ISO 9001:2000 – What does it mean in the supply chain?

What is ISO 9001:2000?

ISO 9001:2000 is an international standard that gives requirements for an organization’s Quality Management System (“QMS”).

It is part of a family of standards published by the International Organisation for Standardisation (“ISO”) often referred to collectively as the “ISO 9000 series”.

For this reason, you may sometimes hear suppliers refer to being “ISO 9000 certified”, or having an “ISO 9000-compliant QMS”. This will normally mean that they are claiming to have a QMS meeting the requirements of ISO 9001:2000, the only standard in the ISO 9000 family that can be used for the purpose of conformity assessment.

It is important to understand however, that ISO is the body that develops and publishes the standard - ISO does not “certify” organizations, as will be explained later in this brochure.

The objective of ISO 9001:2000 is to provide a set of requirements that, if they are effectively implemented, will provide you with confidence that your supplier can **consistently** provide goods and services that:

- Meet your needs and expectations and
- Comply with applicable regulations
The requirements cover a wide range of topics, including your supplier's commitment to

quality,

its customer focus,

adequacy of its resources,

employee competence,

process management (for production, service delivery and relevant administrative and support processes),

quality planning,

product design,

review of incoming orders,

purchasing,

monitoring and measurement of its processes and products,

calibration of measuring equipment,

processes to resolve customer complaints,

corrective/preventive actions and

a requirement to drive continual improvement of the QMS.

Last but not least, there is a requirement for your supplier to monitor customer perceptions about the quality of the goods and services it provides.
ISO 9001:2000 does not specify requirements for the goods or services you are purchasing. That is up to you to define, by making clear your own needs and expectations for the product. You might, for example, refer to product specifications, drawings, national or international product standards, supplier’s catalogues or other documents as appropriate.

**What does “Conformity to ISO 9001:2000” mean?**

This means that your supplier has established a systematic approach to quality management, and is managing its business to ensure that your needs are clearly understood, agreed and fulfilled. A statement of conformity to ISO 9001:2000 should not, however, be considered as a substitute for a declaration or statement of product conformity.

**How does ISO 9001:2000 help you in selecting a supplier?**

ISO 9001:2000 provides some requirements for the purchasing process that include you as the customer. These requirements address the following topics:

- requirements regarding the purchasing information that should be provided so that suppliers clearly understand their customers' needs
- the ways in which supplied products can be verified as meeting the requirements of the customer

Note that whenever ISO 9001:2000 refers to “products”, this also includes intangible products like services, or software.
Not a Guarantee of Suitable Quality

You have an important role to play, by specifying to your supplier what you actually want. If you don’t do this, you might find that you receive a product that meets all your stated requirements and the applicable regulatory requirements, but which is absolutely wrong for your intended application.

So, first of all, you should concentrate on specifying your needs related to the intended use of the product. To help in this task you may consider the following:

- What is the specific product (goods or service) you are buying?
- What impact does this product have on your own business?
- What are the risks to your business if you experience problems with this product?
- How can you be sure that the product you receive will actually meet your requirements?
- What do you know about the reputation and historical performance of your supplier?
- What level of confidence do you need in your supplier’s ability to provide you with conforming product on a consistent basis?
- If you decide that conformity to ISO 9001:2000 is important, (based on your assessment of the risks associated with the goods and services you are buying) how can you be sure that your supplier does have a QMS that meets ISO 9001:2000 requirements?
- Are the goods and services you require covered by your supplier’s QMS? (You may need to ask for a copy of your supplier’s actual certificate or declaration of conformity to find this out!)
How can you have confidence that your supplier meets ISO 9001:2000?

There are various ways in which your supplier can claim that its QMS meets the requirements of ISO 9001:2000. These include:

- **‘Supplier’s declaration of conformity’**: A declaration by your supplier itself affirming that its QMS meets ISO 9001:2000 requirements, usually supported by legally-binding signatures. This declaration can be based on your supplier’s internal audit system, or on second party or third party audits;

- **Second party assessment**: your supplier has been assessed directly by its customer (for example by you, or by another customer, whose reputation you respect) to check if its QMS meets ISO 9001:2000 requirements and your own requirements - sometimes used in contractual “business-to-business” transactions;

- **Third party assessment**: (Often referred to as certification or registration): your supplier hires an impartial third party (a certification body, or “registrar”) to conduct an assessment to verify conformity to ISO 9001:2000 requirements. This third party then issues a certificate to your supplier describing the scope of its QMS, and confirming that it conforms to ISO 9001:2000.

- Additional confidence may be derived from the fact that some certification bodies (“registrars”) are accredited by nationally or internationally recognized accreditation bodies, who verify the certification body’s independence and competence to carry out the certification process. Many accreditation bodies have multi-lateral arrangements under the umbrella of the IAF (International Accreditation Forum) to promote worldwide mutual recognitions in support of WTO (World Trade Organization) free trade principles.
Figure 1 explains this in simple schematic terms.

The IAF is an association of Accreditation Bodies and other interested parties from around the world, who work together to promote confidence and consistency in the ISO 9001 accreditation and certification process.

The accreditation process provides additional confidence that the certification body is competent and has the necessary integrity to issue an ISO 9001 certificate. Accreditation is usually carried out by national or regional accreditation bodies, and their accreditation mark will appear on the certificate.

A common way for a supplier to demonstrate conformity to ISO 9001 is via an independent ("Third-party") certification process. A certification body (sometimes known as a "registrar") conducts an audit of the supplier and if all is OK, they will issue a certificate of conformity.

If you know your supplier well and have confidence in them, it may be sufficient for you to accept a "Supplier Declaration of Conformity to ISO 9001" issued by them. Alternatively, you may choose to audit your supplier yourself or rely on audits that have been carried out by other reputable customers. These are known as a "second-party audits".

You are the one who is buying the goods or the services from your supplier. You need to make sure you tell them clearly what you want. Depending on how well you know your supplier, the confidence you have in their products, and the importance of their products for your own business, you might not even need them to demonstrate conformity to ISO 9001 at all.
Can suppliers claim that their goods or services meet ISO 9001:2000?

No. The reference to ISO 9001:2000 indicates that the supplier has a quality management system that meets the requirements of ISO 9001:2000. As mentioned earlier, this should provide you with confidence in your supplier’s ability to provide consistent, conforming goods or services. ISO 9001:2000 requires your supplier to monitor the levels of satisfaction of its customers, and to feed back this information in order to improve the effectiveness of its QMS.

What to do if things go wrong?

In the event you are not happy with specific goods or services you receive, you should first of all bring this to your supplier’s attention. You will typically do this via the normal technical and/or commercial communication channels that have been established. Your supplier is obliged to investigate your complaint, and should take appropriate actions to avoid or reduce the chances of it happening again.

If, however, you are dissatisfied with the overall performance of your supplier, (for example if they continue to provide non-conforming products, do not address your complaints, or are not taking appropriate corrective actions) then this is an indication of problems in their quality management system. Depending on the responses you receive, you should be aware that you can escalate your complaint as follows:

- If your supplier has a QMS that meets ISO 9001:2000 requirements, they are required to have nominated a person (the “management representative”) to have the responsibility and authority to ensure the system is working properly. You should find out who this is, and make a formal complaint.

- If you are still not satisfied with the response from your supplier, and if they are certified by an independent (third party) certification body (“registrar”), you should bring the matter to the certification body’s
attention. You can find the certification body’s name by looking at your supplier’s certificate. The certification body will investigate the problems during their surveillance audits of your supplier’s QMS, or, in critical cases, may decide to carry out an additional specific investigation.

- If you do not receive a satisfactory response from the certification body, and if it is accredited (see Figure 1), you should complain to the relevant accreditation body. Details of any such accreditation will appear on your supplier’s ISO 9001:2000 certificate. If you have difficulty in getting this information, you can consult the list of accreditation bodies who are members of the International Accreditation Forum on the IAF website (http://www.iaf.nu).

- If you feel that you have not received a satisfactory response from the accreditation body, and if it is a member of the International Accreditation Forum (see Figure 1), you can complain to the IAF (http://www.iaf.nu).

Remember that none of the above will affect your statutory rights as a purchaser, and it may be appropriate to take legal action against your supplier instead of, or in parallel with the above channels. The way in which you do this may vary from one country to another.

**To summarize.....**

ISO 9001:2000 is a useful basis for organizations to be able to demonstrate that they are managing their business so as to achieve consistent (hopefully good or better!) quality goods and services.
Points To Note

The ISO 9000 family of standards represents an international consensus on good quality management practices. It consists of standards and guidelines relating to quality management systems and related supporting standards.

ISO 9001:2000 is the standard that provides a set of standardized requirements for a quality management system, regardless of what the user organization does, its size, or whether it is in the private, or public sector. It is the only standard in the family against which organizations can be certified – although certification is not a compulsory requirement of the standard.

The other standards in the family cover specific aspects such as fundamentals and vocabulary, performance improvements, documentation, training, and financial and economic aspects.

Why an organization should implement ISO 9001:2000

Without satisfied customers, an organization is in peril! To keep customers satisfied, the organization needs to meet their requirements. The ISO 9001:2000 standard provides a tried and tested framework for taking a systematic approach to managing the organization's processes so that they consistently turn out product that satisfies customers' expectations.
How the ISO 9001:2000 model works

The requirements for a quality system have been standardized - but many organizations like to think of themselves as unique. So how does ISO 9001:2000 allow for the diversity of say, on the one hand, a "Mr. and Mrs." enterprise, and on the other, to a multinational manufacturing company with service components, or a public utility, or a government administration?

The answer is that ISO 9001:2000 lays down what requirements your quality system must meet, but does not dictate how they should be met in any particular organization.

Checking that it works

1. The standard requires the organization itself to audit its ISO 9001:2000-based quality system to verify that it is managing its processes effectively - or, to put it another way, to check that it is fully in control of its activities.
2. In addition, the organization may invite its clients to audit the quality system in order to give them confidence that the organization is capable of delivering products or services that will meet their requirements.
3. Lastly, the organization may engage the services of an independent quality system certification body to obtain an ISO 9001:2000 certificate of conformity. This last option has proved extremely popular in the market-place because of the perceived credibility of an independent assessment.

The organization may thus avoid multiple audits by its clients, or reduce the frequency or duration of client audits. The certificate can also serve as a business reference between the organization and potential clients, especially when supplier and client are new to each other, or far removed geographically, as in an export context.
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