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An Introduction to ISO

Volume XVIII

Introduction to ISO

History:

Quite simply, ISO 9000 is a series of standards which a company can use as a guideline for setting up a quality management system. The critical word in this definition is *system*. The ISO 9000 series has nothing to do with product quality. It is solely concerned with offering a generic guideline for setting up an effective quality management system, ensuring a company has such a system in place, and that it is understood and adhered to by everyone in the company.

The Standards were first published in 1987, by the International Organization for Standardization (ISO), headquartered in Geneva, Switzerland. The ISO has over 90 member countries, who share the goal of developing and promoting common standards worldwide. The American National Standards Institute (ANSI) represents the United States. To a certain extent, the British Standard BS 5750 served as a basis for the ISO 9000 series. In reality, the concept of establishing quality standards goes back even further, originating in the US. Based on product quality experiences during World War II, the US developed military specifications, which were later published in Europe as the NATO AQAP series. Further modifications to these standards gave rise to BS 5750, from which the ISO 9000 series is derived. The ANSI Q90 through Q94 standards are the technical equivalent of the ISO 9000 standards.

The ISO 9000 series is actually made up of five separate but interrelated documents which are identified as ANSI/ASQC Standard Q90-94-1987 in the United States. ISO 9000 (ANSI Q90) is a guideline for the selection and use of the actual standards, ISO 9001, 9002 and 9003. ISO 9000 includes definitions for the five key terms used within the series: Quality Policy, Quality Management, Quality System, Quality Control and Quality Assurance.

ISO 9000 Series:

Since its introduction it has had a growing impact on international trade and is considered the common language of quality. The standards are purposely written to be very generic in scope. They can be applied to all sizes of organizations in different sectors of the economy such as manufacturing and service industries. The standards have been adopted in the United States as the ANSI/ASQC Q90 series.

> The driving force behind the ISO 9000 series in recent years has been the Single European Act. This European Union (EC) needed a system to harmonize the individual member's standards. ISO provided this linkage.

Roles of the ISO 9000 Series:

The purpose of the ISO 9000 series is to increase the confidence of customers in the quality systems of their suppliers. This is particularly important when there are great distances between parties, different languages and different terms. It provides for a common framework, a reference point from which to work. It provides generic requirements against which a customer can evaluate the adequacy of a supplier's quality system.

It does not propose that one product is superior to another but rather more consistent and reliable. ISO 9000 insures that the product is the same from lot to lot within the supplier's specifications. Out of specification production (Non-Conforming) is not released for use, and systems are in place to correct any abnormalities. Simply stated it is:

ASame as it ever was - Same as it ever was@

What is Quality and a Quality System?

Quality means many things to many people. It is a highly subjective term. A high quality product is not necessarily the best for a job. It is the ability to satisfy stated or implied needs, in general terms it is a AFitness to Use.@ A quality system is AAll the planned and systematic activities implemented within the quality system and demonstrated as needed to provide adequate confidence that an entity will fulfill requirements for quality@[ISO8402.] The purpose as Ian Durand simply states A is to say what you do, do what you say, record what you did, check the results, and act on the differences.@

Why are there Five ISO 9000 Standards?

In the 9000 series there are two types of standards, one type are Guidance Standards, ISO 9000 and 9004. They are descriptive documents intended to help select the appropriate ISO Standard for an organization and to assist management in determining if the intended quality has been achieved.

The second type is Conformance Standards, ISO 9001, 9002, and 9003. These are designed for external quality assurance. Organizations can only be certified for a Conformance Standard.

What is the difference between the Conformance Standards?

The three Conformance Standards are not levels of quality but vary in how comprehensive the standard is.

ISO 9003 Model for Quality Assurance in Final Inspection

Supplier demonstrates the capability to inspect and test a product using proper sampling plans, monitoring and testing equipment.

ISO 9002 Model for Quality Assurance in Production, Installation and Servicing

ISO 9003 capability plus demonstrate that the manufacturing processes are capable of maintaining requirements as per design specifications, i.e., process capability studies.

ISO 9001 Model for Quality Assurance in Design/Development, Production, Installation and Servicing

ISO 9002 capability plus control of the design/development of new products. This is the most comprehensive standard and is designed to ensure product conformance throughout its entire life cycle.

The Conformance Standards are broken down into 20 elements, each of which has several subsections that define the scope and requirements for the element. The basic elements of the Conformance Standards and which elements applied to that standard are listed in Table 1.

ISO 9000 Series
Table 1

		9001	9002	9003
1	Management Responsibility	4.1	4.1a	4.1b
2	Quality System Principles	4.2	4.2	4.2a
3	Contract Review	4.3	4.3	---
4	Design Control	4.4	---	---
5	Document Control	4.5	4.4	4.3a
6	Purchasing	4.6	4.5	----
7	Purchaser Supplier Product	4.7	4.6	----
8	Product Identification and Traceability	4.8	4.7	4.4a
9	Control of Production	4.9	4.8	----
10	Inspection and Testing	4.10	4.9	4.5a
11	Inspection, Measuring and Test Equip.	4.11	4.10	4.6a
12	Inspection and Test Status	4.12	4.11	4.7a
13	Control of Nonconforming Product	4.13	4.12	4.8a
14	Corrective Action	4.14	4.13	----
15	Handling, Storage, Packaging and Delivery	4.15	4.14	4.9a
16	Quality Records	4.16	4.15	4.10a
17	Internal Audits	4.17	4.16a	4.1b
18	Training	4.18	4.17a	4.1b
19	After-Sales Servicing	4.19	-----	----
20	Statistical Techniques	4.20	4.18	4.12a

ISO Wit and Wisdom

1) **ASay What You Do - Do What You Say@** — When writing procedures, put down what you actually do, not what sounds good. Once on paper, you have to do it.

2) **How long does the Certification Process Take?** — From 2 years to Forever, it all depends on commitment or being committed, whichever comes first.

3) **Once Certified, I can forget this ISO ____!!** — Wrong, Wrong, Wrong, You will be reaudited periodically to insure that you stay in compliance.

4) **K I S S** — AKeep It Simple Stupid@, don't make a paper dragon, it will grow enough on its own.

5) **AI'm spending way too much time on this@** — Plan on everyone spending a minimum of 10% of their time working towards certification. It will slow down after everything is in place, but it never goes away.

6) **ISO is the Same as TQM** — Not; ISO is a system to insure consistency. TQM is a process of continuous improvement.

7) **If something is not important, don't make it important** — If the temperature and humidity of the testing lab are not critical, don't make it an issue in a SOP. But if the temperature of the Brookfield viscosity test chamber is required to be 25°C, then you better check it and the thermometer you used.

Where Do You Begin?

If a company is interested in using the ISO 9000 standards, one of the first questions to be answered is: AWhat activities are a necessary part of my business?@ ISO 9000 (ANSI/ASQC Q90-1987) provides a chart identifying quality system activities and which part of the ISO 9000 series applies. Most companies focus their certification efforts on achieving ISO 9001 or 9002 status.

Next, make sure the management understands the time and commitment involved in pursuing certification. The actual man-hours and time involved varies with the number of people involved, the size of the organization, the extent to which a quality system is already in place and the amount of consistent, day-to-day effort put forth by all individuals in the organization.

The Standard requires that the quality system be defined and documented, as required. No individual should be required to write all the documentation. Get everyone involved.

Once the written documentation has been completed (i.e. Quality Manual, Procedures, Work Instructions, Forms), the company should contact a third-party registrar to review the adequacy of the documentation, and the degree to which the quality system has been implemented and is effective. Most registrars will be able to point out additional items that require correction.

Once the deficiencies have been corrected, a preassessment is done by the third-party registrar. Final correction activities should be completed prior to the final assessment. (It has been noted that 70 percent of all companies who do not use preassessment activities, fail the assessment the first time.)

The final assessment will be the audit done by the third-party registrar (Certification Assessment Body) that will result in a recommendation to certify the company or to re-assess it, after any additional deficiencies have been resolved.

Provided the final assessment activities are completed to the satisfaction of the assessment body, the company will be recommended for Acertification@ to the applicable ISO 9000 standard.

The expense of this process varies by company and will certainly be a consideration in pursuing ISO 9000.

ISO 9000 Misconceptions

The ISO 9000 standards tell a company how to set-up and run its business.

The standards are generic guidelines as to what might be included in a quality management system. It does not dictate how any business should be run. One of the criticisms of the standard is that it does not tell a company how to write its documentation.

If I buy products/services from a supplier Acertified@ to one of the ISO 9000 standards, this means my company is getting a product or service of the highest quality.

If a supplier is Acertified@ to an ISO 9000 standard, it means that the supplier has a quality management system in place and in use. But, a supplier must also have an intense commitment to quality, by all employees, in order to actually provide high quality products and services. This does not mean that the product is of the highest quality, just that it will be consistently produced in a documented manner. Also the product may not be specific to your application, which could create some differences in how you perceive the product.

The main reason for pursuing ISO 9000 certification is because my customers want my company to be certified.

While it is true that many companies pursue certification at a customer's (purchaser's) request, this is not the best reason. The main reason to pursue any quality system activity is to demonstrate that your company's management has given thought and support to defining and implementing a quality system.

Once my company becomes@certified,@ no further activity is necessary.

This isn't a one-time deal. Once your company has been Acertified,@ an independent assessor (third-party registrar) will be required to review the quality system every six months. A complete reaudit of the company must be done, every three years, by an independent assessor. Both of these activities are at the company's expense. Additionally, the ISO 9000 Standards are scheduled for re-evaluation/revision every five years. ACertified@ companies must be in compliance with all revisions.

To save time, my company will hire an outside consultant to write all the necessary application documentation for certification.

The best way to pursue certification is to get everyone involved. It is not recommended that a company have individuals, outside the organization, write the documentation (i.e., Quality Manuals, Procedures Manuals, Instruction Manuals). While a consultant can certainly help with the Aformat@ of the documents, the documentation should be written by the company employees doing that work.

Benefits of ISO 9000

Pursuing ISO 9000 certification requires the total focus and support of an organization. Although this entails a concerted and continuous effort from all levels of the company, the rewards can be numerous. Companies who have become certified cite the following benefits:

1. **Helps focus the organization on quality.**

2. **Has been used to improve a situation, prior to being documented.**

3. **Organizations that can claim certification to ISO 9000 have seen a decrease in the number of audits done on their facility by the customer (purchaser).**

4. **Ensures that everyone in the organization understands the quality system and his/her responsibilities.**

5. **Increases the marketability of products/services, including new markets that request/require certification.**

6. **Can be a competitive edge for a company.**

7. **Being listed with registered suppliers in a registry used by your customers industry.**

8. **Can decrease overall operating costs.**