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ISO 9000

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Introduction

ISO is sometimes referred to as International Organization for Standardization. The organization’s objective is to promote development of standardization to facilitate international exchange of goods and services. In addition, ISO also tries to promote cooperation in intellectual, scientific, technological, and economic activity (Kantner 9). In 1988, ISO published ISO 9000.

ISO 9000 is rapidly becoming the most popular quality standard in the world (www.connect.ab.ca/~praxiom/). It is a written set of rules (“Standards”) published by an international standards writing body. The rules define practices that are universally recognized and accepted for assuring that organizations consistently understand and meet the needs of their customers. (Kantner 1) The standards were developed to help companies effectively document the quality system elements required to maintain an efficient quality system. ISO 9000 standards set the platform for global competition. A company can’t just go out and buy ISO 9000 since it is not a product. It is a quality improvement process that must be cultivated in-house. (Badiru 17) A key strategy is that, ISO 9000 is applied to all types of firms, including manufacturing firms, law offices, colleges, trading firms, and hospitals (Kantner 4). ISO 9000 certification certifies that an organization is doing what it says it is doing with respect to operating procedures. (Badiru 17)

Benefits of ISO 9000

ISO 9000 brings advantages to implemented companies. First of all, it optimizes company structure and operational integration. Besides, ISO 9000 improves customer focus and process orientation within the organization because it allows the companies to understand their responsibilities and also improves awareness in meeting their customers’ needs.

These programs also facilitate continuous improvement by tracing the ‘root causes’ of quality problems. This improvement provides confidence to customers in the capability of your organization to meet quality commitment. ISO 9000 improves management decision making. Since a quality system is an information system, internal audits, management reviews, analysis of organization-level data, an effective document and data control provide management with the intelligent it needs to make the right decisions. Furthermore, ISO 9000 system reduces dependence upon individuals by assuring techniques and skills will carry on even when performed by different individuals. (Kantner 7)

ISO 9000 formalizes systems to ensure consistency of the quality and punctual delivery. It improves communications and quality of information in a sense of strengthening relationship between your organization and its suppliers and customers. On the other side, it tends to assure fewer rejects, and therefore less repeated work and warranty cost are needed. This also helps to
improve utilization of time and materials. Lastly, documented system provides useful reference and training tool to organizations. (http://www.commerce-associates.com/iso/iso_adv.html)

**The ISO 9000 Registration**

Registration to ISO 9000 generally involves having an accredited independent third party conduct an on-site audit of your company's operations against the requirements of the appropriate standard. Upon successful completion of this audit, your company will receive a registration certificate that identifies your quality system as being in compliance with ISO 9001, 9002, or 9003. Your company will also be listed in a register maintained by the accredited third-party registration organization. You may publicize your registration and use the third-party registrar's certification mark and the accreditation body's mark on your advertising, letterheads, and other publicity materials (but not on your products). (http://www.asq.org/standcert/iso.html)

According to Rob Kantner, there are 7 steps to get the ISO 9000 registration/certification, as follows:

1. **Implement ISO 9000**
   
The key thing here is, your system must be fully implemented and up and running for a minimum of three, and preferably six, months prior to the registration audit. This is the amount of time it takes to build up the amount of evidence, records, and so on that assessors expect to see.

   “Implementation” means that all required elements of ISO 9000 are in operation, at least one complete cycle of internal audits has been completed and one “management review” has been completed. Furthermore we have to ensure that a “corrective and preventive action activity” is ongoing.

   “Internal audits” is a process to make sure the quality management system (QMS) meets the requirement of the Standard and is working effectively. Audits must be done by people who are independent of the work they are auditing. It is highly recommended that you select your audit team from a cross-section of the levels and functions of the organization. You must record results of internal audits, and report them to management.

   “Management review” helps keep top management (in particular) focused on the QMS. Organizations that pursue the process with vigor usually find it to be not just a worthwhile process, but an essential one as well.

   “Corrective action” prevents recurrence of nonconformities by identifying and eliminating their root causes. Analyzing corrective action by tallying causes and looking for commonalities is a highly effective and beneficial activity that organizations lacking a disciplined corrective action system miss out on. “Preventive action process” heads off a
potential nonconformity by identifying its cause(s) and implementing solutions before the nonconformity actually occurs.

2. **Select your registration body**

   Begin this process while implementation is carried on. You want to have your registrar selected, on board, and scheduled no later than three months prior to your target registration date. Most registrars offer general training in ISO 9000. Your registrar will also answer questions about interpreting the Standard. The registrar can answer questions about how to structure your system; however, registrar will not tell you how to implement your system nor how to develop systems that will meet the requirements.

3. **Obtain a pre-assessment (Readiness Review)**

   This step is optional because it is costly. However, it is highly recommended since it is a sort of “practice audit” although its result does not count. It gives your people a taste for what an ISO 9000 audit is like by giving you feedback on how your system is doing. Always has it assess the parts of your system about which you are the least confident. Since this is a good practice for you, do remember to cover the management review, internal audit, and lastly the corrective and preventive action.

4. **Undergo the desktop study of your quality system**

   This may happen prior to pre-assessment. It depends on your registrar’s policies. Some policies only want your Quality Manual (it describes the QMS and cross-references to procedures and other QMS documents). Some policies want to see your standard operating procedure (describing and controlling the processes required to assure that product/service meets customer needs). And some will review them as the first part of the On-Site Assessment (see step 5).

   Almost every registrar does a “desktop study” of your quality system. This means that they view at least your Quality Manual. They compare it with the ISO 9000:2000, and make sure that your Quality Manual complies with it. If you have done a thorough and conscientious job of developing your quality system, the desktop study should not be a problem to you.

5. **Undergo the on-site audit**

   The registrar’s audit team shows up on the appointed day, checklists in hand. Now they want to see if you are actually doing what the manual and related documents say you are doing. The audit team usually consists of two or more people, depending on the size of the facility and the scope of the process. Lead auditor handles relations between the audit team and the auditee personnel. This person plans the audit, supervises the auditors, and takes the lead on interpreting the Standard and audit results. The auditors follow a predetermined planned and checklist, audit your system. At this phase assessors do a thorough, fair, and objective job of
assessing your system to evaluate its compliance with ISO 9000 requirements. At the end they give you a verbal report of their findings.

6. **Correct and close out noncompliance**

All major noncompliances reported during registration audit must be closed out before registration can be issued. You are not allowed to claim that you got registered until all majors are corrected, closed out, and confirmed by the registration body. Sometimes, the registrar will require on-site verification that the noncompliance may be fixed. Other noncompliances may be closed out via the submission, review, and approval of revised documents or procedures. The registrar will report them to you and agree to review your corrective action at the first surveillance assessment. In the meantime, you are considered registered.

7. **Registration and the certificate**

Registration is conferred when the registrar issues its certificate of registration to you. This includes the scope of registration, which spells out exactly what processes and locations are covered by the registration. Now, you are registered, but this is not the end. You need to keep ISO 9000 registration. You must deal effectively with the outcomes of the surveillance assessments, and pay your registrar’s invoices.

At prescribed intervals, often every 6 months or so, the registrar re-assesses a part of your ISO 9000 system. You can arrange this in advance because you always know when they are coming. You must resolve any noncompliances that arise from surveillance assessments in an agreed amount of time, and they must be closed out by the registrar. Otherwise you put your registration in jeopardy.

(Kantner)

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**References**


http://www.asq.org/standcert/iso.html


http://www.connect.ab.ca/~praxiom/

http://www.easyiso.org