

BRITISH SECURITY INDUSTRY ASSOCIATION

A guide to the contents of

**ISO 9001 : 2000
Quality Management Systems
Requirements**

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BACKGROUND

In late 2000 the current, large number of ISO 9000 quality standards were replaced by just three standards:

- ISO 9000 Quality Management Systems
Fundamentals and vocabulary
- ISO 9001 Quality Management Systems
Requirements
- ISO 9004 Quality Management Systems
Guidance for performance improvement

The contents and significance of these standards are:

ISO 9000

This gives general background information to quality management, and lists definitions and terms used in quality management. It is a guidance document only and will **not** be used by assessment bodies for surveillance or certification purposes. However, it is called up as a Normative reference in ISO 9001 and could be used by auditors to support their interpretation of ISO 9001 requirements.

ISO 9001

This will replace the current series of ISO 9001/9002/9003. There are some significant changes to the current requirements, and this guide highlights some of these changes.

This is the standard which assessment bodies will use for surveillance or certification purposes.

ISO 9004

This is a guidance document which is designed to be used in conjunction with ISO 9001 by companies wishing to link to other quality systems, such as TQM or Business Excellence. This will **not** be used by assessment bodies for surveillance or certification purposes.

The key document, therefore, for assessment and certification purposes is **ISO 9001**, and this guide highlights the new requirements contained in the standard.

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A GENERAL OVERVIEW OF ISO 9001 : 2000

A user-friendly standard

The requirements and language of the standard are intended to be more user-friendly, and it now caters for all sizes of company, including those that provide a service.

A requirement to demonstrate customer satisfaction

One interesting point is that the title of the new standard does not include the term 'quality assurance'. This is to reflect the fact that a company must demonstrate its capability to achieve customer satisfaction.

There is a clear requirement for continual improvement of the quality management system (QMS), although this could be difficult for an assessment body to measure objectively.

'Design' is now a requirement for all companies

One significant change is that the design element of a process is included in the Scope as a requirement for all companies. This could include companies that install security systems or supply a manned security service. Some inspectorates are already implying that these services are 'designed' on an individual basis.

It is possible for an organisation to claim 'permitted exclusions' from the design section of the standard (sub-clause 7.3) in their QMS, but an organisation would need a strong case to put to an inspectorate. This raises an interesting point regarding the use of a certification body's logo on company literature. It is expected the logos will only show that companies are registered to ISO 9001, and will not differentiate between those companies including elements of design in their scope and those who do not.

It should not be necessary to make significant changes to your current written procedures, but you will need to identify the relevant clause numbers of the new standard. The standard contains 8 sections, and 4 of these are clearly identified as being crucial to good quality management. These are highlighted below in **bold**:

Section 1	Scope
Section 2	Normative references
Section 3	Terms and definitions
Section 4	Quality management systems
Section 5	Management responsibility
Section 6	Resource management
Section 7	Product realisation
Section 8	Measurement, analysis and improvement

Key changes from the current requirements in ISO 9001/9002, and any new requirements, are listed below.

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SECTION 1 - SCOPE

Clause 1.1 General

The Scope has been enhanced, and there is now a need for an organisation

“... to demonstrate its ability to provide consistently product that meets customer and applicable regulatory requirements, and to include processes for the continual improvement of the system and the prevention of nonconformity.”

Note: In ISO 9001:1994 - Clause I, the requirements specified are aimed primarily at achieving customer satisfaction only by **preventing nonconformity**.

Clause 1.2 Application

This requirement is **new** and gives information on the “permissible exclusions” an organisation may apply to its QMS.

“The only exclusions permitted are those that do not affect an organisation’s ability to provide product that meets customer and applicable regulatory requirements. These exclusions may be due to:

- c) the nature of the organisation’s product;*
- d) customer requirements;*
- e) the applicable regulatory requirements.”*

Permitted exclusions only apply to “Clause 7 : Product realisation” of ISO 9001:2000.

SECTION 3 - TERMS AND DEFINITIONS

The term ‘organisation’ (company) used in ISO 9001:2000 replaces the term ‘supplier’, that was used previously to mean the unit to which ISO 9001 applied. The term ‘supplier’ is now used instead of the previous term ‘subcontractor’.

Old terms: sub-contractor - - > supplier - - - - - > customer

New terms supplier - - - - - > organisation - - - - > customer

SECTION 4 - QUALITY MANAGEMENT SYSTEM

There is more emphasis on the need to continually improve a QMS.

“The organisation shall establish, document, implement, maintain and continually improve a QMS. This should be achieved by identifying relevant processes, determining the sequence and criteria of these processes, ensuring information is available on the processes, and by measuring and monitoring these processes.”

Clause 4.2.2 Quality Manual

This requirement has been enhanced to include the requirement for an organisation to specify “**any reduction in scope**” in the quality manual. (refer to clause 1.2 of ISO 9001:2000).

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SECTION 5 - MANAGEMENT RESPONSIBILITY

Clause 5.1 Management commitment

More emphasis is placed on Top Management commitment by:

- “a) *communicating to the organisation the importance of meeting customer as well as regulatory and legal requirements;*
- *establishing the quality policy and quality objectives;*
- *conducting management reviews;*
- *ensuring the availability of necessary resources.”*

Clause 5.2 Customer focus

This requirement reinforces the involvement of Top Management, which should:

“... ensure that customer needs and expectations are determined, converted into requirements and fulfilled with the aim of achieving customer satisfaction.”

Clause 5.3 Quality policy

This requirement has been enhanced to ensure that Top Management establishes its policy for quality. Particular attention should be given to:

- sub-clause (b):
“there should be a commitment to meeting requirements and to continual improvement”
and
- sub-clause (c):
“a framework should be provided for establishing and reviewing quality objectives;”

Clause 5.4.1 Quality objectives

There is a requirement that:

“Quality objectives are established at relevant functions and levels within the organisation, which should be measurable and consistent with the quality, including the commitment to continual improvement.”

Clause 5.4.2 Quality management systems planning

This requirement has been revised for clarity and to ensure that managing change is included in planning.

“Planning shall cover:

- a) *the planning of the QMS;*
- b) *the integrity of the QMS*

Planning shall ensure that change is conducted in a controlled manner and that the integrity of the QMS is maintained during this change.”

Clause 5.5.3 Management Representative

This requirement further clarifies that:

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“Top Management shall appoint a member of the management who, irrespective of other responsibilities, shall have responsibility and authority for:

- a) ensuring the processes of QMS are established and maintained;*
- b) reporting to Top Management on the performance of the QMS, including needs for improvement;*
- c) promoting awareness of customer requirements throughout the organisation.”*

Clause 5.5.4 Internal Communication

This is a **new** requirement that requires the organisation:

“to establish and maintain procedures for internal communication between the various levels and functions regarding the QMS and its effectiveness.”

Clause 5.6 Management Review

Emphasis is placed on the organisation establishing a QMS procedure for Management Review. Further text has been included to address key input and output requirements of a Management Review.

Attention should be given to sub-clause **5.6.2 Review input**, particularly the following:

- “bullet b) customer feedback;*
- bullet c) process performance and product*
- bullet d) status of preventive and corrective actions*
- bullet f) changing circumstances.”*

Under ISO 9002: 1994 : clause 4.1.3 it was not a requirement to establish a formal procedure for Management Review.

SECTION 6 - RESOURCE MANAGEMENT

Clause 6.1 Provision of resources

This requirement further clarifies the requirement for an organisation to:

“... determine and provide resources needed to establish and maintain the QMS, in order to address customer satisfaction.”

Clause 6.2.2 Competency, awareness and training,

The scope of training requirements has been enhanced to include not only training needs but competence and awareness. Procedures and system level procedures are required to:

- “a) determine competency and training needs;*
- b) provide training to address identified needs;*
- c) evaluate the effectiveness of training at defined intervals;*

- d) ensure employees are aware of the importance of their activities;*
- e) maintain appropriate records of education, training, skill and experience.”*

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Clause 6.3 Infrastructure

The organisation shall:

“... identify, provide and maintain the facilities it needs to achieve the conformity of product, including:

- a) workspace and associated facilities;*
- b) equipment, hardware and software;*
- c) supporting services.”*

Clause 6.4 Work environment

This is a very general requirement:

“ The organisation shall identify and manage the human and physical factors of the work environment needed to achieve conformity of product.”

It is not clear how a “work environment “ is defined.

SECTION 7 - PRODUCT REALIZATION

Note: The title of Process Control as traditionally referred to in ISO 9001:1994 has been replaced with the title “Product Realisation”.

This is quite a complex section, and organisations will need to consider carefully whether they wish to include any “**permitted exclusions**” in their QMS (see clause 1.2). An organisation would have to justify any permitted exclusions to its assessment body. This will not be easy to do as a product is defined in ISO 9000 : 2000 as:

Product result of a process

There is a NOTE to this definition which states that there are 4 agreed generic product categories – **hardware, software, services and processed materials**. Assessment bodies may well argue that security companies offer ‘services’ and as such no permitted exclusions should be allowed. There are 6 sub-clauses of Section 7, and most, if not all, the requirements are probably what all security companies already provide. The exception may well be sub-clause 7.3 : Design. The sub-clauses are:

Clause 7.1 Planning of realisation processes

Product realisation is that sequence of processes and sub-processes required to achieve the product, and the clause specifies the requirements to be met to achieve this.

Clause 7.2 Customer-related processes

This is divided into 3 sub-clauses:

- 7.2.1** *Determination of requirements related to the product*
- 7.2.2** *Review of requirements related to the product*
- 7.2.3** *Customer communication*

This sub-clause is essentially a **new** requirement, the organisation being required to implement effective liaison with customers, with the aim of meeting customer requirements.

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Clause 7.3 Design and/or development

This is divided into 7 sub-clauses:

- 7.3.1 *Design and development planning*
- 7.3.2 *Design and development inputs*
- 7.3.3 *Design and development outputs*
- 7.3.4 *Design and development review*
- 7.3.5 *Design and development verification*
- 7.3.6 *Design and development validation*
- 7.3.7 *Control of design and development changes*

Clause 7.4 Purchasing

This is divided into 3 sub-clauses:

- 7.4.1 *Purchasing process*
- 7.4.2 *Purchasing information*
- 7.4.3 *Verification of purchased product*

Clause 7.5 Production and service operations

This is divided into 4 sub-clauses:

- 7.5.1 *Control of production and services*
- 7.5.2 *Validation of process for production and service provision*
- 7.5.3 *Identification and traceability*
- 7.5.4 *Customer property*
- 7.5.5 *Preservation of product*

Clause 7.6 Control of monitoring and measuring devices

New requirements for software developed for tests has been added:

“Software used for monitoring and measuring of specified requirements shall be validated prior to use.”

SECTION 8 - MEASUREMENT, ANALYSIS AND IMPROVEMENT

Clause 8.1 General

This clause requires that a measurement, monitoring, analysis and *improvement processes* must be used as a means of demonstrating that the QMS, processes and product and/or service conforms to specified requirements.

“The organisation shall identify and use appropriate statistical tools.

The results of data analysis and improvement activities shall be used as input to the management review process”

Clause 8.2.1.1 Customer Satisfaction

This requirement is **new** and emphasises that a process for obtaining and monitoring information and data on customer satisfaction **SHALL** be implemented.

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It is the responsibility of the organisation to define the methods and measures for obtaining and utilising customer satisfaction information and data.

Clause 8.2.3 Measurement and monitoring of processes

This requirement is essentially the same, however it places more emphasis on the method used for the measurement of processes necessary to meet customer requirements.

In particular, “*Measurement results SHALL be used to maintain and/or improve those processes*”.

Clause 8.4 Analysis of data

In addition to the traditional statistical technique requirement of the 1994 standard, this clause focuses on the analysis of applicable data as one means of determining where QMS improvements can be made.

“*The organisation SHALL analyse applicable data to provide information on:*

- a) *customer satisfaction, and dissatisfaction*
- b) *conformance to customer requirements and*
- c) *characteristics of processes, products and/or services*”
- d) *supplier*

This clause is essentially limited to the **identification of a need for the use of** statistical techniques and then **establishing an appropriate procedure** to implement and control the application of the statistical techniques.

Clause 8.5.1 Continual improvement

This requirement is quite clear:

“*The organisation shall **continually improve** the QMS. The organisation shall establish a system level procedure that describes the use of quality policy, objectives, internal audit results, analysis of data, corrective and preventive action and management review to facilitate continual improvement.*”