

YES-documented and in compliance
 IN-Improvement needed
 NO-Not yet addressed
 N/A-Not applicable

Document Checklist for ISO 9001:2000

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Important: This checklist shall assist with the assessment of the requirements of the 2000 version of the international quality management system standard ISO 9001. It shall be used for the assessment of existing documentation of an implemented ISO 9001/9002 Quality System, rev. 1994 or for the development of required quality management system documentation of a Quality Management System ISO 9001:2000 or ISO 9002:2000 for implementation in the year 2001. The DIS ISO 9001:2000 and later the final document of the standard must be used for the interpretation of the standard.

Review performed by: _____ Date: _____

ISO 9001 System Elements / Requirements	MNL	QMS	Procedures	YES	IN	NO	N/A
4 Quality Management System Requirements							
4.1 General Requirements							
A quality management system in accordance with this international standard shall be							
- established							
- documented							
- implemented							
- maintained							
- continuously improved							
For the implementation of the quality management system, the organization shall							
- identify the processes needed for the quality management system							
- determine the sequence of these processes							
- determine the interaction of these processes							
- determine criteria for the effective operation of these processes							
- determine criteria for the effective control of these processes							
- determine methods for the effective operation of these processes							
- determine methods for the effective control of these processes							
- ensure the availability of information necessary to support the operation of these processes							
- ensure the availability of information necessary to support the monitoring of these processes							
- measure these processes							
- monitor these processes							
- analyze these processes							

YES-documented and in compliance
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ISO 9001 System Elements / Requirements	MNL	QMS	Procedures	YES	IN	NO	N/A
(continues 4.1 General Requirements)							
- implement necessary action to achieve planned results							
- implement necessary action to achieve continual improvement							
These processes shall be managed							
- according to the requirements of this international standard							
4.2 General Documentation Requirements							
The quality management system documentation shall include							
- documented procedures required in this international standard							
documents required by the organization to ensure							
- the effective operation of its processes							
- the effective control of its processes							
The extent of the quality management system documentation shall be dependent on							
- the size and type of the organization							
- the complexity and interaction of the processes							
- the competence of personnel							
5 Management Responsibility							
5.1 Management Commitment							
Top management shall provide evidence of its commitment to the							
- development of the quality management system							
- improvement of the quality management system							
Evidence shall be provided by							
a) communicating to the organization the importance of meeting							
- customer requirements							
- regulatory requirements							
- legal requirements							

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ISO 9001 System Elements / Requirements	MNL	QMS	Procedures	YES	IN	NO	N/A
(continues 5.1 Management Commitment)							
b)establishing							
- the quality policy							
- quality objectives							
c) - conducting management reviews							
d) - ensuring the availability of necessary resources							
5.2 Customer Requirements							
With the aim of achieving customer confidence, top management shall ensure that							
- customer needs are determined							
- customer needs are converted into requirements							
- customer needs are fulfilled							
- customer expectations are determined							
- customer expectations are converted into requirements							
- customer expectations are fulfilled							
5.3 Quality Policy							
Top management shall ensure that the quality policy							
- is appropriate to the purpose of the organization							
- includes a commitment to meet requirements							
- includes commitment for continual improvement							
- provides a frame work for establishing quality objectives							
- provides a frame work for reviewing quality objectives							
- is communicated to appropriate levels in the organization							
- is understood at appropriate levels in the organization							
- is reviewed for continuing suitability							
The quality policy shall							
- be controlled							

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ISO 9001 System Elements / Requirements	MNL	QMS	Procedures	YES	IN	NO	N/A
5.4 Planning							
5.4.1 Quality Objectives							
At relevant function and level within the organization - quality objectives shall be established							
These quality objectives shall - be measurable							
and shall be consistent with - the quality policy							
- the commitment to continuous improvement							
Quality objectives shall include those needed to - meet requirements for products							
5.4.2 Quality Planning							
Top management shall ensure that resources needed to achieve the quality objectives							
- are identified							
- are planned							
Quality planning shall include							
a) - the processes of the quality management system							
- permissible exclusions							
b) - resources needed							
c) - continual improvement of the quality management system							
Planning shall ensure							
- that change is conducted in a controlled manner							
- that the integrity of the quality management system is maintained during this change							

YES-documented and in compliance

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ISO 9001 System Elements / Requirements	MNL	QMS	Procedures	YES	IN	NO	N/A
5.5 Administration							
5.5.1 General (clause 5.5.1 does not include requirements)							
5.5.2 Responsibility and Authority To facilitate effective quality management: functions shall be							
- defined							
- communicated							
interrelation of functions within the organization shall be							
- defined							
- communicated							
responsibilities shall be							
- defined							
- communicated							
authorities shall be							
- defined							
- communicated							
5.5.3 Management Representative Top management shall appoint member(s) of the management who, irrespective of other responsibilities shall have the responsibility and authority for							
a) ensuring that processes of the quality management system							
- are established							
- are maintained							
b) reporting to top management							
- on the performance of the quality management system							
- on needs for improvement							

YES-documented and in compliance

IN-Improvement needed

NO-Not yet addressed

N/A-Not applicable

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ISO 9001 System Elements / Requirements	MNL	QMS	Procedures	YES	IN	NO	N/A
(continues 5.5.3 Management Representative)							
c) - promoting the awareness of customer requirements throughout the organization							
5.5.4 Internal Communication Communication regarding the processes of the quality management system and their effectiveness shall be ensured - between the various levels in the organization - between the various functions in the organization							
5.5.5 Quality Manual A quality manual shall be - established - maintained The manual shall include a) - the scope of the quality management system - details of any exclusions - justification for any exclusions b) - documented procedures or reference to them c) - a description of the sequence and interaction of the processes included in the quality management system The quality manual shall be - controlled							
5.5.6 Control of Documents Documents required for the quality management system - shall be controlled A documented procedure shall be established a) - to approve documents for adequacy prior to issue b) - to review documents as necessary							

YES-documented and in compliance
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ISO 9001 System Elements / Requirements	MNL	QMS	Procedures	YES	IN	NO	N/A
(continues 5.5.6 Control of Documents)							
- to update documents as necessary							
- to re-approve documents							
c) - to identify current revision status of documents							
d) - to ensure that applicable documents are available at points of use							
e) to ensure that documents remain							
- legible							
- readily identifiable							
- readily retrievable							
f) to ensure that documents of external origin are							
- identified							
- and their distribution is controlled							
g) - to prevent the unintended use of obsolete documents							
- to apply suitable identification to them if they are retained for any purpose							
Documents defined as quality records							
- shall be controlled							
5.6.7 Control of Quality Records							
Records required for the quality management system shall							
- be controlled.							
Such records shall							
- be maintained							
to provide evidence of							
- conformance to requirements							
- effective operation of the quality management system							
A documented procedure shall be established for quality records to define their							
- identification							
- storage							

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ISO 9001 System Elements / Requirements	MNL	QMS	Procedures	YES	IN	NO	N/A
(continues 5.5.7 Control of Quality Records)							
- retrieval							
- protection							
- retention time							
- disposition							
5.6 Management Review							
5.6.1 General							
Top management shall review the quality management system							
- at planned intervals							
to ensure its continuing							
- suitability							
- adequacy							
- effectiveness							
The review shall evaluate the need for change to the							
- quality management system							
including							
- quality policy							
- quality objectives							
5.6.2 Review Input							
Inputs to management review shall include:							
current performance related to							
a) - results of audits							
b) - customer feedback							
c) - process performance							
- product conformance							
d) - status of preventive actions							
- status of corrective actions							

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ISO 9001 System Elements / Requirements	MNL	QMS	Procedures	YES	IN	NO	N/A
(Continues 5.6.2 Review Input)							
e) - follow-up actions from earlier management reviews							
f) - changes that could affect the quality management system							
improvement opportunities related to							
a) - results of audits							
b) - customer feedback							
c) - process performance							
- product conformance							
d) - status of preventive actions							
- status of corrective actions							
e) - follow-up actions from earlier management reviews							
f) - changes that could affect the quality management system							
5.6.3 Review Output							
Outputs from management reviews shall include actions related to							
a) - improvement of the quality management system							
- improvement of the processes of the quality management system							
b) - improvement of product related to customer requirements							
c) - resource needs							
Results of management reviews							
- shall be recorded							
6 Resource Management							
6.1 Provision of Resources							
Resources needed shall be determined in a timely manner							
- to implement the processes of the quality management system							

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NO-Not yet addressed

N/A-Not applicable

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ISO 9001 System Elements / Requirements	MNL	QMS	Procedures	YES	IN	NO	N/A
(continues 6.1 Provision of Resources)							
- to address customer satisfaction							
Resources needed shall be provided in a timely manner							
- to implement the processes of the quality management system							
- to address customer satisfaction							
6.2 Human Resources							
6.2.1 Assignment of Personnel							
Personnel with assigned responsibilities defined in the quality management system, shall be competent on the basis of							
- education							
- training							
- skills							
- experience							
6.2.2 Training, Awareness and Competency							
The organization shall							
a) - identify competency needs for personnel performing activities affecting quality							
b) - provide training to satisfy the needs of personnel performing activities affecting quality							
c) - evaluate the effectiveness of training provided							
d) ensure that employees are aware of the relevance / importance of							
- their activities regarding the achievement of quality objectives							
- how they contribute to the achievement of the quality objectives							
e) maintain appropriate records of							
- education							
- experience							
- training							
- qualifications							

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ISO 9001 System Elements / Requirements	MNL	QMS	Procedures	YES	IN	NO	N/A
7 Product Realization							
7.1 Planning of Realization Processes							
Product realization is the sequence of processes/sub-processes to produce the product.							
Planning of the realization processes shall be							
- consistent with other requirements of the quality management system							
- documented in a form suitable to the organization's method of operation							
When planning the processes for realization of product, the following shall be determined, as appropriate:							
a) quality objectives for the							
- product							
- project							
- contract							
b) the need to							
- establish processes							
- establish documentation							
- provide resources specific to the product							
- provide facilities specific to the product							
c) - verification activities							
- validation activities							
- criteria for acceptability							
d) records that are necessary to provide confidence of conformity of							
- processes							
- resulting product							

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ISO 9001 System Elements / Requirements	MNL	QMS	Procedures	YES	IN	NO	N/A
7.2 Customer-related Processes							
7.2.1 Identification of Customer Requirements							
Customer requirements shall be							
- determined							
including							
a) - product requirements specific to the customer							
requirements for							
- availability							
- delivery							
- support							
b) - product requirements not specified by the customer but necessary for indented or specified use							
c) obligation related to							
- product							
- regulatory requirements							
- legal requirements							
7.2.2 Review of Product Requirements							
The organization shall review							
- identified customer requirements							
together with							
- additional requirements determined by the organization							
This review shall be conducted							
- prior to the commitment to supply the product to the customer							
The review shall ensure that							
a) - product requirements are defined							
b) - where the customer provides no documented statement of requirements, the customer requirements are confirmed prior to acceptance							

YES-documented and in compliance

IN-Improvement needed

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N/A-Not applicable

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ISO 9001 System Elements / Requirements	MNL	QMS	Procedures	YES	IN	NO	N/A
7.3 Design and/or Development							
7.3.1 Design and/or Development Planning							
The design and/or development of product shall be							
- planned							
- controlled							
The design and/or development planning shall determine							
a) - stages of design process and/or development processes							
b) as appropriate for each design and/or development stage							
- design review activities							
- design verification activities							
- design validation activities							
- responsibilities for design and/or development activities							
- authorities for design and/or development activities							
Interfaces between different groups involved in design and/or development shall be managed to ensure							
- effective communication							
- clarity of responsibilities							
As the design and/or development progresses							
- planning output shall be updated, as appropriate							
7.3.2 Design and/or Development Inputs							
Inputs relating to product requirements shall be							
- defined							
- documented							
This shall include							
a) - functional requirements							
- performance requirements							

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N/A-Not applicable

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ISO 9001 System Elements / Requirements	MNL	QMS	Procedures	YES	IN	NO	N/A
(continues 7.3.2 Design and/or Development Inputs)							
b) - applicable regulatory requirements							
- applicable legal requirements							
c) - applicable information derived from previous similar designs							
d) - any other requirements essential for design and/or development							
These inputs							
- shall be reviewed for adequacy							
- incomplete requirements shall be resolved							
- ambiguous or conflicting requirements shall be resolved							
7.3.3 Design and Development Outputs							
The outputs of the design process shall be							
- recorded in a format that enables verification against the input requirements							
The outputs of the development process shall be							
- documented in a manner that enables verification against the design and/or development inputs							
Design and/or development output shall							
a) - meet the design and/or development input requirements							
b) provide appropriate information for							
- production operations							
- service operations							
c) - contain or reference product acceptance criteria							
d) define the characteristics of the product that are essential to its							
- safe use							
- proper use							
Design and/or development output documents shall be							
- approved prior to their release							

YES-documented and in compliance

IN-Improvement needed

NO-Not yet addressed

N/A-Not applicable

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ISO 9001 System Elements / Requirements	MNL	QMS	Procedures	YES	IN	NO	N/A
7.3.4 Design and/or Development Review At suitable stages, systematic reviews of design and/or development - shall be conducted							
The purpose of these reviews is to							
a) - evaluate the ability to fulfill requirements							
b) - identify problems							
- propose follow-up actions							
The design and/or development review - shall include representatives of functions concerned with the design and/or development stage being reviewed							
The results of							
- reviews shall be recorded							
- follow-up actions shall be recorded							
7.3.5 Design and/or Development Verification To ensure that the output meets the design inputs - design and/or development verification shall be performed							
- results of verification activities shall be recorded							
- subsequent follow-up shall be recorded							
7.3.6 Design and/or Development Validation To confirm that resulting product is capable of meeting the requirements for intended use - design and/or development validation shall be performed							

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ISO 9001 System Elements / Requirements	MNL	QMS	Procedures	YES	IN	NO	N/A
7.4 Purchasing							
7.4.1 Purchasing Control							
To ensure that purchased product conforms to requirements							
- purchasing processes shall be controlled (the type and extent of control shall be dependent upon the effect on subsequent realization processes and their output)							
Base on the ability to supply product according to requirements, suppliers shall be							
- evaluated							
- selected							
Criteria shall be defined for							
- selection							
- periodic evaluation							
- Results of evaluations shall be recorded							
- Follow-up actions shall be recorded							
7.4.2 Purchasing Information							
Purchasing information shall							
- contain information describing the product to be purchased							
This information shall include							
a) requirements for approval or qualification of							
- product							
- procedures							
- processes							
- equipment							
- personnel							
b) quality management system requirements							
The adequacy of specified requirements contained in purchasing documents shall be							
- ensured							

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ISO 9001 System Elements / Requirements	MNL	QMS	Procedures	YES	IN	NO	N/A
7.4.3 Verification of Purchased Product							
The activities necessary for verification of purchased product shall be							
- identified							
- implemented							
Where the organization or its customers proposes to perform verification activities at the supplier's premises, the purchasing information shall specify							
- the intended verification arrangements							
- the method of product release							
7.5 Product and Service Operations							
7.5.1 Operations Control							
- Production operations shall be controlled							
- Service operations shall be controlled							
These controls shall be performed through							
a) - the availability of information that specifies the characteristics of the product							
b) - the availability of work instructions, where necessary							
c) the use of suitable equipment							
- for production operations							
- for service operations							
the maintenance of suitable equipment							
- for production operations							
- for service operations							
d) the availability of							
- measuring devices							
- monitoring devices							
the use of							
- monitoring devices							

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ISO 9001 System Elements / Requirements	MNL	QMS	Procedures	YES	IN	NO	N/A
(continues 7.5.1 Product and Service Operations)							
- measuring devices							
e) - the implementation of monitoring devices							
f) - the implementation of defined processes for							
- release activities							
- delivery activities							
- applicable post-delivery activities							
7.5.2 Identification and Traceability							
Where appropriate, the product shall be identified by suitable means - throughout production operations							
- throughout service operations							
The status of the product shall be identified with respect to							
- measurement requirements							
- monitoring requirements							
Where traceability is a requirement, the unique identification of the product shall be							
- controlled							
- recorded							
7.5.3 Customer Property							
While customer property is under the organization's control or is being used by the organization							
- care shall be exercised with customer property							
Customer property provided for use or incorporation into product shall be							
- identified							
- verified							

YES-documented and in compliance
 IN-Improvement needed
 NO-Not yet addressed
 N/A-Not applicable

Document Checklist for ISO 9001:2000

Quantum Associates Inc, for internal use only

Important: This checklist shall assist with the assessment of the requirements of the 2000 version of the international quality management system standard ISO 9001. It shall be used for the assessment of existing documentation of an implemented ISO 9001/9002 Quality System, rev. 1994 or for the development of required quality management system documentation of a Quality Management System ISO 9001:2000 or ISO 9002:2000 for implementation in the year 2001. The DIS ISO 9001:2000 and later the final document of the standard must be used for the interpretation of the standard.

ISO 9001 System Elements / Requirements	MNL	QMS	Procedures	YES	IN	NO	N/A
7.5.5 Validation of Processes							
Where the resulting output cannot be verified by subsequent measuring or monitoring							
- any production processes shall be validated							
- any service processes shall be validated							
- This includes processes where deficiencies may become apparent only after the product or service is in use							
- Validation shall demonstrate the ability of the process to achieve planned results							
Arrangements for validation shall be							
- defined							
As applicable, validation arrangements shall include							
a) - qualification of processes							
b) qualification of							
- equipment							
- personnel							
c) use of							
- defined methodologies							
- procedures							
d) - requirements for records							
e) - re-validation							
7.6 Control of Measuring and Monitoring Devices							
To assure conformity of product to specified requirements, the organization shall identify							
- measurements to be made							
- measuring devices required							
- monitoring devices required							

YES-documented and in compliance
IN-Improvement needed
NO-Not yet addressed
N/A-Not applicable

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ISO 9001 System Elements / Requirements	MNL	QMS	Procedures	YES	IN	NO	N/A
8 Measurement, Analysis and Improvement							
8.1 Planning							
Measuring activities needed to assure conformity shall be							
- defined							
- planned							
- implemented							
Measuring activities needed to achieve improvement shall be							
- defined							
- planned							
- implemented							
Monitoring activities needed to assure conformity shall be							
- defined							
- planned							
- implemented							
Monitoring activities needed to achieve improvement shall be							
- defined							
- planned							
- implemented							
This shall include the determination of							
- the need for applicable methodologies, incl. statistical techniques							
- the use of applicable methodologies, incl. statistical techniques							
8.2 Measurement and Monitoring							
8.2.1 Customer Satisfaction							
As one of the measurements of performance of the quality management system							
- customer satisfaction/dissatisfaction shall be monitored							

YES-documented and in compliance
IN-Improvement needed
NO-Not yet addressed
N/A-Not applicable

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ISO 9001 System Elements / Requirements	MNL	QMS	Procedures	YES	IN	NO	N/A
(continues 8.2.2 Internal Audit)							
ensuring their							
- independence							
- recording results							
- reporting to management							
Management shall							
- take timely corrective action on deficiencies found during the audit							
Follow-up actions shall include							
- the verification of the implementation or corrective action							
- the reporting of verification results							
8.2.3 Measurement and Monitoring of processes							
For those realization processes necessary to meet customer requirements, suitable methods for							
- measurement of these processes shall be applied							
- monitoring of these processes shall be applied							
These methods shall							
- confirm the continuing ability of each process to satisfy its indented purpose							
8.2.4 Measurement and Monitoring of Product							
In order to verify that product requirements are met, the characteristics of the product shall be							
- measured							
- monitored							
This shall be carried out							
- at appropriate stages of the product realization process							
Evidence of conformity with acceptance criteria shall be							
- documented							

