of the importance of their activities and how they contribute to achievement of objectives?		
2	Are there records? Are appropriate education, training, skills, experience records maintained?		
6.2.2.1>	**Product design skills**		
1>	Does the organization ensure that personnel with product design responsibility are competent to achieve design requirements and are skilled in applicable tools and techniques?		
2>	Are design (applicable) tools and techniques identified?		
6.2.2.2>	**Training**		
1>	Is there a **documented procedure** for identifying training needs and achieving competence of all personnel performing activities affecting product quality? Is it maintained? >16949 NOTE: For clarification that this applies to all employees having an effect on quality at all levels of the organization.		
2>	Are personnel that perform specific assigned tasks qualified? Is particular attention placed on the satisfaction of customer-specific requirements? >16949 NOTE:: An example of the customer-specific requirements is the application of digitized mathematically-based data.		
6.2.2.3>	**Training on the job**		

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1>	Is on-the-job training provided for personnel in any new or modified job affecting product quality, including contract or agency personnel?		
2>	Are personnel, whose work can affect quality, informed about the consequences to the customer of nonconformity to quality requirements?		
6.2.2.4>	**Employee motivation and empowerment**		
1>	Does the organization have a process to motivate employees to achieve quality objectives, to make continual improvements, and to create an environment to promote innovation?		
2>	Does the process to motivate employees include the promotion of quality and technological awareness?		
3>	Is there a process (*method*) to measure the extent to which its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives [see 6.2.2 d)?		
6.3	**Infrastructure**		
1	Has the organization identified, provided and maintained infrastructure to achieve conformity of product? Infrastructure could include workspace, buildings, utilities, equipment, hardware, software, and support services (transportation, communication, information systems). *[Verify that infrastructure items have been determined in some manner (such as in a document). If during the audit, there was a nonconformity as a result of not providing the needed facilities (infrastructure), this clause could be cited]*		
6.3.1>	**Plant, facility and equipment planning** >16949 NOTE: These requirements (for this clause) should focus on lean manufacturing principles and the link to the effectiveness of the quality management system.		
1>	Does the organization use a multidisciplinary approach (see 7.3.1.1) for developing plant, facility and equipment plans?		
2>	Do plant layouts optimize material, travel, handling and value-added use of floor space, and facilitate synchronous material flow?		
3>	Are there methods to evaluate and monitor the effectiveness of existing operations?		
6.3.2>	**Contingency plans**		
1>	Are contingency plans prepared to satisfy customer requirements in the event of an emergency such as utility interruptions, labor shortages, key equipment failure and field returns?		
6.4	**Work environment**		
1	Have factors of the work environment needed to achieve conformity been determined and managed? *[Can the organization provide evidence of how they are determined and manage (control) factors in the work environment? Work environment may include noise, temperature, lighting, humidity, weather, work conditions, ergonomics, and so on.]*		

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6.4.1>	**Personnel safety to achieve product quality**		
1>	Is product safety and means to minimize potential risks to employees addressed? Does it include the design and development process and in-manufacturing process activities?		
6.4.2>	**Cleanliness of premises**		
1>	Does the organization maintain its premises in a state of order, cleanliness and repair consistent with the product and manufacturing process needs?		

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7	**Product realization**		
7.1	**Planning of realization processes**		
1	Is there planning of realization processes? Is it in suitable form consistent with the method of operation? *[Look for something that is documented such as a quality plan, procedure or diagram. It can be an overall plan or individual plans for the realization processes.]*		
2	Is the planning consistent with other requirements of the QMS? Has the organization determined (as appropriate) - quality objectives - requirements for product - need for establishing processes and documents - providing resources for the product - product measuring, monitoring, verification, validation - criteria for product acceptance - records of product and process meeting Requirements		
Note>	>16949 Note: Some customers refer to project management or advanced product quality planning as a means to achieve product realization. Advanced product quality planning embodies the concepts of error prevention and continual improvement as contrasted with error detection, and is based on a multidisciplinary approach.		
7.1.1>	**Planning of product realization**		
1>	Are customer requirements and references to their technical specifications included as a component of the quality plan?		
7.1.2>	**Acceptance criteria**		
1>	Does the organization define acceptance criteria and, when required, is it approved by the customer?		
2>	Is the acceptance level for attribute data sampling zero defects? (See 8.2.3.1).		
7.1.3>	**Confidentiality**		
1>	Does the organization ensure the confidentiality of customer-contracted products and projects under development, and related product information? *[Ask how they ensure confidentiality. Do they restrict access? Are documents marked?]*		
7.1.4>	**Change control** >16949 NOTE: The requirements in this clause applies to both product and manufacturing process changes.		
1>	Does the organization have a process to control and react to changes that impact product realization? *[Does the process include notifying the customer when appropriate, See note]* >16949 NOTE: Any product realization change affecting customer requirements requires notification to, and agreement from, the customer.		

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2>	Are the effects of any change assessed? Are verification and validation activities defined to ensure compliance with customer requirements? Are changes validated before implementation? Does any change include changes caused by suppliers? *[This checklist item has multiple questions but all relate to control of changes that impact product realization. This is not about control of document changes, that would be in clause 4.2.3]*		
3>	Are proprietary designs, impact on form, fit and function (including performance and/or durability) reviewed with the customer?		
4>	When required by the customer, does the organization conform to additional verification/identification requirements? Such as: those required for new product introduction.		
7.2	**Customer-related processes**		
7.2.1	**Identification of customer requirements**		
1	Are customer requirements determined *[identified]*? Do requirements include product requirements, delivery and post delivery activities, not stated requirements but necessary, and obligations such as statutory, regulatory and legal requirements, and additional requirements considered necessary by the organization? *[Verify items the prescriptive list of requirements. For example, there could be a nonconformity for not determining necessary but unspecified customer requirements such as a need for traceability. A note explains that post delivery activities include warranty, contract maintenance, recycle and disposal]*		
	>16949 Note1: Clarifies that post-delivery activities include any after-sales product service provided as part of the customer contract or purchase order. [*The emphasis here is on the customer contract or purchase order*.] 16949 Note 2: This note clarifies that this requirement includes recycling, environmental impact and characteristics identified as a result of the organization's knowledge of the product and manufacturing processes (see 7.3.2.3). *[When supplying a part or product of some kind, recycling or other environmental issues should be specified as well.]* 16949 Note 3: This note clarifies that compliance to item c) (*statutory and regulatory*) includes all applicable government, safety and environmental regulations, applied to acquisition, storage, handling, recycling, elimination or disposal of materials. *[For hazardous issues, an MSDS (material safety data sheet) should be issued as part of the requirements.)]*		
7.2.1.1>	**Review of product requirements**		
1>	Has the organization demonstrated conformity to customer requirements for designation, documentation and control of special characteristics?		
7.2.2	**Review of product requirements**		

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1	Are customer requirements (new or changed contracts, tenders and orders) reviewed prior to commitment?		
2	Are customer requirements defined?		
3	When requirements are not written (documented by the customer), are they confirmed by the organization before acceptance?		
4	Are contracts or order requirements that differ from previous expressed (those in the tender or offer) resolved?		
5	Are customer requirements reviewed to ensure the organization has the ability to meet them?		
6	Are results of reviews and (*follow-up*) actions recorded? Are records maintained?		
7	Are relevant documents amended and personnel notified of order changes?		
7.2.2.1>	**Review of requirements related to the product**		
1>	If the requirements for formal review (in 7.2.2.) have been waived, has it been authorized by the customer. [*If the organization has not conducted a formal review, has the customer okayed it?]*		
7.2.2.2>	**Organization manufacturing feasibility**		
1>	As part of the contract review process, has the organization investigated (including risk analysis), confirmed and documented the manufacturing feasibility of the proposed product(s)?		
7.2.3	**Customer communication**		
7.2.3	Has the organization determined and implemented communication requirements for: a) product/ service information, b) inquiry, contracts, order handling and amendments, c) customer feedback including customer complaints?		
7.2.3.1>	**Customer communication — Supplemental**		
1>	If the customer has specified a specific communication language and format, does the organization communicate information and data according to the language and format requirements (e.g. computer-aided design data, electronic data exchange)?		

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7.3	**Design and development**		
>	16949 Note: The note clarifies that the 7.3 clause includes both product and manufacturing process design and development, and focuses on error prevention rather than detection?		
7.3.1	**Design and development/ planning**		
1	Do project plans exist that determine design stages, review-verification-validation activities, and responsibility and authority. *[verification and validation are design stages]*		
2	Are the interfaces between different design/ verification groups managed to ensure effective communication and clear responsibilities?		
3	Are plans updated as the project progresses?		
7.3.1.1>	**Multidisciplinary approach**		
1>	Does the organization use a multidisciplinary approach to prepare for product realization? (Note: A multidisciplinary approach typically includes the organization's design, manufacturing, engineering, quality, production and other appropriate personnel.) *[Is the following prescriptive list of actions included in developing and planning?]* Does it include: ___development/finalization and monitoring of special characteristics, ___development and review of FMEAs, including actions to reduce potential risks, and ___development and review of control plans?.		
7.3.2	**Design and development inputs**		
1	Are product functional and performance requirements determined and recorded?		
2	Are regulatory and legal requirements determined? *[should include industry standards]*		
3	Are information from previous designs and other essential requirements determined?		
4	Have the requirements been reviewed for adequacy to ensure complete unambiguous or non-conflicting requirements?		
	>16949 Note: There is a reminder that special characteristics (see 7.2.1.1) are included in this requirement/*clause*.		

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7.3.2.1>	**Product design input**		
1>	Does the organization identify, document and review the **product design** input requirements? *[Is the following prescriptive list of actions included in developing design inputs? Note that ISO/TS 16949 uses a style where there may be one "shall" followed by a prescriptive list that must be addressed by QMS organizations.]* Does the review include the following? ___customer requirements (contract review) such as special characteristics (see 7.3.2.3), identification, traceability and packaging; ___use of information: The organization shall have a process to deploy information gained from previous design projects, competitor analysis, supplier feedback, internal input, field data, and other relevant sources, for current and future projects of a similar nature; ___targets for product quality, life, reliability, durability, maintainability, timing and cost.		
7.3.2.2>	**Manufacturing process design input**		
1>	Does the organization identify, document and review the **manufacturing process design input** requirements [*the same as product design and similar lists]?* Does the review include the following? ___product design output data, ___targets for productivity, process capability and cost, ___customers requirements, if any, and ___experience from previous developments**.**		
	>16949 NOTE: The note clarifies that the manufacturing process design includes the use of error-proofing methods to a degree appropriate to the magnitude of the problems and commensurate with the risks encountered. *[This reinforces the use of error prevention techniques throughout the design process (see 7.3 note)].*		

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7.3.2.3>	**Special characteristics**		
1>	Does the organization identify special characteristics (see 7.3.3 d)? ___Are all special characteristics in the control plan? ___Does the organization comply with customer-specified definitions and symbols? ___Does the organization identify process control documents including drawings, FMEAs, control plans, and operator instructions with the customer's special characteristic symbol or the organization's equivalent symbol or notation to include those process steps that affect special characteristics? *[There is only one shall but it has 4 parts.]*		
	>16949 Note: The note clarifies that special characteristics can include both product characteristics and process parameters.		
7.3.3	**Design and development outputs**		
1	Is the design output in a form that is suitable for verification against inputs? *Note: The word document was avoided to provide flexibility, but most organizations document design in the form of drawings, specification sheets in various forms and mediums.*		
2	Does design output meet input requirements?		
3	Does design output provide appropriate information for purchasing, production and service operations (7.5)? *[There may be some type of transition or start-up plan.]*		
4	Does design output contain or reference acceptance criteria? *[These may include items such as performance target values, tolerances and attributes, durability, safety, reliability, maintainability under storage and operating conditions, validation of computer systems and software, statistical validation of tests/ inspections to the appropriate confidence level, etc.]*		
5	Does the design output specify those requirements that are crucial to the safe and proper use of the product? *[These may include operating, storage, handling, maintenance, disposal, reliability and maintainability, serviceability for the product (project) life cycle, project/ product failure, decomposition, etc.]*		
6	Are design outputs approved prior to release?		

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7.3.3.1>	**Product design outputs**		
1>	Does the organization express the **product** design output in terms that can be verified and validated against product design input requirements? Does the product design output include: ___design FMEA, ___reliability results, ___product special characteristics, ___product specifications, ___product error-proofing, as appropriate, ___product definition (including drawings or mathematically-based data), ___product design review results, ___diagnostic guidelines where applicable.		
7.3.3.2>	**Manufacturing process design output**		
1>	Does the organization express the **process** design output in terms that can be verified against manufacturing process design input requirements and are they validated? Does the manufacturing process design output include the following? ___specifications and drawings, ___manufacturing process flowchart/layout, ___manufacturing process FMEAs, ___control plan (see 7.5.1.1), ___work instructions, ___process approval acceptance criteria, ___data for quality, reliability, maintainability and measurability, ___results of error-proofing activities, as appropriate, ___methods of rapid detection and feedback of product/manufacturing process nonconformities. .		
7.3.4	**Design and development review**		
1	Are systematic design reviews conducted according to planned arrangements? Do the reviews include evaluation of ability to meet requirements, and identify problems and propose necessary actions?		
2	Does design review meeting attendance include representatives of functions concerned with the design stage being reviewed?		
3	Are there records of the design reviews?		
7.3.4.1>	**Monitoring**		
1>	Are measures (*progress*) defined for specified stages of design and development? Are they analyzed and reported with summary results used as an input to management review? >16949 Note: Measures can include quality risks, costs, lead-times, critical paths and, so on**.**		

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7.3.5	**Design and development verification**		
1	Is the design verified according to planned arrangements? *[verification such as qualification tests, alternative calculations, or comparison to similar designs, prototype testing, simulation, etc.]*		
2	Are design verification results and required actions recorded?		
7.3.6	**Design and development validation**		
1	Are validation activities performed according to planned arrangements? (Ref. 7.3.1)		
2	Is the design validated to ensure it meets requirements for its specified application or intended use? *[This may include evaluation of the final product or service to ensure it meets specification and performance requirements.]*		
3	Whenever practical is the validation conduct prior to delivery or implementation? *[some designs cannot be validated until they are installed or assembled in place.]*		
4	Are design validation results and any necessary actions recorded?		
	> 16949 Note: The validation process normally includes an analysis of reports, such as field reports for similar products. The requirements of 7.3.5 and 7.3.6 above apply to both product and manufacturing processes.		
7.3.6.1>	**Design and development validation — Supplemental**		
1>	Is design and development validation performed in accordance with customer requirements? Is program timing included?		
7.3.6.2>	**Prototype program**		
1>	Does the customer require a prototype program and control plan? If so, is there a prototype program and control plan?		
2>	Whenever possible, does the organization use the same suppliers, tooling and manufacturing processes as is currently used? [*This will be difficult to audit against but the idea is to control cost and not create new risks if avoidable.*]		
3>	Is prototype performance-testing activities monitored for both timely completion and conformity to requirements? [T*he design personnel will set the timeline. Have they been following it?]*		

Ref.	Question *(author comments are in italic, 16949 shalls are marked with arrow (>))*	Yes/ No	Comments *[evidence - data - collection plan]*
4>	If prototype services are outsourced, does the organization maintain overall responsibility, including technical leadership? [*This process may be managed like a mini project with inputs, outputs and review meetings.]*		
7.3.6.3>	**Product approval process**		
1>	Does the customer recognize the product/process approval process? If so, does the organization conform to the 'product' and 'manufacturing process' approval procedure? >16949 Note: The manufacturing process should be verified before product approval.		
2>	Is the product approval procedure applied to suppliers too?		
7.3.7	**Control of design and development changes**		
1	Are design changes identified, and recorded?		
2	Are changes evaluated for effect on constituent parts and product already delivered? Are changes verified and validated and approved prior to implementation? *[Changes must go back through the same checks as the original.]*		
3	Are review of changes and necessary actions recorded?		
	>16949 Note: Changes include all changes during the product program life (see 7.1.4).		

Ref.	Question *(author comments are in italic, 16949 shalls are marked with arrow (>))*	Yes/ No	Comments *[evidence - data - collection plan]*
7.4	**Purchasing**		
1	Does the organization ensure that incoming purchased product/ service conforms to requirements? Is the type and extent of control dependent on the effect of realization processes? *[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 as critical as it is in manufacturing]*		
2	Are suppliers evaluated and selected on the basis of their ability to supply product/ service that meets organization requirements?		
3	Are there established criteria for evaluation, re-evaluation and selection?		
4	Do supplier records show results of: evaluations and actions arising from the evaluation (*subsequent follow-up actions*)?		
	>16949 Note: Purchased products include all products and services that affect the customer such as sub-assembly, sequencing, sorting, rework, kit building and calibration services.		
7.4.1.1>	**Regulatory conformity**		
1>	Does all purchased product or materials used in product, conform to applicable regulatory requirements?		
7.4.1.2>	**Supplier quality management system development**		
1>	Does the organization perform supplier QMS development with a goal of supplier conformity with this Technical Specification (with conformity with ISO 9001 being the first step in achieving this goal)? [*Another way to verify this requirement is: Are all suppliers certified to ISO 9001 or the 16949 standard? If not, is there a plan to do so?]* >16949 Note: The need for supplier development depends upon the supplier's quality performance and the importance of the product supplied.		
2>	If there is a supplier not registered to ISO 9001:2000 by an accredited third-party certification body, has the customer specified it [*approved it*].		
7.4.1.3>	**Customer-approved sources**		

Ref.	Question *(author comments are in italic, 16949 shalls are marked with arrow (>))*	Yes/ No	Comments *[evidence - data - collection plan]*
1>	Does the organization purchase products, materials or services from approved sources when specified by the customer contract (e.g. customer engineering drawings, specifications)?		
2>	Does the organization take responsibility for ensuring the quality of purchased products from customer-designated sources (i.e. tool/gauge suppliers)?		
7.4.2	**Purchasing information**		
1	Does purchasing information (*contracts and purchase orders*) describe the product ordered? *[This may be type, class, style, grade, model, part number, etc.*]		
2	If appropriate, are requirements for approval of product, procedures, processes, processing equipment and qualification of personnel described?		
3	If appropriate, is the applicable quality management system requirements identified in purchase documents? *[This may be the ISO 9001 or other recognized standards.]*		
4	Is the adequacy of purchasing information ensured prior to communication to the supplier?		
7.4.3	**Verification of purchased product**		
1	Are activities established and implemented for inspection (or other activities) of incoming purchased product/service, to ensure requirements are met?		
2	When the organization or its customer performs on-site supplier verification, are arrangements and methods for on-site (supplier) verification (source inspection) specified (defined) in purchasing information?		
7.4.3.1>	**Incoming product quality**		
1>	Does the organization have a process to assure the quality of purchased product that utilizes one of the following methods? __ receipt of, and evaluation of, statistical data by the organization __ receiving inspection and/or testing such as sampling based on performance __ second- or third-party assessments or audits of supplier sites, when coupled with records of acceptable delivered product quality __ part evaluation by a designated laboratory __ another method agreed upon with the customer		
7.4.3.2>	**Supplier monitoring**		
1>	Does the organization monitor supplier performance through the following indicators? __ delivered product quality; __ customer disruptions including field returns; __ delivery schedule performance (including incidents of premium freight); __ special status customer notifications related to quality or delivery issues.		

Ref.	Question *(author comments are in italic, 16949 shalls are marked with arrow (>))*	Yes/ No	Comments *[evidence - data - collection plan]*
2>	Does the organization promote supplier monitoring of the performance of their manufacturing processes? *[This is a way to integrate the idea that process, not just product, need to be controlled.]*		
7.5	**Production and service provision**		
7.5.1	**Control of product and service provision control**		
1	Are provisions (product and service) carried out under controlled conditions?		
2	Is there product/ service information available that describes product characteristics? [Acceptance criteria]		
3	Are there work instructions for activities necessary to achieve quality? (Where necessary)		
4	Is suitable equipment used on each of these identified processes (*production, service*)? *[linked to 6.3 and 6.4]*		
5	Are measurement and monitoring equipment available and used? [check the devices used to control the process*]*		
6	Are measuring and monitoring activities (processes) implemented?		
7	Are processes for product release, delivery, and applicable post delivery implemented?		
7.5.1.1>	**Control plan**		
1>	Does the organization develop control plans? Are there control plans for system, subsystem and component part (or material) levels for the product supplied?		
2>	Do pre-launch and production control plans take into account the design FMEA and manufacturing process FMEA outputs?		
3>	Does the control plan include: __ list the controls __ methods for monitoring of control exercised over special characteristics __ the customer-required information __ reaction plan when the process becomes unstable or not statistically capable		
4>	Are control plans reviewed and updated when any change occurs?		

Ref.	Question *(author comments are in italic, 16949 shalls are marked with arrow (>))*	Yes/ No	Comments *[evidence - data - collection plan]*
7.5.1.2>	**Work instructions**		
1>	Are there documented work instructions for all employees having responsibilities for the operation of processes that impact product quality? Are they accessible for use at the work station/location?		
2>	Are the work instructions derived from sources such as the quality plan, the control plan and the product realization process? *[As an auditor, you can look for cross-referencing to other important documents such as the control plan, specifications, etc. This clause appears to try to address organizations writing dopey work instructions just to meet the requirement.]*		
7.5.1.3>	**Verification of job set-ups**		
1>	Are job set-ups verified whenever performed (i.e., initial run, material changeover or job change). Does the organization use statistical methods of verification where applicable?		
2>	Are work instructions available for set-up personnel? [*An auditor may view the work instructions at the work station, view a set-up and/or ask set-up personnel where were the work instructions on the last set-up job]*		
7.5.1.4>	**Preventive and predictive maintenance**		
1>	Is there a preventive maintenance (PM) program for all key process equipment? Are necessary resources provided? Does the PM plan include: __ planned maintenance activities __ packaging and preservation of equipment, tooling and gauging __ availability of replacement parts for key manufacturing equipment __ documenting, evaluating and improving maintenance objectives		
2>	Does the organization use predictive maintenance methods to continually improve the effectiveness and the efficiency of production equipment? *(For example, predictive could be monitoring a variable such as cycles or conducting measurements to predict useful life or reliability]*		
7.5.1.5>	**Management of production tooling**		

Ref.	Question *(author comments are in italic, 16949 shalls are marked with arrow (>))*	Yes/ No	Comments *[evidence - data - collection plan]*
1>	Has the organization established and implement a system for production tooling management (tool and gauge design, fabrication and verification activities)? Are necessary resources provided? Does tooling management include: __ maintenance and repair facilities and personnel __ storage and recovery __ set-up __ tool-change program for perishable tools __ tool design modification documentation, including engineering change level __ tool modification and revision to documentation __ tool identification, defining the status, such as production, repair or disposal		
2>	Are outsourced activities monitored?		
7.5.1.6>	**Production scheduling**		
1>	Is product scheduled to meet customer requirements (order driven)? Note that requirements may include as just-in-time supported by an information system that permits access to production information at key stages of the process.		
7.5.1.7>	**Feedback of information from service**		
1>	Is there an established process for communication of information on service concerns to manufacturing, engineering and design activities? Is it maintained >16949 Note: Service concerns include awareness of nonconformities that occur externally.		
7.5.1.8>	**Service agreement with customer**		
1>	Is there a service agreement with the customer? If so, has the QMS organization verified effectiveness of: __ any organization service centers __ any special-purpose tools or measurement equipment __ the training of service personnel [*This is included in product realization because the product may be a service. However, some portions of this clause may be redundant if other clauses of 16949 are properly applied*]		
7.5.2	**Validation of (production and service) provision processes**		
1	Have processes that result in a product/ service that cannot be verified by subsequent measurement and monitoring *(inspection and testing)* and result in deficiencies after delivery or use, been validated? *[for 16949 QMS organizations, this clause applies to all production and services processes. Production process cannot be verified before delivery or execution]*		
.2	Does the validation demonstrate that the process achieves planned results? *[Does evidence verify processes achieve results?]*		

Ref.	Question *(author comments are in italic, 16949 shalls are marked with arrow (>))*	Yes/ No	Comments *[evidence - data - collection plan]*
3	Are arrangements defined for validation? Does the organization consider: __ review and approval of the process __ approval of equipment __ qualification of personnel __ use of methods and procedures __ requirements for records __ re-validation requirements		
7.5.2.1>	**Validation of processes for production and service provision**		
1>	Has the organization applied clause 7.5.2 to all processes for production and service provisions? [*See above.*]		
7.5.3	**Identification and traceability**		
1	Is product/ service identified throughout production, and service operations (delivery and installation)?		
2	Is there provision to identify the status of the product/ service with regard to measurement and monitored activities throughout product realization?		
3	Are there controls for unique identification of individual products (or batches) when traceability is a requirement? Are records maintained?		
	> 16949 Note: Organizations cannot claim the inspection and test status is known by the location of product in the production flow unless inherently obvious (such as material in an automated production transfer process). Alternatives are permitted, if the status is clearly identified, documented and achieves the designated purpose.		
7.5.3.1>	**Identification and traceability**		
1>	The words “Where appropriate” in 7.5.3 shall not apply to 16949 QMS organizations. [*Where appropriate has been removed from 7.5.3, #1.*]		
7.5.4	**Customer property** Note: Customer property includes intellectual property and personal data.		
1	Does the organization exercise care with customer property? *[see 7.1]*		
2	Is customer property, identified, verified, protected and safeguarded?		
3	If customer property is lost, damaged, or otherwise unsuitable, is this recorded and reported to the customer?		

Ref.	Question *(author comments are in italic, 16949 shalls are marked with arrow (>))*	Yes/ No	Comments *[evidence - data - collection plan]*
7.5.4.1>	**Customer-owned production tooling**		
1>	Are 'customer-owned' tools, manufacturing, test, inspection tooling and equipment permanently marked so that the ownership of each item is visible, and can be determined? [*You can check for customer-owned equipment on the shop floor and in the tool room or inspection department.]*		
7.5.5	**Preservation of product**		
7.5.5	Does the organization ensure conformity (quality) is maintained (**including constituent parts**) from internal processing to final delivery. Is product/ service conformity maintained and where applicable, during identification, handling, packaging, storage, and protection? *[apply 7.1, verify plan exists]*		
7.5.5.1>	**Storage and inventory**		
1>	Is the condition of the stock assessed (*checked*) at appropriate planned intervals in order to detect deterioration? [*Appropriate could be consideration for such things as shelf-life the product that would not lend it to monthly assessments. Appropriate may also be consistent with high-risk times or periods due to activities or climate.]*		
2>	Does the organization use an inventory management system to optimize inventory turns over time and assure stock rotation, such as "first-in-first-out" (FIFO)?		
3>	Is obsolete product controlled in a similar manner to nonconforming product?		
7.6	**Control of monitoring and measuring equipment**		
1	Have measurements and devices been determined that are needed to assure conformity of product to requirements?		
2	Are there processes for measuring and monitoring equipment to ensure they are capable of and carried out in a manner that meets measuring and monitoring requirements? (including software)		
3	Has measuring equipment (and measurement devices) been calibrated? (when required to maintain valid results)		
4	Is this equipment adjusted at prescribed intervals, or prior to use, against certified equipment having a known valid relationship to nationally recognized standards? (when required to maintain valid results)		
5	Where no calibration standards exist, is the basis for calibration recorded? (when required to maintain valid results)		
b-6	Is equipment adjusted and readjusted as necessary? *Note: There may be situations where events require calibrations checks beyond the established interval.*		

Ref.	Question *(author comments are in italic, 16949 shalls are marked with arrow (>))*	Yes/ No	Comments *[evidence - data - collection plan]*
c-7	Is equipment identified such that the calibration status can be determined? >16949 Note: A number or other identifier traceable to the device calibration record meets the intent of this requirement .		
d-8	Are there safeguards against adjustments that would invalidate calibration settings? (when required to maintain valid results)		
e-9	Are the handling, maintenance, and storage of this equipment such that it is protected from damage or deterioration?		
f-10	Are records of the results of calibration and verification maintained?		
11	Is the validity of previous results assessed when equipment is found to be out of calibration? Is action taken on the equipment (device) and any product affected?		
12	Is computer software confirmed as being able to satisfy the intended application prior to use? Is the software reconfirmed as necessary? [*Hint: Does the organization use configuration management to confirm software capability?]*		
7.6.1>	**Measurement system analysis (MSA)**		
1>	Are statistical studies conducted to analyze the variation present in the results of each type of measuring and test equipment system reference in a control plan?		
2>	Do the analytical methods and acceptance criteria used conform to those in customer reference manuals (on measurement systems analysis) or are methods approved by the customer?		
7.6.2>	**Calibration/verification records**		
1>	Do calibration/verification records for gauges, measuring and test equipment (including employee- and customer-owned equipment) include? __ equipment identification and the measurement standard against which the equipment is calibrated __ revisions following engineering changes __ any out-of-specification readings as received for calibration/verification __ an assessment of the impact of out-of-specification condition __ statements of conformity to specification after calibration/verification __ notification to the customer if suspect product or material has been shipped		
7.6.3	**Laboratory requirements**		
7.6.3.1>	**Internal laboratory**		

Ref.	Question *(author comments are in italic, 16949 shalls are marked with arrow (>))*	Yes/ No	Comments *[evidence - data - collection plan]*
1>	Does the laboratory facility have a defined scope? Does the scope include its capability to perform the required inspection, test or calibration services? Is the laboratory scope included in the quality management system documentation?		
>2	Does the laboratory specify and implement technical requirements for: __ adequacy of the laboratory procedures __ competency of the laboratory personnel __ testing of the product __ capability to perform these services correctly, traceable to the relevant process standard (such as ASTM, EN, etc.) __ review of the related records? >16949 note: Accreditation to ISO/IEC 17025 may be used to demonstrate supplier in-house laboratory conformity to this requirement but is not mandatory.		
7.6.3.2>	**External laboratory**		
1>	If an external/commercial/independent laboratory is used for inspection, test or calibration services, does it have a defined laboratory scope? Does the scope include capability to perform the required inspection, test or calibration?		
2>	Is there evidence that the external laboratory is acceptable to the customer or is the laboratory accredited to ISO/IEC 17025 or national equivalent.		
	>16949 Note: Such evidence may be demonstrated by customer assessment or by customer-approved second-party assessment that the laboratory meets the intent of ISO/IEC 17025 or national equivalent. >16949 Note: When a qualified laboratory is not available for a given piece of equipment, calibration services may be performed by the equipment manufacturer. In such cases, the organization should ensure that the requirements listed in 7.6.3.1 have been met.		

Ref.	Question *(author comments are in italic, 16949 shalls are marked with arrow (>))*	Yes/ No	Comments *[evidence - data - collection plan]*
8	**Measurement, analysis, and improvement**		
8.1	**General**		
1	Are measuring, monitoring, analyzing, and continual improvement processes planned and implemented for: - demonstrating conformity to product requirments - assuring conformity of the QMS - achieving an effective and improving QMS?		
2	Has the organization determined what methods (extent and use) are applicable (including statistical techniques) for measuring, monitoring, analysis?		
8.1.1>	**Identification of statistical tools**		
1>	Are statistical tools for each process determined and included in the control plan?		
2>	Were the statistic tools determined during advanced quality planning?		
8.1.2>	**Knowledge of basic statistical concepts**		
1>	Are basic statistical concepts (i.e. variation, in-control, capable, and so on) understood and utilized throughout the organization? *[An auditor needs to assess this requirement throughout the audit making observations and asking statistical-related questions during interviews. A guide would be on a need-to-know basis. A purchasing agent may not be expected to know about out-of-control points, but an operator or manufacturing supervisor would]*		
8.2	**Measurement and monitoring**		
8.2.1	**Customer satisfaction**		
1	Are customer perceptions regarding meeting requirements (customer satisfaction) monitored and used as a measure of quality management system performance? *[cross check management review records].* Note; data may include customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims, dealer reports.		
2	Are methods for obtaining *[collecting]* and using such information determined?		
	>16949 Note: Consideration should be given to both internal and external customers. [*This note is not a requirement, but organizations may consider the value of measuring internal customer satisfaction.]*		
8.2.1.1>	**Customer satisfaction — Supplemental**		

Ref.	Question *(author comments are in italic, 16949 shalls are marked with arrow (>))*	Yes/ No	Comments *[evidence - data - collection plan]*
1>	Is customer satisfaction monitored (*assessed*) through continual evaluation of performance of the realization processes (clauses 7.1-7.6)? Are performance indicators based on objective data? Does the performance data include the following? __ delivered part quality performance __ customer disruptions including field returns __ delivery schedule performance (including incidents of premium freight), and __ customer notifications related to quality or delivery issues? [*Objective data is information that is uninfluenced by emotion, surmise, or personal prejudice. It is based on observable phenomena, and presented factually. Organizations not taking this requirement seriously may report self-assessments based on individual judgments.]*		
2>	Does the organization monitor the performance of manufacturing processes to demonstrate compliance with customer requirements for product quality and efficiency of the process? *[This could be covered in #1 above, but the emphasis here is on the manufacturing process.]*		
8.2.2	**Internal auditing**		
1	Are internal audits conducted at planned intervals?		
2	Are audits carried out to determine conformance of the QMS to planned arrangements, the organizations QMS requirements, this International Standard, and that the QMS has been effectively implemented and maintained?		
3	Does the audit program plan consider status and importance of the activities and areas to be audited and results of previous audits?		
4	Are audit criteria, scope, frequency, and methods defined?		
5	Are auditors selected and audits conducted to ensure objectivity and impartiality of the audit process? Are auditors prevented from auditing their own work?		
6	Are there documented procedures? Do the procedures cover responsibilities, requirements for planning and conducting, establishing records and reporting results?		
7	Are records of audits and their results maintained? [4.2.4]		
8	Is action taken by management responsible for the area to address the nonconformities (correction)? Is this done without undue delay? *[Note that actions can include corrections and corrective actions]*		
9	Are follow-up activities carried out to verify the effectiveness of actions taken? Are the verification results reported? [8.5.2]		
8.2.2.1>	**Quality management system audit**		

Ref.	Question *(author comments are in italic, 16949 shalls are marked with arrow (>))*	Yes/ No	Comments *[evidence - data - collection plan]*
1>	Does the organization audit its quality management system to verify compliance with this Technical Specification and any additional quality management system requirements?		
8.2.2.2>	**Manufacturing process audit**		
1>	Is each manufacturing process audited to determine its effectiveness? *[Effectiveness is the extent to which planned activities are realized and planned results achieved (ISO 9000). Effectiveness does not include efficiency.]*		
8.2.2.3>	**Product audit**		
1>	Does the organization conduct product audits at a defined frequency and at appropriate stages of production and delivery?		
2>	Does the product audit scope include verification of all specified requirements, such as product dimensions, functionality, packaging and labeling?		
8.2.2.4>	**Internal audit plans**		
1>	Do internal audits cover all quality management related processes, activities and shifts? Are they scheduled according to an annual plan? >16949 Note: Specific checklists should be used for each audit. *[Clause 8.2.2.1 covers the QMS system audit. This checklist could be used for that. The audits in this clause are audits of all the QMS related processes such as manufacturing processes or service processes. A checklist may be a checklist made up from procedures or work instructions.]*		
2>	When there are internal/external nonconformities or customer complaints, is audit frequency appropriately increased?		
8.2.2.5>	**Internal auditor qualification**		
1>	Are the internal auditors qualified to audit the requirements of this Technical Specification (see 6.2.2.2)?		
8.2.3	**Monitoring and measurement of processes**		
1	Are there suitable methods for monitoring (and measuring when applicable) the QMS processes to achieve planned results? *[Can the organization provide evidence that applied methods achieve planned results.] [A note explains that suitable methods are determined by the organization considering the type and extent of monitoring or measurement appropriate for each in relation to their impact on the conformity to product requirements and on the effectiveness of the quality management system.*		

Ref.	Question *(author comments are in italic, 16949 shalls are marked with arrow (>))*	Yes/ No	Comments *[evidence - data - collection plan]*
2	Is correction or corrective action taken on processes not achieving planned results?		
8.2.3.1>	**Monitoring and measurement of manufacturing processes**		
1>	Does the organization perform and document process studies on **all new manufacturing** (including assembly or sequencing) processes to verify process capability and to provide additional input for process control? __ Is the documented information used in manufacturing (specifications, procedures, instructions, maintenance)? __ Are the documents/studies objectives for manufacturing process capability, reliability, maintainability and availability, as well as acceptance criteria?		
2>	Does the organization maintain manufacturing process capability or performance as specified by the customer part approval process requirements? *[Good requirement to verify during an internal audit of a process.]*		
3>	Does the organization ensure that the control plan and process flow diagram are implemented? Do they adhere to: __ measurement techniques __ sampling plans __ acceptance criteria __ reaction plans when acceptance criteria are not met *[Good requirement to verify during an internal audit of a process.]*		
4>	Are significant process events, such as tool change or machine repair, recorded? *[Good requirement to verify during an internal audit of a process.]*		
5>	Does the organization initiate a reaction plan (from the control plan) for characteristics that are either not statistically capable or are unstable? __ Do the plans include containment of product and 100 % inspection as appropriate? __ Is a corrective action plan initiated that indicates specific timing and assigned responsibilities to assure that the process become stable and capable? __ Are plans reviewed with and approved by the customer when so required? [*All the requirements for responding to out-of-control condition are included rather than create 4 different questions.*]		
5>	Are the process change effective dates (*implemented*) recorded?		
8.2.4	**Monitoring and measurement of product *[service]***		
1	Are the product characteristics measured and monitored to verify product requirements are met?		
2	Are measuring and monitoring carried out at appropriate stages of the realization process and in accordance with planned arrangements?		

Ref.	Question *(author comments are in italic, 16949 shalls are marked with arrow (>))*	Yes/ No	Comments *[evidence - data - collection plan]*
3	Is evidence (measurement & monitoring evidence) showing conformance to acceptance criteria recorded?		
4	Are there records? Do the records indicate the person(s) authorizing release of the product for delivery to the customer?		
5	Is product/ service released and delivery to the customer held until all planned arrangements (*specified activities*) are satisfactorily completed, unless otherwise approved by the customer or other relevant authority? *[Quality wavier]*		
	>16949 Note: When selecting product parameters to monitor compliance to specified (internal and external) requirements, the organization determines the types of product characteristics, leading to 1) the types of measurement; 2) suitable measurement means, and 3) the capability and skills required.		
8.2.4.1>	**Layout inspection and functional testing**		
1>	Are layout inspection and a functional verification (to applicable customer engineering material and performance standards) performed for each product as specified in the control plans? Are results available for customer review?		
2>	16949 Note: Layout inspection is the complete measurement of all product dimensions shown on the design records		
8.2.4.2>	**Appearance items**		
1>	Are the following provided for manufacturing of "appearance items," if applicable: __ appropriate resources including lighting for evaluation, __ masters for color, grain, gloss, metallic brilliance, texture, distinctness of image (DOI), as appropriate, __ maintenance and control of appearance masters and evaluation equipment __ verification that personnel making appearance evaluations are competent and qualified?		
8.3	**Control of nonconforming product**		
1	Are there controls to prevent nonconforming (off-specification) product/ service from unintended use or delivery? Are they being used?		
2	Are nonconforming activities defined in a documented procedure? Is responsibility and authority for review and resolving nonconforming product defined in the documented procedure?		

Ref.	Question *(author comments are in italic, 16949 shalls are marked with arrow (>))*	Yes/ No	Comments *[evidence - data - collection plan]*
3	Does the organization deal with nonconforming product by one or more of the following (where applicable): - eliminate the nonconformity (corrected). *[rework, repair, blend]* - authorize its use, release or acceptance by concession from relevant authority (where applicable, the customer) *[use 'as is']* - action to preclude its original intended use or application?*[regrade, scrap]* - appropriate action taken regarding the consequences of the nonconformities found after delivery or use		
4	Is corrected product subject to re-verification activities to demonstrate conformity to requirements?		
5	Is there a record of the nature of the nonconformance and subsequent action (*history*)? Are they maintained?		
8.3.1>	**Control of nonconforming product**		
1>	Is unidentified or suspect status product classified as nonconforming product (see 7.5.3).		
8.3.2>	**Control of reworked product**		
1>	Are rework instruction (including re-inspection requirements), accessible and utilized by the appropriate personnel (*conducting the work)*.		
8.3.3>	**Customer information**		
1>	Are customers promptly informed when nonconforming product has been shipped?		
8.3.4>	**Customer waiver**		
1>	Does the organization obtain a customer concession (or deviation permit) whenever the 'product' or 'manufacturing process' is different from that which is currently approved? Is the customer concession (or deviation permit) obtained prior to further processing? Does the organization: __ maintain a record of the expiration date or quantity authorized. __ ensure compliance with the original or superseding specifications and requirements when the authorization expires. __ identify on each shipping container the material authorization __ apply the same requirements to purchased product (*seek customer approval for deviations from suppliers*).		
8.4	**Analysis of data**		

Ref.	Question *(author comments are in italic, 16949 shalls are marked with arrow (>))*	Yes/ No	Comments *[evidence - data - collection plan]*
1	Is data determined collected and analyzed to demonstrate the suitability, and effectiveness of the QMS and to identify areas for improvement?		
2	Does analysis of data provide information on: __ customer satisfaction [8.2.1] __ conformity to product requirements [8.2.4] __ characteristics of processes, products and their trends, and opportunities for preventive action [8.2.3 and 8.2.4] __ suppliers [7.4]		
8.4.1>	**Analysis and use of data**		
1>	Are trends in quality and operational performance compared with progress toward objectives? Does the comparison lead to follow-up actions such as: __ development of priorities for prompt solutions to customer-related problems __ determination of key customer-related trends and correlation for status review, decision-making and longer term planning __ an information system for the timely reporting of product information arising from usage		
	>16949 Note: Data can be compared with those of competitors and/or other appropriate benchmarks.		
8.5	**Improvement**		
8.5.1	**Continual improvement**		
1	Is there continual improvement through the use of a quality policy, objectives, management review, audit results, corrective and preventive actions and analysis of data?		
8.5.1.1>	**Continual improvement of the organization**		
1>	Has the organization defined a process for continual improvement (see examples in annex B of ISO 9004:2000)?		
8.5.1.2>	**Manufacturing process improvement**		
1>	Does manufacturing process improvement continually focus upon control (*in-control*) and reduction of variation (*Cpk*) in product characteristics and manufacturing process parameters?		
	>16949 Note: Controlled characteristics are documented in the control plan. >16949 Note: Continual improvement can be implemented once manufacturing processes are capable and stable, or product characteristics are predictable and meet customer requirements.		
8.5.2	**Corrective action**		
1	Are corrective actions implemented based on importance (impact of problems encountered)?		

Ref.	Question *(author comments are in italic, 16949 shalls are marked with arrow (>))*	Yes/ No	Comments *[evidence - data - collection plan]*
2	Is there a documented procedure for corrective action? Is corrective action taken?		
a-3	Does the corrective action procedure include requirements for reviewing nonconformities (including customer complaints)? *[Complaints may be handled separately, perhaps in the sales - marketing department.]*		
b-4	Does the procedure include requirements of determination of causes and their elimination?		
c-5	Does the procedure define the requirements for evaluating the need for actions? (to ensure they do not recur)		
d-6	Are requirements for implementation actions defined in the procedure?		
e-7	Does the procedure require the results (actions) of the investigation to be recorded? Is it being done?		
f-8	Does the procedure establish and define the requirements for reviewing the effectiveness of corrective action taken?		
8.5.2.1>	**Problem solving**		
1>	Does the organization have a defined process for problem solving? Does it include root cause identification and elimination? If there is a customer-prescribed problem-solving format, does the organization use that process?		
8.5.2.2>	**Error-proofing**		
1>	Does the organization use error-proofing methods in their corrective action process?		
8.5.2.3>	**Corrective action impact**		
1>	Are corrective actions applied to other similar processes and products?		
8.5.2.4>	**Rejected product test/analysis**		
1>	Does the organization analyze parts rejected by the customer (manufacturing plants, engineering facilities and dealerships)? Does the organization: __ minimize the cycle time for analyzing __ are there records of these analyses __ can records be made available upon request __ perform analysis and initiate corrective action to prevent recurrence of reject parts		

Ref.	Question *(author comments are in italic, 16949 shalls are marked with arrow (>))*	Yes/ No	Comments *[evidence - data - collection plan]*
	>16949 Note: Cycle time related to rejected product analysis should be consistent with the determination of root cause, corrective action and monitoring the effectiveness of implementation.		
8.5.3	**Preventive action**		
1	Are preventive actions implemented based on importance (impact of the potential problems)?		
2	Is there a documented procedure for preventive action? Is preventive action taken?		
a-3	Does the procedure define the requirements for potential nonconformity determination and their causes?		
b-4	Does the procedure define the requirements for evaluating the need for action to prevent occurrence?		
c-5	Does the procedure define the requirements for determining and implementation of *(preventive*) actions needed?		
d-6	Are results of (*preventive*) actions recorded?		
e-7	Are requirements defined for reviewing the effectiveness of preventive action taken?		