# UL's ISO 9000 Registration Program – ISO 9001:2000 Quality System Checklist RP-2

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RP-2:2000 Issued: 11/27/00 Revised: 3/12/01

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UL's ISO 9000
Registration Program

**The *Quality System Checklist* is intended to help organize and streamline your effort in determining compliance with the ISO 9001:2000 standard.**

**You can gain a better understanding of ISO 9001:2000 standard as it applies to your company by reviewing these questions. You may wish to discuss them with your colleagues to enhance everyone's understanding of the ISO 9001:2000 requirements and the assessment process.**

**You should be aware that although the following questions include all the requirements of the ISO 9001:2000 standard, they do not necessarily cover all aspects of the Standard. So, the use of this checklist will give you only a sample of your organization's compliance to the ISO 9001:2000 standard.**

**Assessment Summary Sheet**

The *Assessment Summary Sheet* may be used for visualizing the big picture: what areas were checked and where discrepancies were found. You'll see from the sample *Assessment Summary Sheet* that assessment of the Purchasing Department uncovered discrepancies for clauses 4.1, 4.2, 5.5 and 7.4. This may be a sign of problems in that department or its processes, which warrant planning and close monitoring of corrective actions. The *Areas/Functions Assessed* column reveals that for clause 4.2 *Documentation Requirements*, discrepancies were uncovered in all applicable areas. This may give evidence of a system breakdown.

On the sample *Assessment Summary Sheet*, the circled numbers correspond to the following:

① The *ISO 9001:2000 Assessment Standard* correspond to the ISO:9001:2000 International Standard which your company has selected for assessment.

② The column *Areas/Function Assessed* lists the areas (i.e. process functions, departments, sections, offices, etc.) where compliance to given clauses will be evaluated.

③ These columns contain the list of clauses for the applicable ISO Standard to which compliance is being sought. NOTE: All clauses of the ISO 9001 Standard must be addressed. *See section 1.2. "Application", for further information.*

④ Use this grid to indicate where discrepancies are found by entering a "D" into the corresponding boxes. Where no discrepancies are uncovered, enter an "X" in the appropriate boxes.

## Assessment Summary Sheet - SAMPLE

| | ISO 9001:2000 ① | Areas/ Functions Assessed* ② | | | | | | | | | | | | | | | | | | Discrepancy |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | *Quality Management Systems: Requirements* | Management | Sales | Design | Planning | Purchasing | Production | Test | Stock & Ship | | | | | | | | | | | Reference Number |
| Clause Number | Clause Description ③ | | | | | | | | | | | | | | | | | | | |
| 4.1 | Quality management system | X | X | X | X | D | X | X | X | X | | | | | | | | | | |
| 4.2 | Documentation requirements | D | D | D | D | D | D | D | D | D | | | | | | | | | | |
| 5.1 | Management commitment | X | | | | | | | | | | | | | | | | | | |
| 5.2 | Customer focus | X | | | | | | | | | | | | | | | | | | |
| 5.3 | Quality policy | X | | | | | | | | | | | | | | | | | | |
| 5.4 | Planning | X | | | | | | | | | | | | | | | | | | |
| 5.5 | Responsibility, authority and communication | X | X | X | X | D | X | X | X | X | | | | | | | | | | |
| 5.6 | Management Review | X | | | | | | | | | | | | | | | | | | |
| 6.1 | Provision of resource | X | | | | | | | | | | | | | | | | | | |
| 6.2 | Human resources | D | | | | | | | | X | | | ④ | | | | | | | |
| 6.3 | Infrastructure | | | X | | | | | | | | | | | | | | | | |
| 6.4 | Work environment | | | X | | | | | | | | | | | | | | | | |
| 7.1 | Planning of product realization | | | X | | | | | | | | | | | | | | | | |
| 7.2 | Customer-related processes | | X | | | | | | | | | | | | | | | | | |
| 7.3 | Design and development | | | X | | | | | | | | | | | | | | | | |
| 7.4 | Purchasing | | | | | D | | | | | | | | | | | | | | |
| 7.5 | Production and service provision | | | | X | | X | | | X | | | | | | | | | | |
| 7.6 | Control of monitoring and measuring devices | | | | | | X | X | | | | | | | | | | | | |
| 8.1 | Measurement, analysis and improvement | X | | | | | | | | | | | | | | | | | | |
| 8.2 | Monitoring and measurement | | | | | | X | X | | | | | | | | | | | | |
| 8.3 | Control of nonconforming product | | | | | | X | X | | D | | | | | | | | | | |
| 8.4 | Analysis of data | X | | | | | | | | | | | | | | | | | | |
| 8.5 | Improvement | X | | | | | | | | | | | | | | | | | | |

*** Use an "X" to indicate that the clause was assessed in the area described. Use a "D" to indicate that a discrepancy was found**

## Assessment Summary Sheet

| | ISO 9001:2000 | Areas / Functions Assessed | | | | | | | | | | | | | | | | | Discrepancy Reference Number |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | *Quality Management Systems: Requirements* | | | | | | | | | | | | | | | | | | |
| Clause Number | Clause Description | | | | | | | | | | | | | | | | | | |
| 4.1 | Quality management system | | | | | | | | | | | | | | | | | | |
| 4.2 | Documentation requirements | | | | | | | | | | | | | | | | | | |
| 5.1 | Management commitment | | | | | | | | | | | | | | | | | | |
| 5.2 | Customer focus | | | | | | | | | | | | | | | | | | |
| 5.3 | Quality policy | | | | | | | | | | | | | | | | | | |
| 5.4 | Planning | | | | | | | | | | | | | | | | | | |
| 5.5 | Responsibility, authority and communication | | | | | | | | | | | | | | | | | | |
| 5.6 | Management Review | | | | | | | | | | | | | | | | | | |
| 6.1 | Provision of resource | | | | | | | | | | | | | | | | | | |
| 6.2 | Human resources | | | | | | | | | | | | | | | | | | |
| 6.3 | Infrastructure | | | | | | | | | | | | | | | | | | |
| 6.4 | Work environment | | | | | | | | | | | | | | | | | | |
| 7.1 | Product realization | | | | | | | | | | | | | | | | | | |
| 7.2 | Customer-related processes | | | | | | | | | | | | | | | | | | |
| 7.3 | Design and development | | | | | | | | | | | | | | | | | | |
| 7.4 | Purchasing | | | | | | | | | | | | | | | | | | |
| 7.5 | Production and service provision | | | | | | | | | | | | | | | | | | |
| 7.6 | Control of monitoring and measuring devices | | | | | | | | | | | | | | | | | | |
| 8.1 | Measurement, analysis and improvement | | | | | | | | | | | | | | | | | | |
| 8.2 | Monitoring and measurement | | | | | | | | | | | | | | | | | | |
| 8.3 | Control of nonconforming product | | | | | | | | | | | | | | | | | | |
| 8.4 | Analysis of data | | | | | | | | | | | | | | | | | | |
| 8.5 | Improvement | | | | | | | | | | | | | | | | | | |

| QUALITY SYSTEM CHECKLIST | | | |
|---|---|---|---|
| **ISO 9001:2000** | **Quality System Requirements** | **Document References** | **Explanatory Notes and Comments** |
| **4.0** | **Quality Management System** | | |
| **4.1.** | ***General Requirements*** | | |
| 4.1 | Has a quality management system been established, documented, maintained and Continually improved in accordance with the requirements ISO 9001:2000 ? | | |
| 4.1. | How will it be demonstrated that the following activities have been accomplished in accordance with the requirements of ISO 9001:2000 ?<br>• Processes needed for the quality management system and their application identified?<br>• Sequence and interaction of quality management system processes determined?<br>• Criteria and methods needed to ensure the effective operation and control of quality management system processes determined?<br>• Information and resources made available to support the operation and monitoring of quality management processes?<br>• Measuring, monitoring and analysis of quality management system process implemented?<br>• Has action necessary to achieve planned results and continual improvement of the quality management system been implemented? | | |
| 4.1 | Is evidence available confirming that all outsourced processes affecting product conformance with requirements have been identified and controlled within the quality management system? | | |
| **4.2** | ***Documentation requirements*** | | |
| 4.2.1 | Does the quality management system documentation include:<br>• Documented quality policy and objectives?<br>• A quality manual?<br>• Documented procedures required by ISO 9001:2000 ?<br>• Documents needed to ensure effective planning, operation and control of processes?<br>• Quality records required by ISO 9001:2000 ? (see 4.2.4) | | |

| ISO 9001:2000 | Quality System Requirements | Document References | Explanatory Notes and Comments |
|---|---|---|---|
| **4.2.2** | ***Quality Manual*** | | |
| 4.2.2 | Has a quality manual been established and maintained that includes the following?<br>• The scope of the quality management system, including details of, and justification for, any exclusions? ***( see Clause 1.2, "Application"of ISO 9001:2000 )***<br>• Documented procedures for the quality management system or reference to them?<br>• A description of the interaction between the processes of the quality management system? | | |
| **4.2.3** | ***Control of Documents*** | | |
| 4.2.3 | Have all documents required for the quality management system been placed under control? | | |
| 4.2.3 | Are records controlled in accordance with the requirements of 4.2.4? | | |
| 4.2.3 | Is there a documented procedure for control of documents, which addresses all requirements of 4.2.3? | | |
| 4.2.3 | Are documents approved for adequacy prior to use? | | |
| 4.2.3 | Are documents reviewed, updated and reapproved as necessary? | | |
| 4.2.3 | Are changes and the current revision status of documents identified? | | |
| 4.2.3 | Are the relevant versions of applicable documents available at points of use? | | |
| 4.2.3 | Are the documents legible and readily identifiable? | | |
| 4.2.3 | Are documents of external origin identified and their distribution controlled? | | |
| 4.2.3 | Are controls in place to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose? | | |

| ISO 9001:2000 | Quality System Requirements | Document References | Explanatory Notes and Comments |
|---|---|---|---|
| **4.2.4** | **Control of quality records** | | |
| 4.2.4 | Do quality records provide evidence of conformance to requirements and the effective operation of the quality management system? | | |
| 4.2.4 | Has a documented procedure been established for the identification, storage, retrieval, protection, retention time and disposition of quality records? | | |
| 4.2.4 | Are quality records legible, readily identifiable and retrievable? | | |
| **5.0** | ***Management Responsibility*** | | |
| **5.1** | ***Management commitment*** | | |
| 5.1 | Can top management demonstrate evidence of commitment to the development, implementation and improvement of the effectiveness of the quality management system by:<br>• Communicating to the organization the importance of meeting customer requirements?<br>• Establishing the quality policy?<br>• Ensuring that quality objectives are established?<br>• Conducting management reviews?<br>• Ensuring the availability of resources? | | |
| **5.2** | ***Customer focus*** | | |
| 5.2 | How does top management ensure that customer requirements are determined and fulfilled with the aim of enhancing customer satisfaction? | | |
| **5.3** | ***Quality Policy*** | | |
| 5.3 | Is top management able to demonstrate how they ensure that the quality policy is:<br>• Appropriate to the organization?<br>• Includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system?<br>• Provides a framework for establishing and reviewing quality objectives?<br>• Is communicated and understood throughout the organization?<br>• Is reviewed for continuing suitability? | | |

| ISO 9001:2000 | Quality System Requirements | Document References | Explanatory Notes and Comments |
|---|---|---|---|
| **5.4.** | ***Planning*** | | |
| **5.4.1** | ***Quality objectives*** | | |
| 5.4.1 | Is top management able to demonstrate how they ensure that quality objectives, including those needed to meet requirements for product (see 7.1) are established at relevant functions and levels within the organization? | | |
| 5.4.1 | Are the quality objectives measurable and consistent with the quality policy? | | |
| **5.4.2** | ***Quality management system planning*** | | |
| 5.4.2 | Is top management able to demonstrate how they ensure:<br>• Quality management system planning is carried out in order to meet the requirements given in 4.1 and the quality objectives?<br>• The integrity of the quality management system is maintained when changes to the quality management system are planned and implemented? | | |
| **5.5** | ***Responsibility, authority and communication*** | | |
| **5.5.1** | ***Responsibility and authority*** | | |
| 5.5.1 | Is top management able to demonstrate how they ensure that the responsibilities, authorities and their interrelation are defined and communicated within the organization? | | |

| ISO 9001:2000 | Quality System Requirements | Document References | Explanatory Notes and Comments |
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| **5.5.2** | ***Management Representative*** | | |
| 5.5.2 | Has top management appointed one or more members of management to serve as the management representative? | | |
| 5.5.2 | Does the management representative's authority and responsibility, irrespective of other responsibilities include:<br>• Ensuring that processes for the quality management system are established, implemented and maintained?<br>• Reporting to top management the performance of the quality management system including needs for improvement?<br>• Promoting awareness of customer requirements throughout the organization? | | |
| **5.5.3** | ***Internal Communication*** | | |
| 5.5.3 | Is top management able to demonstrate how they ensure that appropriate communication processes are established within the organization, and that communication takes place regarding the effectiveness of the quality management system? | | |
| **5.6** | ***Management Review*** | | |
| **5.6.1** | ***General*** | | |
| 5.6.1 | Does top management review the quality management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness? | | |
| 5.6.1 | Does management review evaluate the need for changes to the quality management system, including the quality policy and quality objectives? | | |
| 5.6.1 | Are the results of management review recorded? (see 4.2.4) | | |

| ISO 9001:2000 | Quality System Requirements | Document References | Explanatory Notes and Comments |
|---|---|---|---|
| **5.6.2** | ***Review Input*** | | |
| 5.6.2 | Do the inputs to management review include information on the following:<br>• Results of audits?<br>• Customer feedback?<br>• Process performance and product conformance?<br>• Status of preventative and corrective actions?<br>• Follow-up actions from earlier management reviews?<br>• Planned changes that could affect the quality management system?<br>• Recommendations for improvement? | | |
| **5.6.3** | ***Review Output*** | | |
| 5.6.3 | Do the outputs from management review include decisions and actions related to:<br>• Improvement of the effectiveness of the quality management system and its processes?<br>• Improvement of product related to customer requirements?<br>• Resource needs? | | |
| **6.0** | ***Resource Management*** | | |
| **6.1** | ***Provision of resources*** | | |
| 6.1 | How will it be demonstrated that the organization determines and provides the resources needed to:<br>• Implement, and maintain and continually improve the quality management system?<br>• Enhance customer satisfaction by meeting requirements? | | |
| **6.2** | ***Human resources*** | | |
| **6.2.1** | ***General*** | | |
| 6.2.1 | Is evidence available that personnel performing work affecting product quality are competent on the basis of appropriate education, training, skills and experience? | | |

| ISO 9001:2000 | Quality System Requirements | Document References | Explanatory Notes and Comments |
|---|---|---|---|
| **6.2.2** | ***Competence, awareness and training*** | | |
| 6.2.2 | Has the necessary competence for personnel performing work affecting product quality been determined?<br>• Appropriate records of education, training, skills and experience are maintained? | | |
| 6.2.2 | Has Training been provided or other actions taken to satisfy competency needs? | | |
| 6.2.2 | Is the Training provided or other actions taken evaluated for effectiveness in meeting the competency needs? | | |
| 6.2.2 | Are Personnel aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives? | | |
| *6.2.2* | Are appropriate records of education, training, skills and experience maintained? (See 4.2.4) | | |
| **6.3** | ***Infrastructure*** | | |
| *6.3* | How will it be demonstrated that the organization determines, provides and maintains the infrastructure needed to achieve conformity to product requirements? | | |
| 6.3 | Does infrastructure include, as applicable:<br>• Buildings, workspace and associated utilities?<br>• Process equipment including hardware and software?<br>• Supporting services such as transport or communication? | | |

| ISO 9001:2000 | Quality System Requirements | Document References | Explanatory Notes and Comments |
|---|---|---|---|
| **6.4** | ***Work Environment*** | | |
| 6.4. | How will it be demonstrated that the organization determines and manages the work environment needed to achieve conformity to product requirements? | | |
| **7.0** | **Product Realization** | | |
| **7.1** | ***Planning of product realization*** | | |
| 7.1 | How will it be demonstrated that:<br>• Processes needed for product realization are planned and developed?<br>• Planning of product realization is consistent with the requirements of other processes of the quality management system? (see 4.1) | | |
| 7.1 | Is the following determined, as appropriate, during product realization planning?<br>• Quality objectives and requirements for the product?<br>• The need to establish verification, validation, monitoring, inspection and test activities specific to the product and criteria for product acceptance?<br>• Records needed to provide evidence that realization processes and resulting product fulfill requirements (see 4.2.4) | | |
| **7.2** | ***Customer related processes*** | | |
| **7.2.1** | ***Determination of requirements related to the product*** | | |
| 7.2.1 | How will it be demonstrated that the following is determined:<br>• Requirements specified by the customer, including requirements for delivery and post-delivery activities?<br>• Requirements not stated by the customer but necessary for specified use or known and intended use?<br>• Statutory and regulatory requirements related to the product<br>• Any additional requirements determined by the organization? | | |

| ISO 9001:2000 | Quality System Requirements | Document References | Explanatory Notes and Comments |
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| **7.2.2** | **Review of requirements related to the product** | | |
| 7.2.2. | Are Requirements related to the product reviewed prior to the commitment to supply a product to the customer? | | |
| 7.2.2 | Does the review activity ensure:<br>• Product requirements are defined?<br>• Contract or order requirements differing from those previously expressed are resolved?<br>• The organization's ability to meet defined requirements? | | |
| 7.2.2 | Are records of the results of review and actions arising from review activity maintained? (see 4.2.4) | | |
| 7.2.2 | How will it be demonstrated that the organization confirms customer requirements when no documented statement of requirement is provided by the customer? | | |
| *7.2.2* | Is evidence available that relevant documents are amended and relevant personnel made aware of any changed product requirements*?* | | |
| **7.2.3** | ***Customer communication*** | | |
| 7.2.3 | Do effective arrangements exist for customer communication related to:<br>• Product information?<br>• Inquiries, contracts, order handling and amendments?<br>• Customer feedback and customer complaints? | | |

| ISO 9001:2000 | Quality System Requirements | Document References | Explanatory Notes and Comments |
|---|---|---|---|
| **7.3** | **Design and development** | | |
| **7.3.1.** | ***Design and development planning*** | | |
| 7.3.1 | Is evidence available that the organization plans and controls the design and development of product? | | |
| 7.3.1 | Is the following determined during design and development planning?<br>• The design and development stages?<br>• The review, verification and validation that are appropriate to each design and development stage?<br>• The responsibilities and authorities for design and development? | | |
| 7.3.1 | Are the interfaces between different groups involved in design and development managed to ensure effective communication and clear assignment of responsibility? | | |
| 7.3.1 | Are planning outputs updated, as appropriate, as the design and development progresses? | | |
| **7.3.2** | ***Design and development inputs*** | | |
| 7.3.2 | Are inputs relating to product requirements determined and records maintained (see 4.2.4) relating to:<br>• Functional and performance requirements?<br>• Applicable statutory and regulatory requirements?<br>Applicable information from previous similar designs?<br>• Other requirements essential for design and development? | | |

| ISO 9001:2000 | Quality System Requirements | Document References | Explanatory Notes and Comments |
|---|---|---|---|
| **7.3.2** | ***Design and development inputs*** | | |
| 7.3.2 | What evidence is available to indicate:<br>• Design and development inputs are reviewed for adequacy?<br>• Requirements are complete, unambiguous and not in conflict with each other? | | |
| **7.3.3** | ***Design and development outputs*** | | |
| 7.3.3 | Are the outputs of design and development:<br>• In a form that enables verification against the design and development inputs?<br>• Approved prior to release? | | |
| 7.3.3 | Do the design and development outputs:<br>• Meet input requirements for design and development?<br>• Provide appropriate information for purchasing, production and service provision?<br>• Contain or reference product acceptance criteria?<br>• Specify the characteristics of the product that are essential for its safe and proper use? | | |
| **7.3.4** | ***Design and development review*** | | |
| 7.3.4 | Are reviews conducted at suitable stages of design and development to:<br>• Evaluate the ability of the results of design and development to fulfill requirements?<br>• Identify any problems and propose necessary actions? | | |
| 7.3.4 | Do design and development reviews include representatives concerned with the design and development stage (s) being reviewed? | | |

| ISO 9001:2000 | Quality System Requirements | Document References | Explanatory Notes and Comments |
|---|---|---|---|
| **7.3.4** | ***Design and development review*** | | |
| 7.3.4 | Are records of the results of design and development reviews and any necessary actions arising from review activity maintained? (see 4.2.4) | | |
| **7.3.5** | ***Design and development verification*** | | |
| 7.3.5 | Is verification performed to ensure that design and development outputs have satisfied the design and development input requirements? | | |
| 7.3.5 | Are records of the results of verification and any necessary actions maintained? (see 4.2.4) | | |
| **7.3.6** | ***Design and development validation*** | | |
| 7.3.6 | Is design and development validation conducted in accordance with planned arrangements (see 7.3.1), to ensure that the resulting product is capable of fulfilling the requirements for the specified or known intended use or application? | | |
| 7.3.6 | Where practicable, is validation completed prior to the delivery or implementation of the product? | | |
| 7.3.6 | Are records of the results of validation and any necessary actions maintained? (see 4.2.4) | | |
| **7.3.7** | ***Design and development changes*** | | |
| 7.3.7 | Are design and development changes:<br>• Identified?<br>• Reviewed?<br>• Verified and validated as appropriate?<br>• Evaluated for effect on constituent parts and delivered products?<br>• Approved before implementation?<br>• Recorded? | | |

| ISO 9001:2000 | Quality System Requirements | Document References | Explanatory Notes and Comments |
|---|---|---|---|
| **7.3.7** | ***Design and development changes*** | | |
| 7.3.7 | Are records of the results of changes and any necessary actions maintained? (see 4.2.4) | | |
| **7.4** | ***Purchasing*** | | |
| **7.4.1** | ***Purchasing process*** | | |
| 7.4.1 | What processes exist to ensure that purchased product conforms to specified purchase requirements? | | |
| 7.4.1 | Is the type and extent of control applied to suppliers and purchased products are determined based upon the effect of purchased product on subsequent product realization or final product? | | |
| 7.4.1 | Are suppliers evaluated and selected based upon their ability to supply product in accordance with the organization requirements? | | |
| 7.4.1 | Are records of the results of supplier evaluations and any necessary actions arising from evaluations maintained? (see 4.3.4) | | |
| 7.4.1 | Has criteria for supplier selection, evaluation and re-evaluation been determined? | | |
| **7.4.2** | ***Purchasing Information*** | | |
| 7.4.2 | Does purchasing information describe the product to be purchased, including where appropriate:<br>• Requirements for approval of product, procedures, processes and equipment?<br>• Requirements for qualification of personnel?<br>• Quality management system requirements? | | |

| ISO 9001:2000 | Quality System Requirements | Document References | Explanatory Notes and Comments |
|---|---|---|---|
| **7.4.2** | ***Purchasing Information*** | | |
| 7.4.2 | Is the adequacy of specified purchase requirements are ensured prior to their communication to the supplier? | | |
| **7.4.3** | ***Verification of purchased product*** | | |
| 7.4.3 | Have inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements been established and implemented? | | |
| 7.4.3 | When the organization or the customer performs verification at the supplier's premises, has the organization stated the intended verification arrangements and the method of product release in the purchasing information? | | |
| **7.5** | ***Production and service provision*** | | |
| **7.5.1** | ***Control of production and service provision*** | | |
| 7.5.1 | Are production and service operations carried out under controlled conditions? | | |
| 7.5.1 | What evidence is available to demonstrate that controlled conditions include the following, as applicable?<br>• The availability of information that describes the characteristics of the product?<br>• The availability of work instructions?<br>• The use of suitable equipment?<br>• The availability and use of monitoring and measurement devices?<br>• The implementation of monitoring and measurement?<br>• The implementation of release, delivery and post-delivery activities? | | |

| ISO 9001:2000 | Quality System Requirements | Document References | Explanatory Notes and Comments |
|---|---|---|---|
| **7.5.2** | ***Validation of processes for production and service provision*** | | |
| 7.5.2 | Are production and service processes validated where the resulting output cannot be verified by subsequent monitoring or measurement validated? | | |
| 7.5.2 | How do validation activities demonstrate the ability of these processes to achieve planned results? | | |
| 7.5.2 | Do validation processes include the following as applicable?<br>• Defined criteria for review and approval of the processes<br>• Approval of equipment and qualification of personnel<br>• Use of specific methods and procedures<br>• Requirements for records (see 4.2.4)<br>• Re-validation? | | |
| **7.5.3** | ***Identification and traceability*** | | |
| 7.5.3 | Is product identified, as appropriate, by suitable means throughout product realization? | | |
| 7.5.3 | Is product status identified with respect to measuring and monitoring requirements? | | |
| 7.5.3 | Is traceability a specified requirement? If so, is unique identification of the product controlled and recorded? (see 4.2.4) | | |
| **7.5.4** | ***Customer Property*** | | |
| 7.5.4 | Is customer property provided for the use or incorporation into the product under the control or use of the organization? If so, does a process exist which ensures that care is provided for customer property? | | |

| ISO 9001:2000 | Quality System Requirements | Document References | Explanatory Notes and Comments |
|---|---|---|---|
| **7.5.4** | ***Customer Property*** | | |
| 7.5.4 | How will it be demonstrated that customer property is:<br>Identified?<br>Verified?<br>Protected?<br>Safeguarded? | | |
| 7.5.4 | Is lost, damaged, or unsuitable product reported to the customer and records maintained? (see 4.2.4) | | |
| **7.5.5** | ***Preservation of product*** | | |
| 7.5.5 | How will it be demonstrated that conformity of product, and constituent parts of the product, are preserved during internal processing and delivery to the intended destination? | | |
| 7.5.5 | Are product preservation methods established for:<br>Identification?<br>Handling?<br>Packaging?<br>Storage?<br>Protection? | | |
| **7.6** | ***Control of monitoring and measuring devices*** | | |
| 7.6 | Has the organization determined the monitoring and measurement to be undertaken, and the monitoring and measurement devices needed to provide evidence of conformity to determined requirements? (see 7.2.1) | | |
| 7.6 | Are processes established which ensure monitoring and measurement is carried out in a manner consistent with measuring and monitoring requirements? | | |

| ISO 9001:2000 | Quality System Requirements | Document References | Explanatory Notes and Comments |
|---|---|---|---|
| **7.6** | ***Control of monitoring and measuring devices*** | | |
| 7.6 | Is measuring equipment<br>Calibrated or verified at specified intervals or prior to use against traceable international or national measurement standards? (If international or national measurement standards are not available, the basis for calibration or verification shall be recorded)<br>• Adjusted or re-adjusted as necessary?<br>• Identified to enable calibration status to be determined?<br>• Safeguarded from adjustments that would invalidate the measurement result?<br>• Protected from damage and deterioration during handling, maintenance and storage? | | |
| 7.6 | How will it be demonstrated that:<br>• The validity of previous measuring results is assessed by the organization when equipment is found not to conform to requirements?<br>• Appropriate action is taken on the equipment and any affected product? | | |
| 7.6 | Are records of the results of calibration and verification maintained (see 4.2.4)? | | |
| 7.6 | Is computer software used in the measuring and monitoring of specified requirements?<br>If so, is the ability of computer software to satisfy the intended application confirmed prior to initial use and re-confirmed as necessary? | | |

| ISO 9001:2000 | Quality System Requirements | Document References | Explanatory Notes and Comments |
|---|---|---|---|
| **8.0** | **Measurement, analysis and improvement** | | |
| **8.1** | ***General*** | | |
| 8.1 | Are monitoring, measurement, analysis and improvement processes planned and implemented as needed to:<br>• Demonstrate conformity of the product?<br>• Ensure conformity of the quality management system?<br>• Continually improve the effectiveness of the quality management system?<br>• Determine applicable methods including statistical techniques and the extent of their use? | | |
| **8.2** | ***Monitoring and measurement*** | | |
| **8.2.1** | ***Customer satisfaction*** | | |
| 8.2.1 | Is information relating to customer perceptions to whether the organization has fulfilled customer requirements monitored? | | |
| 8.2.1 | What are the methods for obtaining and using customer satisfaction information? | | |
| ***8.2.2*** | ***Internal audit*** | | |
| 8.2.2 | Have the responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) been defined in a documented procedure? | | |

| ISO 9001:2000 | Quality System Requirements | Document References | Explanatory Notes and Comments |
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| **8.2.2** | ***Internal audit*** | | |
| 8.2.2 | Does the internal quality audit activity determine whether the quality management system:<br>• Conforms to planned arrangements? (see 7.1)<br>• Conforms to ISO 9001:2000 ?<br>• Conforms to quality management system requirements established by the organization?<br>• Is effectively implemented and maintained? | | |
| 8.2.2 | Is evidence available to confirm that internal audits are conducted at planned intervals based upon:<br>• The status and importance of the processes and areas to be audited?<br>• The results of previous audits? | | |
| 8.2.2 | Have audit criteria, scope, frequency and methods been defined? | | |
| 8.2.2 | Is evidence available to confirm that internal auditors are objective and impartial of the audit process? | | |
| 8.2.2 | Does the management responsible for the area being audited ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes? | | |
| 8.2.2 | Do the nonconformity follow-up activities include the verification of the actions taken and the reporting of verification results? (see 8.5.5) | | |
| **8.2.3** | ***Monitoring and measurement of processes*** | | |
| 8.2.3 | Can it be demonstrated that suitable methods for monitoring, and where applicable, measurement of the quality management system processes been applied? | | |
| 8.2.3 | Do these methods:<br>• Confirm the ability of these processes to achieve planned results?<br>• Provide for appropriate correction and corrective action when planned results are not achieved to ensure product conformity? | | |

| ISO 9001:2000 | Quality System Requirements | Document References | Explanatory Notes and Comments |
|---|---|---|---|
| **8.2.4** | ***Monitoring and measurement of product*** | | |
| 8.2.4 | Can it be demonstrated that measurement and monitoring of the product is carried out at various stages of the product realization process in accordance with planned arrangements? (see 7.1) | | |
| 8.2.4 | Is evidence of conformity with the acceptance criteria maintained, and do records indicate the person authorizing release of product ? (see 4.2.4) | | |
| 8.2.4 | Are controls in place to ensure that product release and service delivery do not proceed until all planned arrangements (see 7.1) are satisfactorily completed? If not, is release approval evidence from a relevant authority or the customer available? | | |
| **8.3** | ***Control of nonconforming product*** | | |
| 8.3 | Is product that does not conform to requirements identified and controlled to prevent its unintended use of delivery? | | |
| **ISO 9001:2000 FDIS** | **Quality System Requirements** | **Document References** | **Explanatory Notes and Comments** |
| **8.3** | ***Control of nonconforming product*** | | |
| 8.3 | Have the controls and related responsibilities and authorities for dealing with nonconforming product been defined in a documented procedure? | | |

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| 8.3 | Is evidence available that nonconforming product is dealt with by one or more of the following ways:<br>• By taking action to eliminate the detected nonconformity<br>• By authorizing its use, release or acceptance under concession by a relevant authority, and where applicable by the customer<br>• By taking action to preclude its original intended use or application | | |
| 8.3 | Are records of the nature of nonconfomities and any subsequent actions taken, including concessions maintained? (see 4.2.4) | | |
| 8.3 | Is evidence available that corrected nonconforming product is subject to re-verification to demonstrate conformity to the requirements? | | |
| 8.3 | Are actions appropriate to the effects, or potential effects of nonconforming product taken when nonconforming product is detected after delivery or use has started? | | |
| **8.4** | ***Analysis of data*** | | |
| 8.4 | Is appropriate data collected and analyzed to:<br>• Demonstrate the suitability and effectiveness of the quality management system ?<br>• Evaluate where continual improvement of the quality management system can be made? | | |
| 8.4 | Is data generated as a result of monitoring and measurement as well as from other relevant sources collected for analysis? | | |
| 8.4 | Does the data analysis provides information relating to:<br>• Customer satisfaction (see 8.2.1)<br>• Conformance to product requirements (see 7.2.1)<br>• Characteristics and trends of processes and products ?<br>• Opportunities for preventative action?<br>• Suppliers? | | |

| ISO 9001:2000 | Quality System Requirements | Document References | Explanatory Notes and Comments |
|---|---|---|---|
| **8.5** | ***Improvement*** | | |

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| **8.5.1** | ***Continual improvement*** | | |
| 8.5.1 | How will it be demonstrated that the effectiveness of the quality management system is being continually improved? | | |
| 8.5.1 | Are the following being used to improve the effectiveness of the quality management system?<br>• Quality policy?<br>• Quality objectives?<br>• Audit results?<br>• Analyze of data?<br>• Corrective actions?<br>• Preventative actions?<br>• Management review? | | |
| **8.5.2** | ***Corrective action*** | | |
| 8.5.2 | Is action taken to eliminate the cause of nonconformities in order to prevent recurrence? | | |
| 8.5.2 | Are the Corrective actions taken appropriate to the effects of the nonconformities encountered? | | |
| 8.5.2 | Does a documented procedure define requirements for:<br>• Reviewing nonconformity?<br>• Reviewing customer complaints?<br>• Determining the causes of nonconformities?<br>• Evaluating the need for action to ensure that nonconformites do not recur?<br>• Determining and implementing action needed?<br>• Recording results of the action taken (see 4.2.4)<br>• Reviewing corrective action taken? | | |

| ISO 9001:2000 | Quality System Requirements | Document References | Explanatory Notes and Comments |
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| **8.5.3** | ***Preventative action*** | | |
| 8.5.3 | Is action is taken to eliminate the causes of potential nonconforties in order to prevent their occurrence? | | |

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| 8.5.3 | Are the Preventative actions taken appropriate to the effects of the potential problems? | | |
| 8.5.2 | Does a documented procedure define requirements for:<br>• Determining potential nonconformites and their causes?<br>• Evaluating the need for action to prevent occurrence of nonconformities?<br>• Determining and implementing action needed?<br>• Recording results of the action taken (see 4.2.4)<br>• Reviewing preventative action taken? | | |