| **Clause** | **ISO 9001 Question in Human English** |
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| ISO 9001 4.1 | Is the procedure [Context of the Org Proc. Title] up to date and being followed? |
| ISO 9001 4.1 | Is the COTO Log up to date re: issues of concern? |
| ISO 9001 4.1 | Is this reviewed by top management? |
| ISO 9001 4.2 | Is the COTO Log up to date re: interested parties (stakeholders)? |
| ISO 9001 4.2 | Is this reviewed by top management? |
| ISO 9001 4.3 | Is the scope statement in the [Quality Manual Doc Title] still accurate? |
| ISO 9001 4.3 | Are all applicable activities covered by the QMS scope? |
| ISO 9001 4.3 | Are any exclusions from ISO 9001 documented and properly justified in the [Quality Manual Doc Title]? |
| ISO 9001 4.4.1 | Is the [Quality Manual Doc Title] accurate re: the top-level processes are identified and the sequence and interaction chart is accurate? |
| ISO 9001 4.4.1 | Are inputs and outputs defined in some manner for each top-level process? |
| ISO 9001 4.4.1 | Are processes being measured for effectiveness somehow? |
| ISO 9001 4.4.1 | Are process resources (people, facilities and equipment) considered and provided, as necessary? |
| ISO 9001 4.4.1 | Does each top-level process have people assigned for responsibility and authority? |
| ISO 9001 4.4.1 | Does the COTO work address risks and opportunities related to processes? |
| ISO 9001 4.4.1 | If a process doesn’t meet a goal or measurement, is corrective action taken? |
| ISO 9001 4.4.1 | Does management seek to improve the processes over time? |
| ISO 9001 4.4.2 | Are there procedures and other documents, as well as records, in place to support the QMS? |
| ISO 9001 5.1.1 | Interview top management; do you get the sense that top management takes overall responsibility for the QMS? |
| ISO 9001 5.1.1 | Did management develop the quality policy and objectives? |
| ISO 9001 5.1.1 | Does top management communicate the importance of the QMS to all staff? |
| ISO 9001 5.1.1 | Does top management engage, direct and support other staff members responsible for the QMS? |
| ISO 9001 5.1.2 | Does management promote a customer-centric focus on the company’s activities? |
| ISO 9001 5.2.1 | Is the Quality Policy published and still current? |
| ISO 9001 5.2.1 | Does it include a statement about “satisfying applicable requirements?” |
| ISO 9001 5.2.1 | Does it include a statement about “continual improvement?” |
| ISO 9001 5.2.2 | Is the Quality Policy published? |
| ISO 9001 5.2.2 | Can employees describe the Quality Policy? |
| ISO 9001 5.3 | Are company roles and responsibilities defined and communicated through the company? |
| ISO 9001 6.1.1 | Is the procedure [Risk Management Proc. Title] up to date and being followed? |
| ISO 9001 6.1.1 | Is the Risk Register in the COTO Log up to date? |
| ISO 9001 6.1.1 | Is the Opportunity Register in the COTO Log up to date? |
| ISO 9001 6.1.2 | Are actions taken to mitigate risks and maximize opportunities? |
| ISO 9001 6.1.2 | Does management review the risks and opportunities (perhaps at management review)? |
| ISO 9001 6.2.1 | Are quality objectives established and recorded? |
| ISO 9001 6.2.1 | Are quality objectives measurable, and being measured? |
| ISO 9001 6.2.1 | Are the quality objectives communicated as needed throughout the company? |
| ISO 9001 6.2.1 | Is management reviewing the objectives and taking action to achieve them? |
| ISO 9001 6.3 | Is the procedure [Change Mgmt Doc Title] up to date and being followed? |
| ISO 9001 6.3 | Are changes to the QMS done in a controlled manner? |
| ISO 9001 7.1.1 | Is management endeavoring to provide QMS resources where it can? |
| ISO 9001 7.1.2 | Are there enough people available to conduct the QMS work? |
| ISO 9001 7.1.3 | Related to the control of infrastructure (buildings and equipment) is the procedure [Equipment Validation Proc. Title] up to date and being followed? |
| ISO 9001 7.1.3 | Are equipment and facilities implemented to support the QMS and ensure product quality? |
| ISO 9001 7.1.3 | Is there maintenance of facilities and equipment to ensure their adequacy? |
| ISO 9001 7.1.3 | Is the procedure [Preventive Maintenance Proc. Title] up to date and being followed? |
| ISO 9001 7.1.3 | Is the work environment adequate to ensure product quality and QMS efficiency? |
| ISO 9001 7.1.4 | Are any special environments (clean rooms, ESD areas, etc.) properly controlled to ensure product quality? |
| ISO 9001 7.1.5.1 | Is the procedure [Calibration Proc. Title] up to date and being followed? |
| ISO 9001 7.1.5.1 | Are calibrated devices used for inspection and testing? |
| ISO 9001 7.1.5.1 | Are these devices adequate for the measurements which need to be taken (within the range, tolerance, etc.)? |
| ISO 9001 7.1.5.1 | Are calibration records kept? |
| ISO 9001 7.1.5.1 | Is calibration done against traceable standards? |
| ISO 9001 7.1.5.2 | Is the calibration log / database up to date? |
| ISO 9001 7.1.5.2 | Are calibrated devices tagged with their calibration status? |
| ISO 9001 7.1.5.2 | If a device is found to be out-of-calibration, is there a study done to assess the impact on product that may have been inspected with that device prior? |
| ISO 9001 7.1.6 | Does the company determine the organizational knowledge necessary for the QMS? |
| ISO 9001 7.1.6 | Is this knowledge updated to ensure it remains current and useful? |
| ISO 9001 7.2 | Is the procedure [Training Proc. Title] up to date and being followed? |
| ISO 9001 7.2 | For each job affecting quality, are the minimum competency requirements for education, training and/or experience defined? |
| ISO 9001 7.2 | Do the people hired or placed into positions meet those competency requirements, or undergo training if they do not? |
| ISO 9001 7.2 | Are there records of training (including orientation, on-the-job training, classroom training, etc.) |
| ISO 9001 7.3 | Are employees aware of how they contribute to the QMS and product quality? |
| ISO 9001 7.3 | Are employees aware of what could happen if the QMS does not succeed? |
| ISO 9001 7.4 | Does the company have robust methods to communicate with customers, and to accept communication from them? |
| ISO 9001 7.5.1 | Does the QMS include all the following required documents?   * Scope of the QMS * the scope of the quality management system, including boundaries and applicability * Quality Policy * Quality Objectives (may be a record instead; either is fine) * Any procedures needed to support the operation of the processes |
| ISO 9001 7.5.1 | Does the QMS include all the following required documented records? (Only those that are applicable.)   * Calibration records * Training records * Contract review records * Records of design inputs (requirements) * Records of design controls * Records of design test reports and data * Records of design outputs * Records of design changes * Supplier approval records * Record of any received material that is released to production prior to incoming inspection * Record of the description of product for manufacturing * Serialization logs (if applicable) * Records of lost or damaged customer/supplier property * Records of changes to production processes * Inspection and test records * Records of product nonconformities * Records of the analysis of overall QMS effectiveness (may be covered under some other records mentioned) * Internal audit records * Management review records * Corrective action records |
| ISO 9001 7.5.1 | Is the procedure [Control of Documents Proc. Title] up to date and being followed? |
| ISO 9001 7.5.1 | Is the procedure [Control of Records Proc. Title] up to date and being followed? |
| ISO 9001 7.5.1 | Does the QMS documentation include any other procedures deemed necessary by the company itself? |
| ISO 9001 7.5.2 | Are documents controlled to ensure only latest revisions are available? |
| ISO 9001 7.5.2 | Are documents available to employees at the point of use? |
| ISO 9001 7.5.2 | Are documents reviewed and approved before release? |
| ISO 9001 7.5.3.1 | Are documents and records protected from loss or damage? |
| ISO 9001 7.5.3.1 | Are electronic records subject to secure backups? |
| ISO 9001 7.5.3.2 | If there’s a master list of documents, is it up to date and accurate? |
| ISO 9001 7.5.3.2 | Are only controlled documents in use? (In other words, no uncontrolled documents in use.) |
| ISO 9001 7.5.3.2 | Do changed documents also undergo review and approval? |
| ISO 9001 7.5.3.2 | Are record retention times and rules documented? |
| ISO 9001 7.5.3.2 | Are external documents (standards, specs, etc.) also controlled to ensure the proper revision is used? |
| ISO 9001 8.1 | In general, are the QMS processes planned with an eye towards the customer’s product requirements? |
| ISO 9001 8.1 | Are the criteria for each manufacturing process determined? |
| ISO 9001 8.1 | Are outsourced processes controlled and is the procedure [Outsourced Processes Title] up to date and being followed? |
| ISO 9001 8.1 | Is the inspection/test criteria for product determined? |
| ISO 9001 8.1 | Are resource needs (staff, equipment and facilities) determined for each manufacturing process? |
| ISO 9001 8.1 | Are procedures developed to support manufacturing processes (where needed)? |
| ISO 9001 8.1 | If the planning of operations is documented (perhaps as a quality plan), is this sufficient for use? |
| ISO 9001 8.2.1 | Is the procedure [Quoting and Orders Doc Title] up to date and being followed? |
| ISO 9001 8.2.1 | Are customer questions related to jobs, products, etc. routed and processed in an appropriate way? |
| ISO 9001 8.2.2 | Are customer requirements for product captured accurately? |
| ISO 9001 8.2.2 | Are these requirements reviewed before the company commits to deliver the products? |
| ISO 9001 8.2.3.1 | Does this review include the applicable statutory and regulatory requirements? |
| ISO 9001 8.2.3.1 | If a quote was prepared previously, is this reviewed against the incoming order and any deviations resolved with the customer? |
| ISO 9001 8.2.3.2 | Are there records of the contract review? |
| ISO 9001 8.2.4 | If either the customer or the company changes the order requirements after it’s been taken, is this change agreed to with the customer? |
| ISO 9001 8.2.4 | Are changes to all necessary order documentation updated? |
| ISO 9001 8.3.1 | Is the procedure [Design Procedure Doc Title] up to date and being followed? |
| ISO 9001 8.3.1 | Is product design done in accordance with an established process (or processes)? |
| ISO 9001 8.3.2 | Is the overall design plan defined in some manner, including a definition of typical design stages? |
| ISO 9001 8.3.3 | Are design inputs (requirements) fully determined and defined prior to starting any design work? This would include functional requirements, manufacturing requirements, statutory/regulatory requirements, information from previous designs, etc.) |
| ISO 9001 8.3.3 | Are the design requirements reviewed prior to proceeding? |
| ISO 9001 8.3.3 | Are there records of the design input review? |
| ISO 9001 8.3.4 | Do design activities include necessary design reviews? |
| ISO 9001 8.3.4 | Do design reviews include a?ll necessary stakeholders (engineers, customers, etc.) |
| ISO 9001 8.3.4 | Do design activities include “verification,” which is the review of the design itself (drawing, model, spec, etc.) against the requirements? |
| ISO 9001 8.3.4 | Do design activities include “validation,” which is the inspection or testing of a prototype product, first piece or first batch against the design requirements? |
| ISO 9001 8.3.4 | For design reviews, verification and validation, are problems corrected and the design updated? |
| ISO 9001 8.3.4 | Are there records of design review, verification and validation? |
| ISO 9001 8.3.5 | Do the design reviews or other activities ensure the design itself (drawing, model, spec, etc.) is adequate for later manufacturing (if applicable)? |
| ISO 9001 8.3.5 | Do the designs reference the necessary inspection or test equipment, if applicable? |
| ISO 9001 8.3.5 | Are the designs (drawings, models, specs, etc.) approved and authorized before release? |
| ISO 9001 8.3.5 | Are the designs documented in some way? (Again, this may be drawings, models, specs, prints, etc.) |
| ISO 9001 8.3.6 | When designs are changed, is this change done in a controlled manner to ensure the changes don’t worsen anything? |
| ISO 9001 8.3.6 | Are there records of the design changes? |
| ISO 9001 8.3.6 | Are there records on reviews of design changes? |
| ISO 9001 8.3.6 | Are there records of who authorized the changes? |
| ISO 9001 8.3.6 | Are there records of any actions taken to prevent nonconformities? |
| ISO 9001 8.4.1 | Is the procedure [Purchasing Proc. Title] up to date and being followed? |
| ISO 9001 8.4.1 | Are suppliers subject to company controls to ensure the quality of purchased products and services? |
| ISO 9001 8.4.1 | Are controls in place when the company elects to have suppliers “drop ship” product directly to the customer? |
| ISO 9001 8.4.1 | Are suppliers evaluated against some criteria to ensure they meet company expectations for quality? |
| ISO 9001 8.4.1 | Are the records of supplier evaluations up to date and accurate? |
| ISO 9001 8.4.2 | Are items inspected at receiving? |
| ISO 9001 8.4.2 | Is the procedure [Receiving Proc. Title] up to date and being followed? |
| ISO 9001 8.4.2 | Are controls in place for both the suppliers themselves, as well as for any received product sent by them? |
| ISO 9001 8.4.2 | Is the level of control over each supplier adjusted based on the level of risk or impact that supplier could have? (Not all suppliers may have the same levels of control.) |
| ISO 9001 8.4.2 | If done, are other supplier verification activities being performed as required (supplier audits, on-site inspections, etc. – if not done, indicate “N/A.”) |
| ISO 9001 8.4.2 | Is the level of verification activity based on the risks identified by the company? |
| ISO 9001 8.4.3 | Are PO’s reviewed before release to the supplier? |
| ISO 9001 8.4.3 | Do the outgoing PO’s include all necessary information about the items or services being purchased (description, quantity, due date, etc.)? |
| ISO 9001 8.4.3 | Are all other necessary requirements flowed down on the PO to the supplier? (See clause 8.4.3 for a list of possible such requirements.) |
| ISO 9001 8.4.3 | Are requirements imposed by the customer then flowed on the PO to the supplier, if necessary? |
| ISO 9001 8.5.1 | Are production operators provided information describing the product to be made (typically through prints, routers, etc.)? |
| ISO 9001 8.5.1 | Are suitable inspection devices provided which can be used to inspect or test product? |
| ISO 9001 8.5.1 | Are in-process inspections or tests underway and conducted as required? |
| ISO 9001 8.5.1 | Are the facilities and equipment adequate to ensure the quality of the work? |
| ISO 9001 8.5.1 | Are operators trained, as required? |
| ISO 9001 8.5.1 | If operators must have special qualifications to perform work, is their evidence they have these? |
| ISO 9001 8.5.1 | Is the procedure [Special Process Doc Title] up to date and being followed, to ensure all special processes are validated and controlled? |
| ISO 9001 8.5.1 | Is the company attempting to implement controls to prevent human errors? |
| ISO 9001 8.5.1 | Do manufacturing controls include all the necessary activities related to shipping, delivery and any post-delivery work (if any)? |
| ISO 9001 8.5.1 | Is the procedure [Shipping Proc. Name] up to date and being followed? |
| ISO 9001 8.5.2 | Is the procedure [Identification & Traceability Proc. Title] up to date and being followed? |
| ISO 9001 8.5.2 | Is product identified at all stages as to what it is and/or what order it belongs to? |
| ISO 9001 8.5.2 | Does product identification include a means to identify its inspection status? (For example, nonconforming product should be marked as such.) |
| ISO 9001 8.5.2 | If products are subject to individual serialization or batch numbering, is this being done per requirements? |
| ISO 9001 8.5.3 | Is the procedure [Customer Property Proc. Title] up to date and being followed? |
| ISO 9001 8.5.3 | If the company uses customer or supplier provided hardware, is this identified as to the property owner? |
| ISO 9001 8.5.3 | If customer or supplier hardware is lost or damaged, is this reported to the owner? |
| ISO 9001 8.5.3 | If the company uses customer or supplier provided intellectual property, is this protected from loss or unauthorized access? |
| ISO 9001 8.5.4 | Is the procedure [Preservation Proc. Title] up to date and being followed? |
| ISO 9001 8.5.4 | Is the product properly preserved during all processing, handling and manufacturing steps? |
| ISO 9001 8.5.4 | Are shelf life items only used if their expiration dates have not expired? |
| ISO 9001 8.5.4 | Is product protected from contamination, foreign objects, or other corruption? |
| ISO 9001 8.5.4 | Is the product properly handled during all operations, to prevent damage? |
| ISO 9001 8.5.4 | Is the product properly stored while awaiting use or shipment, to prevent damage? |
| ISO 9001 8.5.5 | For product returned under warranty or which is still owned by the customer, but being repaired or reworked, is this work done per normal QMS procedures? |
| ISO 9001 8.5.5 | If the company does post delivery work, does this comply with any statutory or regulatory requirements? |
| ISO 9001 8.5.5 | Does post-delivery work include addressing reports of problems that arise from the products afterwards? |
| ISO 9001 8.5.5 | Does post-delivery work consider the nature, use and lifespan of the products delivered? |
| ISO 9001 8.5.5 | Does post-delivery work address related customer requirements? |
| ISO 9001 8.5.5 | Does post-delivery work address customer complaints or feedback? |
| ISO 9001 8.5.5 | Does post-delivery work include resolving any customer returns or reports of nonconforming product which has already shipped? |
| ISO 9001 8.5.6 | Are changes to manufacturing processes only implemented through a formal method that ensures the changes are reviewed and authorized? |
| ISO 9001 8.5.6 | Are records kept of such manufacturing process changes, including who authorized it? |
| ISO 9001 8.6 | Are final inspections or tests conducted to ensure the product meets requirements before delivery? |
| ISO 9001 8.6 | If product is shipped without a final inspection, is this only done when approved by the customer? |
| ISO 9001 8.6 | Are final inspection records kept? |
| ISO 9001 8.6 | If there are related inspection procedures or work instructions, are these up to date and being followed? |
| ISO 9001 8.6 | Do the final inspection records include inspection results? |
| ISO 9001 8.6 | Do the final inspection records include the name or identification of the person who performed the inspection? |
| ISO 9001 8.7.1 | Is the procedure [Control of NCP Proc. Title] up to date and being followed? [DELETE THIS QUESTION IF YOU ARE A SERVICE PROVIDER AND NOT A MANUFACTURER] |
| ISO 9001 8.7.1 | If services are performed, is the procedure [Control of Nonconforming Service Proc Title] up to date and being followed? [DELETE THIS QUESTION IF YOU ARE A MANUFACTURING COMPANY] |
| ISO 9001 8.7.1 | Are nonconforming products properly identified and controlled in some manner to ensure they are not accidentally used or shipped? |
| ISO 9001 8.7.1 | Are dispositions and corrective actions appropriate as compared to the seriousness or risk of the nonconformity? |
| ISO 9001 8.7.1 | Does the company notify customers if nonconforming product is discovered after it has been delivered? |
| ISO 9001 8.7.1 | Is nonconforming product dealt with by one or more of the following ways: corrected, contained, segregated, reworked, repaired or accepted as is? |
| ISO 9001 8.7.1 | Is nonconforming product segregated or contained, to ensure it does not cross-contaminate conforming products? |
| ISO 9001 8.7.1 | Is the customer notified when applicable? |
| ISO 9001 8.7.1 | If product is reworked or repaired, is it then re-inspected? |
| ISO 9001 8.7.2 | Are records of the nonconformities maintained? |
| ISO 9001 8.7.2 | Do these records include the actions taken, customer approvals or waivers received, and the person(s) authorizing the final disposition? |
| ISO 9001 9.1.1 | In general, is the company monitoring and measuring aspects of the quality system for the purposes of understanding what areas are effective and where improvement may be necessary? |
| ISO 9001 9.1.2 | Are methods underway to monitor and measure customer satisfaction? |
| ISO 9001 9.1.2 | If customer satisfaction measurement reveals problems, is corrective or preventive action taken? |
| ISO 9001 9.1.3 | Is the company measuring product quality data? |
| ISO 9001 9.1.3 | Is the company measuring process KPIs or objectives? |
| ISO 9001 9.1.3 | Is the company assessing, in some manner, if their QMS planning activities are effective? |
| ISO 9001 9.1.3 | Are risk mitigation and opportunity pursuit plans assessed for effectiveness? |
| ISO 9001 9.1.3 | Are suppliers being measured for performance? |
| ISO 9001 9.1.3 | Is the data used to improve the QMS? |
| ISO 9001 9.2.1 | Is the procedure [Internal Auditing Proc. Title] up to date and being followed? |
| ISO 9001 9.2.1 | Are internal audits scheduled, and a schedule or log maintained? |
| ISO 9001 9.2.1 | Are all ISO 9001 clauses addressed in the internal audits is some fashion? |
| ISO 9001 9.2.2 | Is the procedure for Internal Audits up to date and being followed? |
| ISO 9001 9.2.2 | Are audit reports being filled out properly? |
| ISO 9001 9.2.2 | Are the selected auditors objective and impartial? (Auditors must not audit their own work.) |
| ISO 9001 9.2.2 | Are the audit reports provided to the appropriate managers afterwards? |
| ISO 9001 9.2.2 | Are corrective actions filed for audit findings of nonconformities? |
| ISO 9001 9.2.2 | Are the audit records maintained properly? |
| ISO 9001 9.3.1 | Is the procedure [Management Review Proc. Title] up to date and being followed? |
| ISO 9001 9.3.1 | Does the attendance of management review meetings include all required attendees, including top management? |
| ISO 9001 9.3.2 | Does the review include: the status of actions from previous management reviews? |
| ISO 9001 9.3.2 | …changes in external and internal issues that are relevant to the quality management system? |
| ISO 9001 9.3.2 | ... information on the performance and effectiveness of the quality management system, including trends in:   * customer satisfaction and feedback? * quality objectives? * process performance and conformity of products? * status of corrective actions? * Internal audit results? * the performance of suppliers? |
| ISO 9001 9.3.2 | … the adequacy of resources? |
| ISO 9001 9.3.2 | … the effectiveness of actions taken to address risks and opportunities? |
| ISO 9001 9.3.2 | … opportunities for improvement? |
| ISO 9001 9.3.3 | Are the management review records maintained? |
| ISO 9001 9.3.3 | Do management review outputs include opportunities for improvement, resource allocations, and/or updates to the QMS? |
| ISO 9001 10.1 | Are opportunities within the COTO Log being monitored as necessary? |
| ISO 9001 10.1 | Are other improvement efforts underway to improve the quality of products? |
| ISO 9001 10.1 | Are other improvement efforts underway to reduce risk? |
| ISO 9001 10.1 | Are other improvement efforts underway to improve the quality system itself? |
| ISO 9001 10.2.1 | Is the [Corrective Preventive Action Proc. Title] procedure up to date and being followed? |
| ISO 9001 10.2.1 | Are corrective/preventive actions being properly assigned for analysis and action? |
| ISO 9001 10.2.1 | Are root cause(s) determined prior to development of a corrective/preventive action plan? |
| ISO 9001 10.2.1 | Are the action plans appropriate for the nature of the problem being reported? |
| ISO 9001 10.2.1 | Are actions being taken within the time (due dates) required? |
| ISO 9001 10.2.1 | Does root cause analysis include consideration of human error or human factors? |
| ISO 9001 10.2.1 | Are the actions taken later verified for effectiveness? |
| ISO 9001 10.2.1 | If necessary, does the corrective/preventive action system ensure that the COTO Log risk or opportunity register is updated accordingly? |
| ISO 9001 10.2.2 | Are the corrective/preventive action records maintained properly? |
| ISO 9001 10.3 | In general, is the company pursuing continual improvement of the QMS and its processes? |
| ISO 9001 10.3 | Is improvement derived from data provided from management reviews, QMS process measurements, product quality, etc.? |