What does it mean in the supply chain?
As someone who is involved in the selection of suppliers and, possibly, responsible for purchasing decisions, you may have seen or used goods and services that are promoted using reference to ISO ISO 9001:2008, or, more simply, “ISO 9000”.

What does this mean?
How can this help you?

How can you be sure that your suppliers understand what you expect from them, and are capable of providing you with a consistent, conforming product?

This informative text provides some answers to these questions and will inform you about how you can get the most out of using ISO 9001 as a supply chain tool.
ISO 9001 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 Organization for Standardization (ISO) often referred to collectively as the “ISO 9000 series” or “ISO 9000 family”.

For this reason, you may sometimes hear your 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, 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 text.
• Meet your needs and expectations
• Comply with applicable regulations

The requirements cover a wide range of topics, including your supplier’s top management 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 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.
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 should not, however, be considered as a substitute for a declaration or statement of product conformity.

ISO 9001 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 refers to “products”, this also includes intangible products like services, or software.
You have an important role to play by specifying to your supplier what you actually want. You may need to consult with your own internal technical staff (the actual users) in this process. 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 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 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!).
There are various ways in which your supplier can claim that its QMS meets the requirements of ISO 9001. These include:

- **‘Supplier’s declaration of conformity’**: A declaration by your supplier itself affirming that its QMS meets ISO 9001 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 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 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.

- 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 International Accreditation Forum (IAF) to promote worldwide mutual recognition in support of World Trade Organization (WTO) free trade principles.
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 “second-party audits”.

You are the one who is buying the goods or the services from the 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.

Figure 1 explains this in simple schematic terms:
Some ways of demonstrating conformity to ISO 9001
No. The reference to ISO 9001 indicates that the supplier has a **quality management system** that meets the requirements of ISO 9001:2008. As mentioned earlier, this should provide you with confidence in your supplier’s **ability** to provide consistent, conforming goods or services. ISO 9001 requires your supplier to monitor the levels of satisfaction of its customers (this includes you!), and to feed back this information in order to improve the effectiveness of its QMS.

**Can suppliers claim that their goods or services meet ISO 9001?**

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 nonconforming products, do not address your complaints, or are not taking appropriate corrective action). 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 via the steps described below.

1. If your supplier has a QMS that meets ISO 9001 requirements, they are required to have nominated a person – the **management representative** – with the responsibility and authority to ensure the system is working properly. You should find out who this is, and make a formal complaint.

2. 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.

3. 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 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 (www.iaf.nu).
4. 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 (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.

ISO 9001 is a useful basis for organizations to be able to demonstrate that they are managing their business so as to achieve consistent (good !) quality goods and services. 

There are several ways in which your suppliers can claim conformity to ISO 9001, and you need to ensure that the method chosen by your supplier provides you with the necessary degree of confidence.

If you are not satisfied with the performance of your supplier, you must provide them with the appropriate feedback. Learning from complaints helps organizations to improve their future performance – that is what ISO 9001 is about. 

In addition to the abundant information on the ISO 9000 family on the Management standards section of the ISO Website, your national standards body is a further source of assistance.
This above guidance was originally developed by the ISO 9000 Advisory Group, comprising representatives of ISO/TC 176 (the committee responsible for developing and maintaining the ISO 9000 family of standards), the ISO Committee on conformity assessment (ISO/CASCO), the ISO Committee on consumer policy (ISO/COPOLCO) and the International Accreditation Forum (IAF). It has since been updated to take into consideration the publication of ISO 9001:2008 in November 2008.
ISO IN BRIEF

ISO is the International Organization for Standardization. ISO has a membership of 164* national standards bodies from countries large and small, industrialized, developing and in transition, in all regions of the world. ISO’s portfolio of over 19 100* standards provides business, government and society with practical tools for all three dimensions of sustainable development: economic, environmental and social.

ISO standards make a positive contribution to the world we live in. They facilitate trade, spread knowledge, disseminate innovative advances in technology, and share good management and conformity assessment practices.

ISO standards provide solutions and achieve benefits for almost all sectors of activity, including agriculture, construction, mechanical engineering, manufacturing, distribution, transport, healthcare, information and communication technologies, the environment, energy, safety and security, quality management, and services.

ISO only develops standards for which there is a clear market requirement. The work is carried out by experts in the subject drawn directly from the relevant industrial, business and technological sectors that have identified the need for the standard, and which subsequently put the standard to use. These experts may be joined by others with relevant knowledge, such as representatives of government agencies, testing laboratories, consumer associations and academia, and by international governmental and nongovernmental organizations.

An ISO International Standard represents a global consensus on the state of the art in the subject of that standard.

*in May 2012
• ISO’s Website
  www.iso.org
  (in English and French, with top levels in Russian and individual publications in other languages)

• ISO Focus+ magazine
  www.iso.org/iso/iso-focus-plus
  (10 editions annually in English and French)

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