

ISO 9001:2000 Self Assessment Questionnaire

Produced by Solutions Generation

Purpose

At the start of your ISO 9000 program it will be necessary for you to assess the status of your quality management system and to prepare plans for its development to take your company towards ISO 9001:2000 certification.

Help Line

When you have read and completed this assessment and wish our consultant specialists to comment on your self assessment results, free of charge, please e-mail or fax your details to Solutions Generation.

Overview of the 2000 Changes

The structure and contents of the 1994 standards were revised while maintaining the essential requirements of those current standards. Essentially, the proliferation of the ISO 9000:1994 family containing some 20 standards and documents was stopped with the introduction of the ISO 9000 2000 quality management standards.

The three primary standards are: -

- ISO 9000: Quality management systems - Fundamentals and vocabulary
- ISO 9001: Quality management systems - Requirements
- ISO 9004: Quality management systems - Guidance for performance improvement

ISO 9001 and ISO 9004 were produced together, with the same numbering, sequence and structure, in order to form a "consistent pair" of standards. Also ISO 9000 was developed in parallel with ISO 9001 and ISO 9004 to achieve a coherent terminology in the ISO 9000 Family, ISO 14000 Family and other management standards.

New Sections of ISO 9001:2000

The new standard is broken into 4 Main Clauses namely:-

- Clause 4: Quality Management System
- Clause 5: Management Responsibility
- Clause 6: Resource Management
- Clause 7: Product Realisation
- Clause 8: Measurement, Analysis and Improvement

Exclusions from the Quality Management System

Due to the nature of different organisations' products or services, it is possible that some of the clauses in the standard may not be appropriate and can therefore be excluded from the scope of the quality management system. Such exclusions are only permissible within **Clause 7 - Product Realisation**, For example, if the organisation has no design function, then clause **7.3 Design and Development** may be excluded.

Use of this Document

Using this document enables you to quickly confirm if your organisation has addressed all the requirements of the new 2000 standard. Changes between ISO 9001:2000 and ISO 9001:1994 are highlighted in **blue bold text**. The degree of change is indicated as either **(N)** for new, or **(E)** for an enhancement when compared to ISO 9001:1994. Corresponding clauses of ISO 9001:1994 are also provided. You may list your organisations' documents that relate to or support each specific clause in the "OMS Reference" column.

Helpline and Feedback

If you wish our consultant specialists to comment on your self assessment results, or any other concerns you may have, please E-Mail or fax your completed questionnaire and comments to us and we will gladly assist you.

Please provided us with your details:	Contact Name	
Company Name:	Position	
Address:	Post / Zip Code	
Telephone Number:	Fax No:	E-Mail:
Nature of Business:	Web Site Addresss:	

ISO 9001:2000 Assessment Questionnaire Clauses & Checklist	1994 Clause	QMS Reference	Notes and Actions (yes or no)
4.0 Quality Management System			
4.1 General Requirement	4.2.1, 4.5.1		
- Has the organisation established, implemented and maintained a quality management system?	4.2.1, 4.5.1		
- Does the organisation continually improve the effectiveness of the QMS?	4.2.1, 4.5.1		N
a Have processes needed for the QMS been identified and applied throughout the organisation?	4.2.1		
b Have the interaction and sequence of processes been determined?	4.2.2; 4.2.3		E
c Have the criteria and methods necessary for the effective operation and control of these processes been determined?	4.2.2 & 4.2.3, 4.5		
d Are resources and information needed to support the operation and monitoring of these processes available?	4.1.3, 4.2.3		
e Are the QMS processes measured, monitored and analysed to achieve planned results?	4.1.3		
f Are actions implemented necessary to achieve planned results and continual improvement of these processes?			E
- Are the QMS processes managed in accordance with the requirements of ISO9001:2000?			
- Are any out-sourced processes identified for control?			
4.2 Documentation Requirements			
4.2.1 General Requirement	4.2.1, 4.51		
- Does the QMS documentation include the following:			
a statements of quality policy and quality objectives ?			N
b quality manual?			
c documented quality procedures required by ISO9001:2000?	4.2.2.a		
d documents needed for the effective planning, operation and control of QMS processes ?	4.2.2.b		E
e quality records required by ISO 9001:2000?			
Note 1: Are all QMS documented procedures established, implemented and maintained?	4.1.3, 4.2.3		
Note 2: Does the format and extent of the QMS reflect the organisation, its processes and competence of personnel?			E
4.2.2 Quality Manual	4.2.1		
Does the QMS quality manual include the following:			
a scope of the QMS as well as any details of and justifications for exclusions ?	4.2.1		E & N
b specified documented procedures or reference to them?	4.2.1		
c a description of the interaction between the processes of the QMS?	4.2.1		N
Assessor's Notes:etc...			