



ISO 9001:2000 checklist

Any organisation which is implementing ISO 9001 for the first time or developing their quality management system to meet the requirements of ISO 9001:2000 must first review their current processes, procedures, controlled documents and records to determine what they are already doing and identify any gaps.

This checklist provides a framework for the review by presenting each requirement of ISO 9001:2000 as a question and allowing space for comments on the answer.

Section 4.1 of ISO 9001:2000 lists general requirements of the standard which are defined in greater detail in the remaining sections of the standard. The questions should be answered at the start of the review, but the answers may be revised when all other requirements have been considered.

- 4.1a may be summarised as Management responsibility, Resource management, Product realisation, Measurement, analysis and improvement, however these processes should be interpreted in the context of the organisation.
- 4.1b may be answered with a flow chart, which shows the relationship between Management responsibility, Resource management, Product realisation, Measurement, analysis and improvement and other processes of the organisation.

All questions in sections 4.2, 5, 6, 7 & 8 have been phrased to allow one word answers (yes, no or n/a). An additional column has been included for further information.

The "evidence/comments" column may be used for:

- 1 Examples which provide evidence that the requirements have been met;
- 2 Explanation why the requirement is not applicable to the organisation (sections of clause 7 which are not applicable to the organisation should be excluded, however the Quality Manual must include a justification of each exclusion);
- 3 Suggested improvements which would ensure that the requirements are met.

ISO 9000 series standards

I recommend that any organisation which uses this checklist should also read ISO 9001:2000, and refer to ISO 9000:2000 for definitions and ISO 9004:2000 for interpretation of the requirements.

ISO 9000:2000 Quality management systems - fundamentals and vocabulary

Describes and defines the concept of quality management including:

- The process approach to quality management
- The role of top management within the quality management system
- Evaluation of the quality management system and continual improvement.

ISO 9001:2000 Quality management systems - requirements

The standard against which the organisation's quality management system is assessed.

ISO 9004:2000 Quality management systems - Guidelines for performance improvements

Guidelines beyond the requirements of ISO 9001 to be used when reviewing the effectiveness and efficiency of the quality management system.

ISO 9000 series standards may be obtained from:

British Standards Institution
389 Chiswick High Road,
London W4 4AL

www.bsi-global.com
Tel: 020 8996 9001
Fax 020 8996 7001

ISO 9001:2000 Quality management system requirements

4 Quality management system (QMS)	Evidence / comment
4.1 General requirements	
a) What are the processes for management of quality throughout the organisation? (A process is a managed activity, which uses resources to transform inputs into outputs.)	
b) What is their sequence and how do they interact?	
c) By what criteria can the processes be judged to be effective?	
d) What resources and information are required by the processes?	
e) i) How are the processes monitored?	
ii) How is the resulting information analysed?	
f) What action is being taken to continually improve the processes to meet planned objectives?	

4.2 Documentation requirements	Y / N	Evidence / comment
a) Are quality policy and objectives documented?		
b) Is there a quality manual which includes:		
i) The scope of the QMS (including justification for exclusions)?		
<p>Note The scope of the QMS is the general description of the product or services provided by the organisation, which will appear on the certificate. Any requirements in section 7, which are not applicable to the scope, are excluded from the QMS. A justification for any exclusion must be included in the quality manual.</p>		
ii) A list of documented procedures?		
iii) A description of the processes of the organisation (and the QMS) and how they interact?		
c) Are there documented procedures for:		
i) Control of documents? <i>Requirements to include:</i> <i>Approval for adequacy prior to issue;</i> <i>Re-approval following changes;</i> <i>Identification of changes;</i> <i>Ensuring relevant versions are available;</i> <i>Ensuring documents are legible;</i> <i>Control of documents of external origin;</i> <i>Prevention of unintended use of obsolete documents.</i>		
ii) Control of records? <i>Requirements to include:</i> <i>Identification;</i> <i>Storage;</i> <i>Protection;</i> <i>Retrieval;</i> <i>Retention time;</i> <i>Disposition.</i> <i>See 4.2 e) for list of records.</i>		
iii) Auditing the QMS?		
iv) Control of non-conforming product?		
v) Corrective and preventive action?		
d) Do documents exist for effective planning, operation and control of the processes of the organisation?		

4.2 Documentation requirements	Y / N	Evidence / comment
e) Are there records of:		
i) Management reviews?		
ii) Personnel education, training, skills and experience?		
iii) Quality plans for specific products?		
iv) Review of product requirements and actions arising from the review?		
v) Design inputs for product requirements?		
vi) Results of design reviews and action taken?		
vii) Results of design verification and action taken?		
viii) Results of design validation and action taken?		
ix) Results of the review of design changes and action taken?		
x) Results of supplier evaluation and actions arising from the evaluation?		
xi) Validation of production (or provision of service) to demonstrate that planned results have been achieved?		
xii) Unique identification of product (where this is required)?		
xiii) Loss or damage to customer property?		
xiv) Results of calibration and verification of measuring devices?		
xv) Evidence of conformity to acceptance criteria (including the person who has given authority to release the product)?		
xvi) The nature of non-conformities and action taken (including release by concession)?		
xvii) Results of corrective action?		
xviii) Results of preventive action?		
Note Records may be omitted which relate to parts of section 7, which are excluded from the scope of the QMS.		

5	Management responsibility	Y / N	Evidence / comment
5.1	Management commitment		
	Is there evidence that management is fully committed to the QMS?		
5.2	Customer focus		
i)	Are customer requirements effectively determined and met?		
ii)	Is the customer satisfied with the result?		
5.3	Quality Policy		
a)	Is the Quality Policy appropriate?		
b)	Does it include a commitment to continually improve the effectiveness of the QMS?		
c) i)	Does it provide a framework to establish and review quality objectives?		
ii)	Is it communicated effectively throughout the organisation?		
d)	Is it reviewed to confirm suitability?		
5.4	Quality Objectives and Planning		
1	Are Quality Objectives measurable? Are Quality Objectives consistent with quality policy?		
2 a)	Is the planning of the QMS consistent with the organisation's quality objectives and general requirements of ISO 9001 (<i>clause 4.1</i>)?		
b)	Have planned changes to the QMS been reviewed to ensure that its integrity is maintained?		
5.5	Responsibility, authority and communication		
1	Is responsibility and authority effectively defined and communicated throughout the organisation?		
2	Is there a management representative with responsibility and authority for:		
a)	Ensuring that processes needed for the QMS are established, implemented and maintained?		
b)	Reporting on the performance of the QMS to top management?		
c)	Ensuring that customer requirements are effectively communicated throughout the organisation?		
3 i)	Is there an effective communication process throughout the organisation?		
ii)	Is information about the effectiveness of the QMS communicated?		

5	Management responsibility	Y / N	Evidence / comment
5.6	Management review		
1	i) Do Management Reviews take place at planned intervals?		
	ii) Does the Management Review include assessment of the Quality Policy and Objectives?		
	iii) Are records of Management Reviews maintained (<i>in accordance with 4.2.4</i>)?		
2	Does the Management Review consider:		
a)	Results of audits;		
b)	Customer feedback;		
c)	Process performance and product conformity;		
d)	Corrective and preventive actions;		
e)	Actions from previous Management Reviews		
f)	Changes which could affect the QMS;		
g)	Recommendations for improvement?		
3	Are actions agreed and documented relating to:		
a)	Improvement of the effectiveness of the QMS and its processes		
b)	Improvement of product to meet customer requirements		
c)	Resource needs		

6	Resource management	Y / N	Evidence / comment
6.1	Provision of resources		
a)	Are the required resources available to implement, maintain and continually improve the effectiveness of the QMS?		
b)	Are the required resources available to meet customer requirements?		
6.2	Human resources		
a)	Has the organisation determined the level of competence required for personnel performing work, which affects product quality?		
b)	Is training being provided (or is other appropriate action being taken) to ensure that personnel are competent?		
c)	Has the effectiveness of training been evaluated?		
d)	Are personnel made aware of the significance of their activities in relation to achievement of quality objectives?		
e)	Are records maintained of education, training, skills and experience (<i>in accordance with 4.2.4</i>)?		
6.3	Infrastructure		
a)	Are the buildings, workspace and utilities appropriate for the organisations product or service?		
b)	Is process equipment (including computer software) appropriate for the organisations product or service?		
c)	Are support services (e.g. transport, communications, waste disposal) appropriate for the organisations product or service?		
d)	Has the organisation identified any shortcomings and is it taking appropriate action?		
6.4	Work environment		
a)	Is the work environment appropriate for the organisations product or service including:		
i)	Safety and protective equipment;		
ii)	Ergonomics (workstation layout);		
iii)	Canteen and toilet facilities;		
iv)	Heat, humidity, light, airflow;		
v)	Hygiene, cleanliness, noise, vibration and pollution?		
b)	Has the organisation identified any shortcomings and is it taking appropriate action?		

If a requirement of this section is not applicable		write <i>n/a</i> in the Y/N column and give justification in the Evidence / comment column.	
7 Product (or service) realisation	Y / N	Evidence / comment	
7.1 Planning of product realisation			
a) Has the organisation determined quality objectives for its products?			
b) Has the organisation identified processes, documents and resources required by specific products?			
c) Has the organisation identified verification, validation, monitoring, inspection and test activities to meet acceptance criteria for specific products?			
d) Has the organisation determined what records are needed to provide evidence that requirements for specific products have been met?			
e) Is there identifiable output from the planning process, in an appropriate format (<i>in accordance with 4.2.4</i>)?			
7.2 Customer related processes			
1 Has the organisation determined product requirements prior to commitment to supply, including:			
a) Customer's specified requirements, delivery, warranty and service?			
b) Requirements necessary for the product's intended use?			
c) Statutory and regulatory requirements?			
d) Any additional requirements determined by the organisation?			
2 Has the organisation reviewed product requirements to confirm that:			
a) They are adequately defined?			
b) Differences between inquiry and order have been resolved?			
c) Requirements can be met?			
d) Are records maintained of the results of review and actions arising from the review (<i>in accordance with 4.2.4</i>)?			
e) If the customer does not provide a written statement of requirement does the organisation confirm the customer's requirements prior to acceptance?			
f) If product requirements are changed (after the order is accepted) are relevant documents amended and personnel informed?			

If a requirement of this section is not applicable		write <i>n/a</i> in the Y/N column and give justification in the Evidence / comment column.	
7	Product (or service) realisation	Y / N	Evidence / comment
3	Are arrangements in place for communication with customers, including		
a)	Inquiries about products;		
b)	Orders and changes to orders;		
c)	Feedback and complaints?		
7.3	Design and development		
1	Planning		
a)	Have stages of design and development been determined for the product?		
b) i)	Are requirements for review, verification and validation defined for each stage?		
ii)	Is validation completed prior to delivery or use, where practical?		
c) i)	Are responsibilities for design and development defined?		
ii)	Is there effective communication between different members or groups in the design team?		
d)	Is planning output updated as appropriate as the design and development progresses?		
2	Inputs		
a)	Are requirements defined for function and performance?		
b)	Are applicable statutory and regulatory requirements defined?		
c)	Is information to be used from previous designs defined?		
d)	Are other requirements essential for design and development adequately defined?		
e)	Are design inputs reviewed for adequacy to confirm that they are complete, unambiguous and not in conflict?		
f)	Are records of design inputs maintained (<i>in accordance with 4.2.4</i>)?		
3	Outputs		
a)	Do the outputs meet input requirements for design and development?		
b)	Do the outputs provide information required for purchasing, production and service provision?		
c)	Do the outputs contain or reference product acceptance criteria?		
d)	Do outputs specify characteristics for the product's safe and proper use?		

If a requirement of this section is not applicable		write <i>n/a</i> in the Y/N column and give justification in the Evidence / comment column.	
7	Product (or service) realisation	Y / N	Evidence / comment
4	Review		
i)	Have design and development reviews taken place (involving representatives of all relevant functions) in accordance with the design and development plan?		
ii)	Do participants in design reviews include representatives of functions concerned with the design development stage being reviewed?		
iii)	Are records of reviews available (<i>in accordance with 4.2.4</i>) to:		
a)	Confirm that results of design and development have been evaluated?		
b)	Identify problems and propose action?		
c)	Record results of actions?		
5	Verification		
i)	Has verification been completed in accordance with the design and development plan to confirm that design and development outputs meet requirements of inputs?		
ii)	Are records maintained (<i>in accordance with 4.2.4</i>) of the results of verification and any necessary actions?		
6	Validation		
i)	Has validation been completed in accordance with the design and development plan to confirm that the product is suitable for its specified application or intended use?		
ii)	Are records maintained (<i>in accordance with 4.2.4</i>) of the results of validation and any necessary actions?		
7	Control of changes		
i)	Have changes been reviewed to evaluate their effect on constituent parts and on product already delivered?		
ii)	Have changes been approved prior to implementation?		
iii)	Have changes been appropriately verified and validated?		
iv)	Are records maintained (<i>in accordance with 4.2.4</i>) of the results of review of changes and any necessary actions?		

If a requirement of this section is not applicable		write <i>n/a</i> in the Y/N column and give justification in the Evidence / comment column.	
7 Product (or service) realisation	Y / N	Evidence / comment	
7.4 Purchasing			
1 Purchasing process			
i) Are verification requirements appropriate for the product's application?			
ii) Are suppliers evaluated and selected (in accordance with established criteria) on the basis of their ability to meet specified requirements?			
iii) Are suppliers periodically re-evaluated in accordance with established criteria?			
iv) Are records available (<i>in accordance with 4.2.4</i>) of the results of evaluation and any actions arising from the evaluation?			
2 Purchasing information			
i) Does purchasing information adequately describe the product to be purchased including (where appropriate):			
a) Requirements for approval of product, procedures and equipment?			
b) Requirements for qualification of personnel?			
c) Quality management system requirements?			
ii) Does the organisation ensure that purchasing information is adequate prior to issue to the supplier?			
3 Verification of purchased product			
i) Is purchased product verified in accordance with specified requirements?			
ii) Does purchasing information contain details of any verification to be performed at the supplier's premises?			
7.5 Production and service provision			
1 Control of production and service provision			
a) Is required information available to describe product characteristics?			
b) Are necessary work instructions available?			
c) Is suitable equipment available?			
d) Are required monitoring and measuring devices available?			
e) Are required monitoring and measuring devices used in accordance with work instructions and/or the quality plan?			
f) Are requirements for release, delivery and post delivery activities implemented?			

If a requirement of this section is not applicable		write <i>n/a</i> in the Y/N column and give justification in the Evidence / comment column.	
7	Product (or service) realisation	Y / N	Evidence / comment
2	Validation of processes for production and service provision		
i)	Is production or provision of service which cannot be verified by subsequent monitoring or measuring adequately validated to demonstrate that planned results are being achieved, including:		
a)	Are criteria defined for review and approval of the processes?		
b)	Are personnel qualified? Is equipment approved?		
c)	Are methods and procedures approved?		
d)	Are required records maintained (<i>in accordance with 4.2.4</i>)?		
e)	Is the time interval for process re-validation defined?		
ii)	Does validation demonstrate the ability of the process to achieve planned results?		
3	Identification and traceability		
i) a)	Is product identification and traceability required to be maintained throughout production (for any products)?		
b)	If traceability is a requirement are records of unique identification of the product available (<i>in accordance with 4.2.4</i>)?		
ii)	Is inspection and test status adequately maintained throughout production?		
4	Customer property		
i) a)	Does the organisation adequately identify, verify, protect and safeguard customer property?		
b)	Is the customer's intellectual property controlled?		
ii)	Are records maintained of any loss or damage to customer property (<i>in accordance with 4.2.4</i>)?		
5	Preservation of product		
i)	Are components adequately identified, handled, packaged, stored and protected prior to use?		
ii)	Is finished product adequately identified, handled, packaged, stored and protected prior to delivery?		

If a requirement of this section is not applicable		write <i>n/a</i> in the Y/N column and give justification in the Evidence / comment column.
7	<i>Product (or service) realisation</i>	Y / N Evidence / comment
7.6	Control of monitoring and measuring devices	
1	Are monitoring and measuring devices required by the QMS controlled?	Including measuring devices: identified in quality plans (7.1c), required to verify purchased product (7.4.3) and finished product (7.5.1d) required to validate processes (7.5.2b)
a) i)	Where necessary to ensure valid results, is each device calibrated or verified at specified intervals (or prior to use) against measurement standards traceable to national or international standards?	
ii)	Where no such standards exist is the basis of calibration or verification defined?	
b)	Where necessary to ensure valid results, is each device adjusted or re-adjusted as necessary (in accordance with manufacturer's instructions)?	
c)	Is each device identified to enable calibration status to be determined?	
d)	Is each device safeguarded from adjustment, which would invalidate the measurement result?	
e)	Is each device protected from damage or deterioration during handling, maintenance or storage?	
2	Is the validity of previous results assessed (and appropriate action taken) when a device is found not to conform to requirements?	
3	Are records of the results of calibration and verification maintained (<i>in accordance with 4.2.4</i>)?	
4	When computer software is used in the monitoring and measuring equipment is it	
i)	Validated prior to initial use?	
ii)	Re-confirmed as necessary?	

8	Measurement analysis & improvement	Y / N	Evidence / comment
8.1	General		
	Has the organisation implemented appropriate measurement, analysis and improvement processes to:		
a)	Demonstrate product conformity;		
b)	Ensure conformity to the QMS;		
c)	Continually improve the effectiveness of the QMS?		
8.2	Monitoring and measurement		
1 i)	Does the organisation monitor customer satisfaction?		
ii)	Does the organisation use this information in accordance with defined methods?		
2	Internal audit		
a)	Is there a documented procedure which defines responsibility and requirements for:		
i)	Planning and conducting audits?		
ii)	Reporting results?		
iii)	Maintaining records (<i>in accordance with 4.2.4</i>)?		
b)	Is there an audit programme in place defining audit criteria, scope, frequency and methods?		
c) i)	Are records of audits maintained?		
ii)	Do records confirm that audits have been conducted in accordance with the audit programme, by personnel who are not directly involved in the area, being audited?		
d)	Has appropriate follow-up action been taken to:		
i)	Eliminate detected non-conformities and their causes?		
ii)	Verify the results of action taken?		
3	Monitoring and measurement of processes		
i)	Are effective methods used to monitor (and measure if applicable) the processes of the QMS and the organisation?		
ii)	Do the results confirm that they are capable of achieving planned results?		
iii)	If planned results are not achieved has appropriate action been taken?		

8	Measurement analysis & improvement	Y / N	Evidence / comment
4	Monitoring and measurement of product		
i)	Are product characteristics measured to confirm that product requirements are met?		
ii)	Do records (<i>in accordance with 4.2.4</i>) indicate conformity to acceptance criteria and the person authorising release of the product?		
iii)	If product is released prior to completion of planned inspection has a relevant authority approved this?		
8.3	Control of non-conforming product		
1	Is there a documented procedure which describes how non-conforming product is dealt with, including:		
i)	Identification of non-conformity and action to prevent unintended use or delivery?		
ii)	Responsibility and authority for dealing with non-conforming product?		
iii)	Methods of dealing with non-conforming product?		
iv)	Action to be taken if a non-conformity is detected after delivery?		
v)	Records of non-conforming product and subsequent action?		
2	Are there records (<i>in accordance with 4.2.4</i>) of action taken following identification of a non-conformity, including:		
i)	Re-work to eliminate the detected non-conformity, followed by re-verification to demonstrate conformity;		
ii)	Acceptance under concession by a relevant authority;		
iii)	Withdraw from intended use and either scrap or use for another purpose?		
8.4	Analysis of data		
1	Has the organisation identified data to be collected and analysed?		
2	Has data been analysed to provide information relating to:		
a	Customer satisfaction;		
b	Conformity to product requirements;		
c	Process and product characteristics (and trends), including opportunities for preventive action;		
d	Supplier performance?		

8	Measurement analysis & improvement	Y / N	Evidence / comment
3	Does the organisation use this data to demonstrate the effectiveness of the QMS and determine where improvements can be made?		
8.5	Improvement		
1	Does the organisation continually improve the effectiveness of the QMS through use of:		
i)	Quality policy and objectives;		
ii)	Audit results;		
iii)	Analysis of data;		
iv)	Corrective and preventive action		
2 i)	Is there a documented procedure for		
a)	Reviewing non-conformities (including customer complaints);		
b)	Determining the cause of non-conformities;		
c)	Evaluating whether action needs to be taken to prevent recurrence;		
d)	Determining what action is required and ensuring that it is implemented;		
e)	Maintaining records (<i>in accordance with 4.2.4</i>) of the results of action taken;		
f)	Reviewing corrective action taken?		
ii)	Have non-conformities and customer complaints been dealt with in accordance with the documented procedure?		
3 i)	Is there a documented procedure for		
a)	Determining causes of potential non-conformities;		
b)	Evaluating whether action needs to be taken to prevent occurrence;		
c)	Determining what action is required and ensuring that it is implemented;		
d)	Maintaining records (<i>in accordance with 4.2.4</i>) of the results of action taken;		
e)	Reviewing preventive action taken?		
ii)	Have problems requiring preventive action been identified?		
iii)	Has preventive action been implemented in accordance with the documented procedure?		