FAQ

Q: What is ISO 9001?
A: It is an international standard for quality management. The standard is published by the International Organization for Standardization and is used throughout the world. For a company to become registered (certified) to the standard, it must pass an initial audit and then, to maintain the certification, it must pass periodic surveillance audits. The standard is generically written so it can be applied to all type of organizations.

In addition, there are industry-specific standards for automotive, aerospace, and medical companies that include either all or most of ISO 9001, plus additional requirements.

Q: What are the benefits?
A: Many companies are requiring that their suppliers to become certified, and many more prefer it. So it has tremendous marketing potential.

Internally, it can help an organization bring about continuous improvement, resulting in increased efficiencies and reduced costs.

Q: But it is just for manufacturers, right?
A: No, both service companies and manufacturers have been certified. In fact, over the last few years most of the growth in ISO 9001 registrations has been with service organizations.

The standard is written so any organization can become certified.

Q: What is involved in getting certified?
A: The biggest activity is documenting procedures. The 9001 standard itself requires only six; the rest are up to the organization to decide where they need them. Also during the process, the organization must establish and deploy a written quality policy. All employees must understand the policy. Quantifiable quality objectives are also required.

A very important part of implementation is internal audits of the system, including the processes you just documented. You can either perform these using your own trained staff, or these can also be conducted by an outside person. Click [here for additional details](http://www.isoadvice.com/pages/we-can-perform-your-internal-audits.php)

The audit is usually followed by a management review of the system.

A formalized corrective and preventive action system is also required.

After the organization is confident all requirements have been met, it is ready for its external audits, which consist of a desktop review of the company documentation (usually called a Stage One or similar) conducted either on-site or off-site, followed by a comprehensive on-site audit where the system is actually verified as being implemented.

Q: Is there a prescribed format for how procedures should be constructed?
A: No, an organization can document its processes any way that best suits the employees who use them. Many companies use flowcharts (also called process maps) for this, along with narrative procedures. It

really all depends on what you think will suit your needs. If you decide flowcharting is the way to go, we recommend Visio, a flowcharting software program available from Microsoft(TM).

Q: I've heard that extensive and detailed work instructions are required to get certified. Is this true?
A: No, the company gets to decide where, and if, instructions, as a supplement to procedures, will be used. It all depends on the nature of your business and what the process is. Many companies start out with procedures or flowcharts, then later on determine that additional detail is needed in the form of work instructions. Remember, it is up to you, as the user of the standard, to determine the extent and detail of your documentation.

Q: Who does the certification audit?
A: The audits themselves are conducted by a "registrar" that the organization selects.

Q: Where do I get a registrar?
A: All of them have Web sites. Just do a search for ISO 9001 registrars. Also, a list is available from the [American Society for Quality(TM)](www.asq.org). You may reach them at (800) 248-1946.

Q: Where do I get the ISO 9001 standard?
A: Through the ASQ (contact information above). The aerospace standards are available through www.sae.org, and ISO 13485 (medical-related) is available through www.aami.org.

Q: Does it really make that much of a difference which registrar and auditor I use?
A: Very definitely. Because the standards are written generically, there are wide interpretations of how it should be applied.

Contact us and we will be glad to provide names of registrars and specific auditors that we recommend. These are people we have worked with in the past, and who do an excellent job of auditing without telling you how to run your business.

Q: If I get one location of my company certified, does this also cover the rest of the company?
A: No, the scope of your registration is shown on your registration certificate, and only covers the business units or locations that were audited.

Q: Will getting certified require that I hire additional people?
A: Not unless the organization structures its system so complicatedly that it requires more people to administer it, and this is definitely not recommended. It is required that the organization appoint a management representative who functions as a project manager during implementation, and then administers the system after certification, but this is usually an existing employee.

We have helped many companies of all sizes since 1993, and none have ever had to "hire" another person to get or maintain certification.

Q: How much does implementation and certification cost?
A: When you apply with a registrar, they will provide a written quote based on the number of employees and number of facilities involved. Most registrars charge $1,200 per auditor day, plus travel expenses. The number of auditor days is determined by the size and number of facilities involved. Again, you will know all this on the front end, as a written quote package will be prepared by your registrar.

If the organization uses a consultant to help them with implementation, this is additional, of course.

If you are interested in getting a quote for assistance with implementation, this can usually be provided right over the phone or email if we have the above information. We offer assistance to companies in ISO 9001, AS9100, AS9110, AS9120 (aerospace), ISO 13485 (medical-related), or ISO 14001 (environmental).

If you have questions about any aspect of ISO 9001 or the other standards mentioned above, please give us a call without any cost or obligation. We answer questions all the time and are happy to provide this free service.