## Audit Checklist for ISO 9001

<table>
<thead>
<tr>
<th>Requirements</th>
<th>Conformity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.1 General Requirements</strong></td>
<td></td>
</tr>
<tr>
<td>a) Processes needed for QMS and their application throughout the organization are determined</td>
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<tr>
<td>b) Sequence and interaction of these processes is determined</td>
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<tr>
<td>c) Criteria and methods needed to ensure that operation and control of these processes are effective is determined</td>
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<tr>
<td>d) Availability of resources and information necessary to support operation of these processes is ensured</td>
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<tr>
<td>e) Monitoring, measuring (where applicable) and analysis of these processes are done</td>
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<tr>
<td>f) Actions to achieve planned results and continual improvement of processes are implemented</td>
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<tr>
<td>Type &amp; extent of controls defined for the outsourced processes which affect product conformity to requirements</td>
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<tr>
<td><strong>1.2 Documentation Requirements</strong></td>
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<tr>
<td><strong>1.2.1 Quality Manual – Quality Manual includes</strong></td>
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<tr>
<td>a) Statements of quality policy and quality objectives</td>
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<td>b) Quality Manual</td>
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<tr>
<td>c) Procedures and records required by IS/ISO 9001</td>
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<tr>
<td>d) Documents, including records, determined by organization to ensure effective planning, operation and control of its processes</td>
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<tr>
<td><strong>1.2.2 Control of documents – Controls defined under the established procedure implemented for records with respect to</strong></td>
<td></td>
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<tr>
<td>Identification, Storage, Protection, Retrieval, Retention and Disposition</td>
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<tr>
<td>a) Proce</td>
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<tr>
<td><strong>2 Management Responsibility</strong></td>
<td></td>
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<tr>
<td><strong>2.1 Management’s commitment for development &amp; implementation QMS and continually improving its effectiveness by</strong></td>
<td></td>
</tr>
<tr>
<td>a) Communication of importance of meeting customer, statutory and regulatory requirements</td>
<td></td>
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<tr>
<td>b) Establishing the quality policy</td>
<td></td>
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<tr>
<td>c) Ensuring establishment of quality objectives</td>
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<tr>
<td>d) Conducting Management review</td>
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<tr>
<td>Ensuring availability of resources</td>
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<tr>
<td><strong>2.2 Customer Focus</strong></td>
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<tr>
<td>Top Management has ensured that customer requirements are determined and met with aim of enhancing customer satisfaction</td>
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<tr>
<td><strong>2.3 Quality Policy</strong></td>
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<tr>
<td>a) Appropriate to the purpose of the organization</td>
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<tr>
<td>b) Includes commitment to comply with the requirements and continual improvement of effectiveness of QMS</td>
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<td>c) Provides framework for establishing and reviewing quality objectives</td>
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<tr>
<td>d) Communicated and understood within the organization</td>
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<tr>
<td>e) Reviewed for continuing suitability</td>
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</table>
### 2.4 Planning

#### 2.4.1 Quality Objectives
- Established at relevant function & levels within the organization
- Measurable and consistent with quality policy

#### 2.4.2 Quality Management System Planning
a) Planning of QMS carried out to meet the general requirements of QMS (cl. 4.1), as well as the quality objectives
b) Integrity of QMS System is maintained when changes to it are planned and implemented.

### 2.5 Responsibility, Authority and Communication

#### 2.5.1 Responsibilities and authorities are defined and communicated within the organization

#### 2.5.2 Management Representative
Management Representative is a member of organization’s management
Responsibilities & authorities of Management Representative include:
- ensuring that processes needed for QMS are established, implemented and maintained
- reporting to Top Management on performance of QMS and any need for improvement
- ensuring promotion of awareness of customer requirements throughout the organization

#### 2.5.3 Internal Communications
Appropriate communication processes within the organization are established and effectiveness of QMS communicated

### 2.6 Management Review

#### 2.6.1 QMS reviewed at planned intervals to ensure its continuing suitability, adequacy and effectiveness
- Review includes assessing opportunities for improvement & need for changes to QMS including quality policy & quality objectives
- Records from management reviews maintained

#### 2.6.2 Review Input
Input to management reviews includes information on
- Results of audits
- Customer feedback
- Process performance and product conformity
- Status of preventive and corrective actions
- Follow-up actions from previous management reviews
- Changes that could affect the QMS
- Recommendations for improvement

#### 2.6.3 Review Output
Output from management review includes any decisions and actions related to
- Improvement of effectiveness of QMS and its processes
- Improvement of product related to customer requirement
- Resource needs

### 3 Resource Management

#### 3.1 Provision of resources – Resources determined and provided to:
- Implement & maintain QMS and continually improve its effectiveness
- Enhance customer satisfaction by meeting customer requirements

#### 3.2 Human Resources -General

#### 3.2.1 Competency of personnel performing work affecting conformity to product requirements directly or indirectly is on the basis of appropriate education, training, skills and experience
3.2.2 Competence, training and awareness
a) Competence of personnel performing work affecting conformity to product requirements is determined
b) Training provided or other actions taken where applicable to achieve necessary competence
c) Effectiveness of the actions taken evaluated
d) Personnel are aware of relevance and importance of their activities and their contribution to achieve the quality objectives
e) Records of education, training, skills & experience maintained

3.3 Infrastructure
Infrastructure needed to achieve conformity to product requirements are determined, provided and maintained which includes, as applicable:
a) Buildings, workspace and associated utilities
b) Process equipment (both hardware and software)
c) Supporting services (such as transport, communication or information system)

3.4 Work Environment
Work environment needed is determined and managed to achieve conformity to product requirements

4 Product Realization
4.1 Planning of Product Realization—Processes needed for product realization are planned and developed which are consistent with requirements of other processes of QMS. Following are determined, as appropriate:
a) Quality objectives and requirements for the product
b) Need to establish processes and documents, and to provide resources specific to the product
c) Required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance
d) Records needed to provide evidence that the realization processes and resulting products meet requirements.
Output of the planning to be in a form suitable for the organization’s method of operations.

4.2 Customer-related Processes
4.2.1 Requirements related to product—Following are determined
a) Requirements specified by customer, including the requirements for the delivery and post-delivery activities
b) Requirements not stated by the customer but necessary for specified or intended use, where known
c) Statutory and regulatory requirements applicable to the product
d) Any additional requirements considered necessary by the organization

4.2.2 Review of requirements related to the product
Requirements related to product reviewed prior to commitment to supply product to customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) ensuring that:
a) product requirements are defined
b) contract or order requirements differing from those previously expressed are resolved
c) the organization has ability to meet defined requirements
- Records of results and actions from review are maintained.
- Customer requirements are confirmed before acceptance (where the customer provides no documented statement of requirement)
- When product requirements are changed, the relevant documents are amended and relevant personnel are made aware of changed requirements.
<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
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<tbody>
<tr>
<td>4.2.3</td>
<td><strong>Customer communication</strong>&lt;br&gt;Arrangements for communicating with customers are effective in relation to&lt;br&gt;a) product information&lt;br&gt;b) enquiries, contracts or order handling including amendments&lt;br&gt;customer feedback, including customer complaints</td>
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<tr>
<td>4.3</td>
<td><strong>Design &amp; Development</strong></td>
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<tr>
<td>4.3.1</td>
<td><strong>Design and development planning</strong>&lt;br&gt;Design &amp; development of product are planned and controlled. During Design &amp; Development planning, following are determined:&lt;br&gt;a) design and development stages&lt;br&gt;b) review, verification and validation that are appropriate to each design and development stage&lt;br&gt;c) responsibilities and authorities for design &amp; development&lt;br&gt;- Interface between different groups involved in design and development managed to ensure effective communication and clear assignment of responsibility.&lt;br&gt;- Updation of planning output, as appropriate, as the design &amp; development progresses</td>
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<tr>
<td>4.3.2</td>
<td><strong>Design and development inputs</strong>&lt;br&gt;Inputs relating to product requirements determined including:&lt;br&gt;a) functional and performance requirements&lt;br&gt;b) applicable statutory and regulatory requirements&lt;br&gt;c) information derived from previous similar designs, where applicable&lt;br&gt;d) other requirements essential for design and development&lt;br&gt;- Design &amp; development inputs reviewed for adequacy&lt;br&gt;- Requirements are complete, unambiguous and not in conflict with each other</td>
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<tr>
<td>4.3.3</td>
<td><strong>Design and Development Output</strong>&lt;br&gt;Outputs of design &amp; development are in form suitable for verification against design &amp; development input and approved prior to release. Design and development outputs:&lt;br&gt;a) meet the input requirements for design &amp; development&lt;br&gt;b) provide appropriate information for purchasing, production and service provision&lt;br&gt;c) contain or reference product acceptance criteria&lt;br&gt;d) specify the characteristics of the product that are essential for its safe and proper use</td>
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<td>4.3.4</td>
<td><strong>Design and Development Review</strong>&lt;br&gt;Systematic reviews of Design &amp; Development performed at suitable stages in accordance with planned arrangements to:&lt;br&gt;a) evaluate the ability of the results of design &amp; development to meet requirements&lt;br&gt;b) identify any problem and propose necessary actions&lt;br&gt;- Participation by representatives of concerned functions in review&lt;br&gt;- Records of results of reviews and any necessary actions</td>
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<tr>
<td>4.3.5</td>
<td><strong>Design &amp; Development Verification</strong>&lt;br&gt;Verification performed as per the planned arrangements.&lt;br&gt;Records of results of verification and any necessary actions maintained</td>
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<tr>
<td>4.3.6</td>
<td><strong>Design &amp; Development Validation</strong>&lt;br&gt;- Validation performed as per the planned arrangements.&lt;br&gt;- Wherever practicable, validation completed prior to the delivery or implementation of the product&lt;br&gt;- Records of validation and any necessary actions maintained</td>
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<tr>
<td>4.3.7</td>
<td><strong>Control of design and development changes</strong>&lt;br&gt;- Changes to design &amp; development identified and records maintained.&lt;br&gt;- Changes reviewed, verified and validated as appropriate and approval before implementation&lt;br&gt;- Review of design &amp; development changes includes evaluation of effect of changes on constituent parts and product already delivered&lt;br&gt;- Records of results of review of changes and any necessary actions maintained</td>
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### 4.4 Purchasing

#### 4.4.1 Purchasing process
Conformity of purchased product to specified requirements ensured
- Type & extent of control on the supplier and purchased product are dependent upon effect of purchased product on subsequent product realization or its final product
- Criteria for selection, evaluation & re-evaluation of suppliers established
- Records of results of evaluations and any necessary action maintained

#### 4.4.2 Purchasing information
Purchasing information describes product to be purchased, including, where appropriate,
- requirements for approval of product, procedures, processes and equipment
- requirements for qualification of personnel
- quality management system requirements
Adequacy of specified purchase requirements prior to their communication to the supplier

#### 4.4.3 Verification of purchased product
- Inspection or other activities implemented for ensuring that purchased product meets specified purchase requirements
- Verification arrangements and method of product release stated in the purchasing information when organization or its customer intends to perform verification at supplier's premises.

### 4.5 Production and service provision

#### 4.5.1 Control of production and service provision
Production and service provision are planned and carried out under controlled conditions; including, as applicable:
- availability of information that describes characteristics of the product
- availability of work instructions, as necessary
- use of suitable equipment
- availability and use of monitoring & measuring equipment
- implementation of monitoring and measurement
- implementation of product release, delivery & post-delivery activities

#### 4.5.2 Validation of processes for production and service provision
- Processes where the resulting output cannot be verified by subsequent monitoring and measurement are validated.
- Validation demonstrates the ability of these processes to achieve planned results
- Arrangements for these processes including as applicable for:
  - defined criteria for review and approval of the processes
  - approval of equipment and qualification of personnel
  - use of specific methods and procedures
  - requirements for Records
  - revalidation

#### 4.5.3 Identification and Traceability
- Product identified by suitable means throughout product realization, where appropriate
- Product status is identified w.r.t. monitoring and measurement requirements throughout product realization
- Where traceability is a requirement, unique identification of product is controlled and records maintained

#### 4.5.4 Customer Property
- Care exercised with customer property
- Customer property identified, verified, protected & safeguarded
- Loss, damage or non-suitability of customer property reported to the customer and records maintained

#### 4.5.5 Preservation of products
Product preserved during internal processing and delivery to the intended destinations
- Preservation includes identification, handling, packaging, storage and protection, as applicable
- Preservation applied to the constituent parts of a product.
### 4.6 Control of monitoring and measuring equipment

- Monitoring & measurements to be undertaken are determined.
- Monitoring & measuring equipment needed to provide evidence of conformity of product are determined.
- Processes established to ensure that monitoring & measurement can be carried out.
- Monitoring & measurement carried out in manner consistent with the monitoring & measurement requirements.

Where necessary to ensure valid results, measuring equipment are:

- a) calibrated or verified or both, at specified intervals, or prior to use, against measurement standards traceable to national or international measurement standards; where no such standards exist, the basis used for calibration or verification is recorded.
- b) adjusted or re-adjusted as necessary.
- c) identified for determining calibration status.
- d) safeguarded from adjustments.
- e) protected from damage and deterioration during handling, maintenance and storage.

- Validity of previous measuring results assessed and recorded when the equipment is found not to conform to requirements and appropriate action taken on equipment and any product affected.
- Records of result of calibration and verification maintained.
- Ability of computer software to satisfy the intended application, confirmed prior to initial use and reconfirmed as necessary when computer software is used in the monitoring and measurement of specified requirements.

### 5 Measurement, analysis and improvement

#### 5.1 General
- Monitoring, measurement, analysis and improvement processes planned and implemented to:
  a) demonstrate conformity to product requirements
  b) ensure conformity of the QMS
  c) continually improve the effectiveness of QMS.

Planning includes determination of applicable methods, including statistical techniques, and the extent of their use.

#### 5.2 Monitoring and Measurement

##### 5.2.1 Customer Satisfaction
- Monitoring information relating to customer perception
- Method determined for obtaining and using information relating to customer perception.

##### 5.2.2 Internal Audit
- Procedure established for defining responsibilities and requirements for planning and conducting internal audits, establishing records and reporting results.
  - Internal audits conducted at planned interval.
  - Audit programme planned according to status and importance of the processes and areas to be audited as well as results of the previous audits.
  - Selection of auditors and conduct of audits ensures objectivity and impartiality of the audit process.
  - Auditors not auditing their own work.
  - Records of audits and their results maintained.
  - Necessary corrections and corrective actions taken without undue delay to eliminate detected nonconformities and their causes.

Follow-up activities include verification of actions taken and reporting of verification results.

##### 5.2.3 Monitoring and measurement of processes
- Suitable methods applied for monitoring and where applicable, measurement of the QMS processes.
- Methods demonstrate ability of processes to achieve planned results.
- Corrective actions ensure conformity of the product.
### 5.2.4 Monitoring and measurement of product
- Characteristics of product monitored and measured to verify that product requirements have been met.
- Monitoring & measurement carried out at appropriate stages of product realization process in accordance with planned arrangements.
- Evidence of conformity with the acceptance criteria maintained
- Records indicate the person(s) authorizing release of product for delivering to the customer
- Release of product and delivery of service to customer does not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

### 5.3 Control of nonconforming product
- Procedure defines the controls and related responsibilities and authorities for dealing with non-conforming product
- Nonconforming product is identified and controlled to prevent its unintended use or delivery
- Where applicable, nonconforming product dealt with by:
  a) taking actions to eliminate the detected nonconformity
  b) authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer
  c) taking action to preclude its original intended use or application
  d) taking action appropriate to effects, or potential effects, of the nonconformity when the nonconforming product is detected after delivery or use has started.
- Corrected nonconforming product re-verified to demonstrate conformity to the requirements
- Records maintained for the nature of nonconformities and any subsequent actions taken, including concessions obtained

### 5.4 Analysis of data
Appropriate data collected and analyzed to:
- demonstrate suitability and effectiveness of QMS
- evaluate where continual improvement of the effectiveness of QMS can be made
Data includes that generated as result of monitoring and measurement and from other relevant sources.
Analysis of data provides information relating to
  a) Customer satisfaction
  b) Conformity to product requirements
  c) Characteristics and trends of processes and products including opportunities for preventive action
  d) Suppliers

### 5.5 Improvement
#### 5.5.1 Continual improvement
Effectiveness of QM continually improved through the use of quality policy, quality objectives, audit results, analysis of data, corrective & preventive actions and management review
## Audit Checklist for ISO 9001

<table>
<thead>
<tr>
<th>NUMBER OF NONCONFORMITIES RAISED:</th>
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<tbody>
<tr>
<td>MAJOR: __________ MINOR: __________ OBS: __________</td>
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**COMMENTS:**

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<th>SIGNATURE:</th>
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