



ISO 9000

Many companies see the introduction of a quality management system as a major step forward in controlling and improving their key processes. Other companies simply react to customer demands that their suppliers should have suitable systems.

The international quality system standard series, ISO 9000:2000, provides guidance and new requirements for running a quality system.

This briefing outlines:

- The practical benefits of using a quality system.
- How to introduce a quality system.
- How to achieve ISO 9001, the standard against which you can be certified.

1 The benefits

1.1 A quality management system provides improved **control** of key processes.

All employees follow agreed processes for carrying out key activities, minimising the risk of costly mistakes.

1.2 A quality system provides a foundation for **improving quality** and **customer satisfaction**.

- The system defines existing key operations. The system can be adjusted to account for inevitable changes, such as new technologies, new customers and new ideas.
- The system provides a way of collecting and implementing suggestions for improvements. This improves the chances that any broader quality management initiative will be successful and continuous.

1.3 A quality system lets you **manage growth** more effectively.

- The system makes it easier to integrate new employees and activities.
- Having a system makes it easier to stay in control.

1.4 Many **customers** demand that each of their suppliers has a quality system.

- They want to ensure that the quality of your product or service meets their requirements.
- Many larger companies may require the system to be ISO 9001 'certificated'.

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2 Improving existing practice

Implementing a quality system usually involves recording current methods of doing key tasks.

2.1 Start by looking at your practice in **key areas**. These will tend to be:

- 'Mission critical' activities, where errors will cause serious problems. Typically, these will be activities which directly affect customer satisfaction.
- Areas which are causing concern. Concentrating on key areas brings the fastest improvements in effectiveness. The system can be rolled out later to other areas.

2.2 Plan your approach.

- Think about what resources you will need.
- Analyse your current business processes by discussing them with the employees involved.

The ISO 9000:2000 series

A The **ISO 9000:2000** series of standards replace the 1994 version of ISO 9000.

- It is designed to apply to all types of business and focuses on delivering customer satisfaction.
- There is less emphasis on paperwork and each business decides how best to document the planning, operation and control of its processes.

B ISO 9000:2000 consists of a **number** of standards.

- ISO 9000:2000 sets out the fundamentals of quality management requirements and contains a glossary of terms used across the ISO 9000 standards.
- ISO 9001:2000 is the new, unified standard against which you can be certificated.
- ISO 9004:2000 is a new standard to help with developing continual improvement.

C The full series of ISO 9000 publications includes **guidance** on the standards.

- Copies are available from the British Standards Institution (020 8996 9001; www.bsi-global.com;) and the Institute of Quality Assurance (020 7245 6722; www.iqa.org).

- Agree a format for recording information. This will include a description of any processes and any related instructions.
- Document the processes in the agreed format.
- Authorise the processes. Usually, a specified senior manager will be responsible for authorisation.

2.3 Do what is necessary to implement the processes.

- Distribute details of the processes to the employees involved.
- Train employees to ensure they are competent at their job.

2.4 Check the new processes are working.

Problems may occur, because of:

- Errors in the earlier process-writing stage.
- Employees working in a different way from that agreed.
- Changes in circumstances since the original processes were agreed. Finding and fixing problems indicates that the system is being used positively.

2.5 Act to correct the problems, by:

- Reviewing results from the checking process.
- Preparing (and authorising) revised processes.
- Ensuring that employees are trained to follow the revised processes.

In this way, existing practice builds to become an effective quality system. The authorised processes set out the agreed best working method, but can be updated when necessary.

3 ISO 9001

3.1 ISO 9001 (or 'BS EN ISO 9001') is the internationally-agreed **standard** for effective quality systems.

ISO 9001 ensures that your quality system will maintain quality at a consistent level. (It is up to you to decide what that quality level should be in order to meet customer requirements and satisfaction).

- A quality system meeting ISO 9001 will cover the full range of activities that affect the customer. It will also include measures to ensure the smooth running of the quality system.
- A quality system based on ISO 9001 can be independently assessed to prove that it meets the standard (see 4).

➡ If you plan to use a consultant, a good brief is vital. See **Using a consultant**.

“ISO 9001:2000 is less prescriptive and bureaucratic than its predecessor, letting you align quality management with the way you run your business.”
Don Stanley,
Lloyd's Register
Quality Assurance

3.2 ISO 9001 focuses on how your quality system should be **managed**.

- It sets out six procedures you must follow to achieve the standard.
- It requires that you document your systems.
- It involves a commitment to continual improvement.
- It requires full involvement from senior managers.

3.3 The main **advantage** of ISO 9001 is that it is a flexible and logical way to achieve a recognised standard system.

- The requirements of ISO 9001 may be more stringent than a basic 'in-house' quality system.
For example, it is common for in-house systems to bypass internal audit procedures.
- Achieving ISO 9001 certification (see **4**) shows that you are serious about quality.
- Many larger companies, in particular, are reassured by suppliers who have a quality system that is certificated to ISO 9001. This may be especially important if you want key supplier status.

3.4 Be aware of the **costs** involved. These include:

- Designing and introducing the system.
- Using the system.
A poorly-designed system can be an expensive, bureaucratic nightmare (see **6**).
- Certification and 'surveillance' visits.

Costs can run to several thousand pounds but should be more than offset by the benefits the system will bring (see **5**).

Some companies whose customers do not demand ISO 9001 choose to postpone certification. Others feel that the outside audit of their quality system is a worthwhile exercise.

4 Certification

Certification involves an independent assessment of your quality system to confirm that it meets the requirements of ISO 9001.

4.1 You will need to design, document and **implement** your own quality system.

The system will need to cover all the requirements of the ISO 9001 standard.

- You may need outside help (see **5.2**).
- Your quality system cannot be audited until you have generated documentary evidence

to show that you are meeting the standard. Many certification bodies will not conduct a formal assessment until the system has been operating for at least three months.

4.2 To find a **certification body** with relevant experience in your sector and accreditation from the United Kingdom Accreditation Service (UKAS), visit the UKAS website at www.ukas.com.

- Certification by a non-UKAS accredited body is likely to lead to credibility problems with your customers.

4.3 Arrange a **visit** from the certification body's auditors.

- They will seek objective evidence that you are complying with each of the clauses of the ISO 9001 standard.

UKAS prohibits auditors from acting as consultants. They will not tell you how to meet the standard but can offer advice.

4.4 The auditors will tell you of any **shortcomings** in your system.

- If you satisfy the standard, the auditors put your name forward for certification.
- You can also be certificated if the auditors only identify a small number of 'minor' problems.
You will be required to correct these problems within a specified timeframe.
- If the auditors identify more serious 'major' problems, you will be required to correct these before certification.

Once you are certificated, you can display the certification body logo, and if the body is UKAS-accredited, the UKAS 'tick and crown' symbol (consult UKAS about exceptions to this rule).

4.5 All certification bodies are required to **revisit** registered companies to ensure they still meet the requirements of the standard.

These surveillance visits normally take place twice a year at agreed dates.

- You will be given time to deal with any minor or major problems which are identified before any action is taken to withdraw your certificate.

5 Costs and resources

5.1 The largest cost of ISO 9001 is the involvement of company **employees**.

“Most UKAS-approved certification bodies offer low-cost schemes for small and medium-sized companies.”

John Hele,
British Standards Institution

- Reducing this cost by minimising employee involvement is a false economy. The 'ownership' created by involving employees in designing the quality system maximises the chances of them accepting it.

5.2 The next largest cost will be for **designing** and developing the system. This needs to be led by someone with experience in this field.

- You may have someone within your own organisation who has carried out this role, perhaps with a former employer.
- Your Business Link may offer free or subsidised advice and training, and will be able to provide names of approved consultants.

5.3 Grants for work in this area tend to be directed through Business Links. Different areas have different grants, which depend on local conditions.

- A typical grant may cover up to 50 per cent of the cost of an approved consultant. See **Getting a grant for your business**.

5.4 Certification fees are around £650 per assessor per day. Overall costs depend upon company size and the number of locations involved.

- Ask certification bodies for quotes for initial audits and surveillance visits. Many will give an all-inclusive price, including surveillance visits for three years.
- Ask your certification body if it offers special rates for small companies. Typically, special rates will depend on how long the assessment is likely to take and what the company's turnover is.

5.5 The standard requires that companies have trained **internal auditors** to conduct audits on the system.

- For further details, contact the International Register of Certificated Auditors (020 7245 6833; www.irca.org). An internal audit can provide an effective means of monitoring the system and identifying areas for improvement.

6 A healthy system

Most companies that wish to, will eventually achieve certification. In doing so, however, they often build systems that are far too complex for their own needs. To avoid this situation:

6.1 Do not create too much **paperwork**.

- Consider using working documents themselves as a way of keeping records.
- Challenge every new form that is proposed. Can an existing form be modified to accommodate the change instead?
- Keep the number of controlled copies of system documents to a sensible minimum. ISO 9001 does not demand that everyone has a copy of everything.
- Use your IT system to minimise the need for paper copies. Give employees access to key documents through your intranet or network.

6.2 Make sure that **internal audits** are carried out regularly.

- Use these reports to monitor the system and drive improvements.
- Continually question whether you are running the system or the system is running you.

6.3 Introduce a balanced method for dealing with **changes** to the system.

- The method must be formal enough to maintain management control.
- The method must be informal enough to encourage employees to put ideas forward. Otherwise employees will lose respect for the system and may implement changes informally instead.

6.4 Take every opportunity to **compare** your system with those of other companies, eg suppliers, sister companies and customers.

- Use supplier assessment audits.
- Use customer questionnaires.
- Create a forum for discussion.

Expert contributors

Thanks to **Don Stanley** (Lloyd's Register Quality Assurance, 024 7688 2338); **John Hele** (BSI Management Systems, 020 8996 7619).

Further help

There are other Directors' Briefing titles that can help you. These briefings are referred to in the text by name, such as **Using a consultant**.

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