

PART ONE

ISO 9000 Overview

I. What is ISO 9000?

CAPSULE ANSWER

ISO 9000 is a set of universally understood and accepted quality/business practices which, when well implemented, give customers confidence that suppliers can consistently meet their needs.

ISO 9000 is a written set of rules (a “Standard”) published by an international standards writing body (International Organization for Standardization—see Question 5). The rules define practices that are universally recognized and accepted for assuring that organizations consistently understand and meet the needs of their customers.

ISO 9000 is also highly generic. Its principles can be applied to any organization providing any product or service anywhere in the world.

Since meeting customer needs is one of the (many) definitions of quality, ISO 9000 is often called a quality system or a quality management system. But the rules, referred to as *requirements*, go beyond quality matters as they are traditionally understood. The requirements fall roughly into the following types:

- Requirements that help assure that the organization’s output (whether product, service, or both) meets customer specifications. (Making, and keeping, them happy.)

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- Requirements that assure that the quality system is consistently implemented and verifiable. (We must actually do what we say we are supposed to do. This must be verifiable via independent, objective audit.)
- Requirements for practices that measure the effectiveness of various aspects of the system. (In God we trust; all others bring data.)
- Requirements that support continuous improvement of the company's ability to meet customer needs. (We cannot sit still. We must strive to get better all the time, because customers change, and competitors gain strength.)

Nothing in ISO 9000 is new. The first edition, published by ISO in 1987, was drawn almost word for word from a British quality system standard. It in turn evolved from a long succession of written quality system specifications that had their ultimate origin in the defense and arms industries. Most of the practices required by ISO 9000 have been in use in industries of various kinds for decades. One intent of ISO 9000 is to simplify things for organizations. ISO 9000 strives to harmonize the sometimes conflicting, sometimes redundant quality programs that have traditionally been imposed by major corporations on their suppliers. (Note, however, that ISO 9000 is *not* meant to supersede customer, legal, or regulatory requirements.)

PITFALL

Organizations that implement ISO 9000 because they feel coerced—and therefore do a minimal and superficial job of it—end up with a system that adds only cost, not value.

Very often, major customers require or strongly “suggest” that their suppliers implement ISO 9000 systems. Equally often, such customers require independent verification that suppliers are meeting the requirements. So third-party registration bodies (Question 7) audit suppliers, confirm compliance to the ISO 9000 standard, and register the suppliers. It does not stop there. To stay registered, suppliers must undergo periodic (often semi-annual) surveillance audits, also carried out by their registration body.

Implementing an ISO 9000 quality system is neither cheap, nor easy. How costly and difficult it can be depends on:

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- The level of commitment of senior management. (The single most important factor.)
- Where you are when you start. If you have already implemented a disciplined, documented quality system, you will have a less difficult time migrating to ISO 9000. (But that does not mean you will waltz to registration, either.)
- Whether your company (or any part of it) is “design responsible” or not (Question 13).
- How much time you have. If you are under the customer’s gun and have merely months to get the job done, the process will be highly stressful.
- The physical size and configuration of your company.

The bottom line is this. ISO 9000 is a comprehensive set of rules—a business system, really—that can cause the way your organization runs to profoundly change, almost always for the better. Yet, because it is often customer-mandated, many suppliers regard ISO 9000 as “just another hoop to jump through to keep our customers happy.” They see their choice as swallow hard, pony up, and jump through the hoops; or walk away from the customer.

What many do not fully appreciate is that implementing ISO 9000—expensive, exhausting, and annoying as it can be—can also have the salutary effect of improving the performance of your organization. Not just at first, but on an ongoing basis.

2. What is the goal and scope of an ISO 9000 quality system?

CAPSULE ANSWER

The goal of the Standard is customer satisfaction. Its scope is universal.

The Standard states its goal in two blunt words: *customer satisfaction*. How do we achieve customer satisfaction? By meeting customer requirements. The quality management system (QMS) helps us to do this by:

- *Applying the system*. Actually using it. Putting it at the heart of our organization.
- *Continually improving the system*. The QMS is never done. After all, customer requirements do not stand still—they evolve and

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grow tougher. So we have to *improve* continually in order to survive. (The guidance document, ISO 9004: 2000, sets a compatible and in some respects more ambitious goal: “improving the processes of an organization to enhance performance.”)

- *Prevention of nonconformity.* Prevention is the key term here: prevention, rather than detection. Quality management has long since evolved away from the old “inspect quality in” approach. *Prevention* is cheaper, more effective, and more protective of the customer. Detection is also a different mindset. It requires a very high degree of process orientation, upstream thinking, and relentless analysis.

OPPORTUNITY

Many think of ISO 9000 as applying only to manufacturing firms. But ISO 9000 has been implemented in law offices, colleges, trading firms, and hospitals.

To what types of organizations does the Standard apply? All types. The requirements “are generic and applicable to all organizations, regardless of type and size.” A compliant QMS can be implemented by any organization, producing any product or service, anywhere in the world.

Within the organization, the impact of the requirements and the QMS are similarly broad. The Standard “applies to the activities of organizations from the identification of customer requirements, through all quality management system processes, to the achievement of customer satisfaction.” Every activity within the organization that impacts the process of creating customer satisfaction is affected by the requirements of the Standard.

3. Why do organizations implement ISO 9000 systems?**CAPSULE ANSWER**

Many implement because of customer pressure. Others implement to improve their operations.

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More often than not, organizations get ISO 9000 because certain customers force them or encourage them to.

In many market sectors—electronics, pulp and paper, telecommunications, automobile manufacturing, defense—major customers have mandated ISO 9000 registration to their key suppliers. Similarly, some overseas regulatory bodies mandate ISO 9000 for the makers of quality-sensitive products (such as medical devices).

Many of these major customers impose ISO 9000 systems *in place of, or in addition to*, specific quality programs, requirements, specifications, and so on that have been in place for many years. The ISO 9000 Standard becomes a key part of the relationship between the customer and its suppliers.

ISO 9000 is not, however, meant to replace customer-specific requirements in any market segment. Rather, ISO 9000 is meant to be a *floor*: a basic set of generic requirements. They are generic enough to apply to virtually all supplier/customer relationships anywhere in the world. It matters not the size of the supplier, the location of the customer, or the nationalities involved.

In some industrial segments, formalized standards have been created, adding to the generic ISO 9000 requirements additional clauses that are industry specific. Examples include:

- Automotive (QS-9000).
- Aerospace (AS-9000).
- Telecommunications (TL-9000).

To the extent that ISO 9000 replaces customer-specific quality programs and supporting audit/oversight activities, it can relieve both customers and suppliers of a great deal of redundancy, duplication, and waste of resources. The fundamental requirements are understood, agreed to, and (usually) confirmed by objective third-party audit. This gives customers confidence in the integrity and effectiveness of their supplier's basic quality practices. The customer and supplier can then

OPPORTUNITY

If your organization works to a documented quality system of any kind, this can be an ideal springboard for implementing ISO 9000. There is no need to reinvent the wheel.

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invest their energies and resources in agreeing to and working on the specific requirements unique to their relationship.

To some, ISO 9000 sounds like a mandatory, gun-to-your-head, my-way-or-the-highway program. For many suppliers, it is exactly that (“get ISO 9000 or get lost”). For many others, it is perceived that way: “They’re trying to tell us how to run our businesses.”

But the goal of ISO 9000 is not to strengthen customers’ control over how their suppliers run their businesses. The goal is to give customers confidence in the ability of suppliers to meet their needs, resulting in satisfied customers, and growing and prosperous suppliers.

Admittedly, implementing ISO 9000 does not guarantee this. Like most things, what you get out of it depends on what you put into it. You can implement a compliant ISO 9000 system that is all cost and no benefit and it’s even possible to pass registration audit (Question 95) this way. This happens, usually, when the supplier’s approach is to try to:

- Squeak by.
- Do just enough to get registered.
- Get this thing done without changing how we work.

But suppliers who implement ISO 9000 fully—to the spirit, as well as the letter—can and do achieve real benefits.

4. What are the advantages or benefits of implementing an ISO 9000 quality system?

CAPSULE ANSWER

An ISO 9000 system unites the organization in a well-defined, continually improving process that meets customer needs.

If you get into ISO 9000 just to pacify customers (Question 3)—and do not pursue it for the other benefits it provides—you are setting yourself up to be in the worst possible position: ISO 9000 as a cost, rather than as a benefit.

What can a well-implemented ISO 9000 system do for you?

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- *Improves customer focus and process orientation within the organization.* A well-implemented, well-understood system helps all functions within the process to understand their responsibility for meeting customer needs, and appreciate their position in the overall process for doing so.
- *Facilitates continuous improvement.* The requirements are saturated with admonitions to monitor, review, and improve the subprocesses of the quality system. There is even a direct requirement that the quality management system be continually improved (Question 17). The corrective and preventive action activities required by the Standard enlist all levels and functions in the effort to prevent quality problems and quickly mitigate those that do occur.
- *Creates consistency throughout the organization.* It establishes and enforces consistent working methods and quality controls throughout the organization. This can be especially important in larger, multisite organizations whose facilities are major suppliers to each other.
- *Strengthens relationships* between your organization and its suppliers and customers, and among suppliers/customers within your organization. A documented quality system, especially in light of ISO 9000's process orientation, is common ground for addressing quality issues of mutual importance.
- *Provides confidence* to customers in the capability of your organization to meet quality commitments. This benefit is much stronger when the quality system is registered.
- *Improves management decision making.* A quality system is an information system. Internal audits, management reviews, analysis of organization-level data, and effective document and data control—four strong pillars of ISO 9000—provide management with the intelligence it needs to make the right moves.
- *Institutionalizes training* in methods and procedures essential to quality.
- *Reduces dependence upon individuals.* People are vital to quality, but people also come and go. The levels of procedural development, documentation, record-keeping, and training required by an ISO 9000 quality system assure that techniques and skills will carry on even when performed by different individuals.
- *Adds value.* Some 250,000 registrations in, the evidence is clear. Facilities with advanced quality cost tracking controls almost always find that their documented quality system adds value. A

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major home appliance manufacturer saw its failure rate (defined as claims per year divided by sales per year) drop by 70 percent in three years. Its warranty cost per unit declined by 76 percent during the same period.

OPPORTUNITY

ISO 9000 works. Not overnight, and not without pain. It's no panacea, but it works.

Dupont, a pioneer in quality improvement and in ISO 9000 implementation, measured improvements under ISO 9000 in several different categories, including:

- On-time delivery increased from 70 percent to 90 percent.
- Cycle time improved from 15 days to one-half a day.
- First pass yield improved from 72 percent to 92 percent on a product line.
- One site reduced the number of test procedures from more than 3,000 to 2,000.

Lloyd's Register Quality Assurance, the British quality assurance registrar, published a survey of some 400 of its ISO registrants in the United Kingdom. The population was a proportional sample of market sectors and organization sizes. Some of the findings:

- 67 percent felt that the ISO 9000 approach was essential for creating and maintaining viable quality management systems.
- Most originally sought ISO for external benefits, but discovered that internal benefits were more beneficial.
- 86 percent stated that their ISO 9000 systems improved management control.
- 73 percent felt that ISO 9000 quality systems enabled them to deliver better service to customers and ensured consistency.
- 69 percent reported that ISO 9000 improved productivity and efficiency.
- 89 percent agreed that the internal benefits of ISO 9000 "met or exceeded expectations."

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In a 1998 survey, a consulting firm found that “improving quality management and product quality” was cited most often as the main benefit of implementing ISO 9000. Other benefits cited included improvement in consistency, reduction in variability, and expansion of customer base.

5. What is the ISO?

CAPSULE ANSWER

ISO is an international standards development body, including among its membership national Standards bodies from 127 of the world’s leading industrial nations.

ISO is not an acronym. It is a nickname for the International Organization for Standardization. The word “isos” is the Greek root for the word “equal” (isometric, isosceles, etc.). Which fits the organization since ISO (usually pronounced “ice-oh,” not “eye ess oh”) is one of the world’s largest organizations involved in creating and publishing international standards to promote world trade.

Formed in 1947 and based in Geneva, Switzerland, ISO counts some 127 nations as member bodies (actively involved in the nearly 3,000 technical committees and other activities of the organization), correspondent members, and subscriber members.

ISO’s stated objectives are:

- To promote development of standardization to facilitate international exchange of goods and services.
- To promote cooperation in intellectual, scientific, technological, and economic activity.

The chief product of ISO is a body of international agreements that are then published as voluntary international standards. The volume of this work is impressive—the ISO catalog lists some 12,000 Standards. They address nearly every field of commercial activity except electrical and electronic engineering, which are dealt with by a separate body, the International Electrotechnical Commission (IEC). Together, ISO and IEC comprise the largest nongovernmental system for voluntary industrial and technical collaboration.

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Most of ISO's member groups are national standards bodies incorporated by the public laws of their respective countries. The rest—including the U.S. representative, ANSI (American National Standards Institute)—are nongovernmental organizations. Member groups are organized into several thousand technical committees, each responsible for a particular field of standards. For example, there are technical committees on welding (TC/44), essential oils (TC/54), small craft (TC/188), and sieves (TC/24). The technical committee responsible for ISO 9000 is TC/176.

The creation of an international standard begins with discussions among the members of the technical committee. These discussions result in the creation of a committee draft, which is circulated among committee members for analysis and comment. When the committee reaches consensus on the draft, it is published by ISO as a draft international standard and is submitted to all ISO member bodies for voting. Publication as an international standard requires the approval of at least 75 percent of member bodies casting votes.

ISO generally supports the development of more industry specific standards such as QS-9000. ISO 9000 has always been intended to serve as a basic quality system standard, upon which individual industries and suppliers/customers can add their own, more specific requirements.

ISO's role is limited to the development, publication, and revision of Standards. It does not enforce, regulate, or audit. Nor does it publish, or plan to publish, quality standards more specific to particular products or services.

Beyond the requirements documents (ISO 9001: 2000), ISO does provide broad-based interpretive guidance. This includes a series of documents covering:

- Application of the standards (generally).
- Application of the standards to general product/service categories, including services, processed materials, and software.
- Dependability management.
- Quality improvement.
- Quality planning.
- Configuration management.
- Auditing.
- Management of measuring equipment.

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These documents are not part of ISO 9001: 2000, but they can be very helpful in the interpretation and application of the new portions of the requirements.

6. What is ISO 9000 registration or certification all about?

CAPSULE ANSWER

Registration is objective evidence that your organization meets the requirements of ISO 9000.

Registration is documented and objective evidence that an organization's quality system meets the requirements of ISO 9000.

Certification is a term often used interchangeably with registration. In the context of ISO 9000, they mean the same thing. *Registration* is the technically correct term for verification of compliance to standards of *quality systems*. *Certification* usually applies to verification of the quality of *products* (as opposed to quality systems).

Registration is carried out by independent companies called *registrars* (Question 7). These companies are:

- Wholly independent.
- Accredited by a recognized international accreditation body (Question 93).
- Selected, and paid, by you.

Registration can cover:

- The sole location of a single-location organization.
- Multiple locations of a multilocation organization.
- Only certain parts of a multilocation organization (under certain conditions).
- Separate locations under separate certificates. (This is a more costly approach.)

The registration body audits your quality system against the requirements of ISO 9000. It reports its findings in writing. These findings

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may (and usually do) include noncompliances (Question 96). Major noncompliances must be closed out prior to official registration.

When this has been done, the registration body:

- Lists the organization's name in its book of registered companies—in effect, registers the organization in its book.
- Issues a certificate to the registered organization. This registration includes:
 - Identity of the organization.
 - Location(s) covered by the registration.
 - A list of products/services supplied by the registered locations.
 - Revision date of the Standard.
 - Registration effective dates.
 - Name and location of registrar.

Most registrars limit registrations to three years. After that, you must renew your registration by undergoing another complete systems audit. Some registrars do not use the renewal approach. They simply keep checking the system via surveillance audits.

PITFALL

Organizations should not select annual (rather than semi-annual) surveillance unless and until their quality management system is firmly implemented and working well.

Whichever the scheme, the organization, to keep registration, must undergo a surveillance assessment every so often. Six months is the typical interval. Some registrars offer annual surveillance schemes (not recommended except for firms with exceptionally well-implemented quality management systems). Surveillance assessments are scheduled events (there is no such thing as a “surprise” surveillance audit). Only part of the quality system is checked at each surveillance. Usually, the registrar does not disclose what part will be assessed until the day of the assessment, although some registrars will tell you everything up front. The entire quality system is usually checked via surveillance audits over the course of three years.

There is no way to “fail” a surveillance assessment, just as there is no way to “fail” a registration audit (Question 96)—except by refusing

to implement corrective action required by the registrar. Normally, registrars allow adequate time, but corrective actions must be done in a timely and agreed upon manner to keep registration.

One final note: As mentioned, each registrar publishes a list of the firms it has registered to ISO 9000. A comprehensive list of ISO 9000 registered firms is available from Irwin Professional Publishing (703-591-9008).

7. What is a quality systems registrar?

CAPSULE ANSWER

A registrar audits quality systems, registers conforming quality systems to ISO 9000, and oversees continued conformance to the Standard.

A registrar, or registration body (the preferred term), is sometimes called a *certification body*. (Accreditation bodies are entirely different—they are the entities that audit/approve registration bodies.) There are some 573 registration bodies in operation worldwide, including 52 in the United States.

The registrar is the organization that checks your quality system and confirms that it meets ISO 9000 requirements for a prescribed and agreed period of time.

To do this, the registrar:

- Audits your organization's quality system to determine the degree of conformity to ISO 9000 standards. The audit is carried out:
 - On paper (desktop study).
 - On site (throughout your facility).
- Registers your quality system, assuming it conforms, to ISO 9000.
- Monitors conformity on an ongoing basis by means of regular re-audits and other methods.

All quality system registrars perform these functions, with certain variations. Registrars differ in two principal ways:

- Accreditation status.
- Scope of accreditation.

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Reputable ISO 9000 registrars are *accredited* by international accreditation bodies. These enforce a standard, EN 45012 (European Standard for Bodies Certifying Suppliers' Quality Systems), that governs the processes that registrars follow. This standard is quite strict:

- Registrars must make their services available to all qualified suppliers without imposing undue financial or other conditions, and must administer their regulations in a nondiscriminatory manner.
- The registrar's organization must not engage in activities that may affect its impartiality. For example:
 - It must not provide consulting services "on matters to which its certificates are related" (i.e., quality systems). This requirement is superseded by the ISO 9000 restriction noted earlier.
 - It must not directly engage in commerce with firms that it has assessed and/or registered.
 - Individuals involved in the registration process must not have provided consulting services to registration clients, or any related firms, within the previous two years.
 - Its employees and agents must not engage in business activities that would cause others to question the firm's impartiality.
 - The registrar may not market consultancy and registration services together, and may not recommend consulting services to clients.
 - Auditors may not give advice as part of registration audits.
 - The registrar must provide the accreditation body with documentation of its employees' qualifications.
 - The registrar must have appropriate facilities for carrying out its activities.
 - The registrar must have a quality manual and documented procedures. (Curiously, EN 45012 does not require that registrars register to ISO 9000!)
 - Registrars may not grant or renew certificates of registration until all major noncompliances are eliminated.

Another point of differentiation is *scope of accreditation*. All registrars are not accredited, or approved, to register firms in any line of business. Each registrar is accredited to operate within the business or industrial sectors about which it has documented expertise. This is generically referred to as the registrar's *scope*.

For information on the other ways that registrars vary and guidance on how to select the best registrar for your needs, see Question 93.

8. What is the cost of registering to ISO 9000?

CAPSULE ANSWER

The total cost of implementing ISO 9000 depends on factors that vary by organization and situation.

This was the question you turned to first, right? One fairly prominent consultant likes to answer that question this way: “Less than a million.”

Kidding aside, there is only one short, definitive answer that applies to all: It depends. There are two kinds of costs to figure here:

1. The cost of implementing the system.
2. The costs to engage the registration body not only for the registration audit itself, but also for associated activities: pre-assessment, surveillance assessments (Question 94).

IMPLEMENTATION COSTS

It takes time and energy and physical resources to implement an ISO 9000 system and prepare for registration audit. This translates into money. There is no question about it. (Note, however, that it should never increase your overhead to *operate* your ISO 9000 system, once it is implemented and has reached steady state (Question 11).

How much does it cost to implement? There are so many factors to consider, it is impossible to put any kind of meaningful dollar figure here. Head count is a big factor. The more people you have, the more training you have to do. But beyond that, the best we can do is to list the factors that could cause implementation to cost “more” than average or “less”:

- Your implementation will tend to cost more if:
 - You have more than one location.
 - You are design responsible.

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- You have no active quality system now.
- You are undergoing any kind of significant corporate change, such as:
 - Downsizing.
 - Chapter 11 reorganization.
 - Merger/acquisition.
 - Implementing significant new process.
 - Implementing new EDP system.
 - Relocating/reconfiguring.
- Your implementation will tend to cost less if:
 - You already operate a documented quality system (Q1, Targets for Excellence, Pentastar). (But not necessarily.)
 - You dedicate a seasoned, responsible manager to champion the effort. (This person would probably become the Management Representative.) Once registration is achieved, he or she would go back to prior job duties, inasmuch as the ISO 9000 responsibility would, at best, be a 25 percent job.
 - You hire a good consultant to guide you.

OPPORTUNITY

Getting experienced help for implementation (even temporary or contract help, i.e., consultant) costs more in the short term, but saves much in the long term, since you'll avoid repetition, redundancy, and rework of your system.

What?? you ask. Hiring a consultant would save us money? Odds are, yes—if the consultant you hire is in fact a good one (Question 90).

It is fairly easy to estimate the costs of the following activities directly related to the implementation:

- Overview training—30 minutes of time for every employee in the organization.
- Orientation training—perhaps 90 minutes of time for every employee in the organization. (This is a hard one to call.)
- Documentation writing training—Two days of time for perhaps 12 to 15 key operations people from a cross section of the organization.

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- Internal audit training—Two days of time for a number of employees equal to about 10 percent of your head count.
- Internal audit costs (this one is very iffy)—An average of 4 hours per audit for 2 auditors (total of 8 hours per audit), times the number of standard operating procedures in your system (at least 20, could be as many as 26). Remember that at least one complete cycle of internal audits must be completed before registration audit.
- Equipment, supplies, and so on, including a good computer with word processing software and the services of someone who knows how to use it.

PITFALL

While you may need to add resources temporarily during implementation, avoid adding extra headcount to *operate* your quality system. If such seems needed, then your system has not been well designed.

There are other costs that are almost impossible to estimate:

- *Management representative (MR) time.* The typical MR does not work on the project full time. He or she usually has other responsibilities. Many MRs do much of their ISO 9000 work on an overtime basis, especially during implementation.
- *Document review time.* Managers and others need to review standard operating procedures and other documents, make notes, suggest changes, and so on.
- *Corrective/preventive action activities.* This is a hard one to call. If your organization already has such activities in place, then ISO 9000 will not add a lot of time to it. If your organization's activities in this regard are informal and hit-or-miss, the activity will take the time of key people, especially while they are learning how the system works.
- *Document control activities.* This burden usually falls on the MR and/or his or her staff. Once the system is set up and running, it does not seem to take up a lot of time—as long as you keep your document system as lean as possible! (If you let your document system bloat out to dozens and dozens of SOPs, etc., then I have no sympathy for you.)

REGISTRATION COSTS

These can vary also, but at least they are a bit easier to get your arms around. All you have to do is get quotes from a number of reputable registrars (Question 93), analyze, compare, and caveat emptor.

Registrars usually price their services on a sliding scale governed by three factors:

- Design responsibility.
- Number of locations (if a multisite registration).
- Size of facility in terms of number of employees. This translates into the number of audit days required by ISO 9000 and published in a schedule (Question 7).

But then, registration costs can vary all over the place. Registrars have different daily rates. Some have application fees, and some do not. Some have annual administration fees, and some don't. Turning competing registration quotes into "apples and apples" can be an exercise in and of itself.

Here are some documented examples for the total cost of a three-year registration. In both cases, 5 accredited and approved ISO 9000 registrars submitted bids based on the same information:

- A Tier 1 manufacturer with two manufacturing sites, a satellite warehouse, full design responsibility, and about 400 employees: \$41,000 to \$60,000.
- A Tier 2 manufacturer with one site, no design responsibility, and about 100 employees: \$11,500 to \$24,000.

These are real numbers, but you should use them as very rough guides only. Keep in mind, also, that prices are declining. This is because ISO 9000 registration is, in large part, a market driven process, and competition on price is intense. You are free to negotiate price also, and that is strongly recommended.

But you should never let price alone be the determining factor in your selection of a registrar (Question 93).

9. How long does it take to register to ISO 9000?

CAPSULE ANSWER

Registration time depends upon the state of the quality system at inception, as well as other factors. Generally, the registration process can take between 10 and 18 months to complete.

As with the cost of registration (Question 8), the time it takes to get registered varies.* But we are talking months here, not weeks. For one thing, you have to keep running your business. You cannot simply shut down while getting registered.

The entire process can be broken down into the following general phases:

- Implementing the ISO 9000 system.
- Operating it for the minimum time. (A minimum of three, and preferably six, months before registration audit.)
- Selecting a registrar. This can be done during the registration process, to save time.
- Interval between application and registration audit. This depends on the registrar's backlog.

The time it takes to implement the ISO 9000 system depends in large part on where you are when you start. If you already have any of the following, implementation time should be relatively short:

- A documented quality system of any kind that is active, meaningful, but not necessarily compliant with any particular standard.
- Resources temporarily dedicated solely to implementing the system.
- The guidance of a good consultant (with stress on the word *good*) (Question 90).

* This answer assumes that you want a system that is meaningful and adds value. It is possible to develop a "paperwork facade" in three months or so and then brazen and deceive your way through audits and surveillances. No reputable registrar or consultant participates in such fakery, but unfortunately for the integrity of the process, it does happen.

PITFALL

Do not attempt ISO 9000 registration if you are, at the same time, embroiled in such major initiatives as merger/acquisition, implementation of new computer system, and so on.

If you are starting from square one, implementation can take a long time. (Unless you can shut down operations while implementing—but who can do *that*?) Here are some other factors that can extend the time it takes:

- Multiple locations.
- Head count.
- Whether or not you are design responsible.
- Corporate turmoil.
- Lack of ongoing, consistent, persistent top management commitment. This exhibits itself in a host of symptoms, including lack of sufficient resources, other issues taking priority, vacillation, failure to pay attention, failure to learn and understand, and failure to lead.

OPPORTUNITY

This is not a horse race. Take the time to do it right.

All that being said, experience has shown the following:

- On average, the shortest interval for the entire process—from launch through registration audit—seems to be around 6 to 9 months.
- At the other extreme, it's been known to take 18 to 24 to 36 months, even with significant resources and full management commitment.

On average, for the typical organization (whatever that is), you are looking at 10 to 18 months to get the job done.

10. What are the benefits of ISO 9000 registration?**CAPSULE ANSWER**

ISO 9000 registration improves customer confidence, provides access to markets, improves competitive standing, and reduces supplier quality assurance program costs.

The benefits start when you implement (Question 4) and accrue whether you get registered or not. Registration simply leverages those benefits.

By “going for registration,” you are setting a tangible goal for the entire organization to rally around. As implementation moves along, more and more employees get drawn into the effort. By the time of the registration audit, virtually everyone in the organization is aware of what’s going on. (At least, they had better be!) And when the effort of many months pays off by “passing” the registration audit, it is a real morale booster for the entire organization.

But, as has been said, registration is not the checkered flag. It is the green flag. It does not signal a easing of efforts. It triggers greater efforts. And registration does not simply mean that “Great, now our customers will get off our back.” It brings other benefits, too. These can include:

- *Gives customers confidence* that your firm can meet its quality commitments. Customers don’t have to audit you themselves. Nor do they have to take your word for it. They have the judgment of a qualified, objective third-party registrar. And not just once. Their judgment is renewed on an ongoing basis, via surveillance audits (Question 97).
- *Provides access to markets.* Most companies registering to ISO 9000 today are doing so because key customers are pressuring them to do so. But, huge though this market is, it is just one market. There are other markets that put great store in ISO 9000 registration, as well. You would do well not to ignore them.
 - If you make and/or market products covered by EU product directives—or plan to do so in the future—you may be compelled to register your quality system in order to operate in the European Union.

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- Increasingly, other marketplaces may become less and less friendly to unregistered firms as the number of registrations increases.
- In a recent survey, more than 80 percent of respondents said ISO 9000 registration would influence their choice of suppliers.
- If you are like many companies, you are finding that ISO 9000 registration is often an item on supplier surveys.

PITFALL

ISO 9000 registration can have the effect of shifting costs from customer to supplier, since many customers discontinue auditing registered suppliers. That makes it even more important that you keep your system as lean and overhead-free as possible.

- *Reduces cost of customers' supplier programs.* To the extent that customers accept ISO 9000 registration in lieu of supplier quality assurance audits, their own costs go down.
- *Reduces operating costs.* British Standards Institution (BSI), possibly the world's largest and most respected quality assurance registration body, estimates that registered firms reduce operating costs by 10 percent on average. However, don't take this number to the bank; a great deal of how much the system contributes depends on your starting point. If you are already operating at peak efficiency, ISO 9000 registration is not going to pay back at that rate.
- *Provides competitive advantage.* ISO 9000 registration is a powerful marketing tool for its holder. Registered firms proudly display their certificate and logo, and their names appear in registries of approved firms. Quality is already a strong differentiator in parity markets. ISO 9000 registration is objective, confirmed evidence of an active, thriving quality system.
- *Reduces supplier quality assurance (SQA) audits.* Some companies are subject to as many as 30 to 40 supplier quality audits a month! As ISO 9000 gains visibility and credibility, the fact of registration is increasingly easing acceptance to approved supplier lists. In some cases, it eliminates supplier audits entirely.

II. How can we keep our ISO 9000 system from fading away?

CAPSULE ANSWER

Your ISO 9000 system will not fade away as long as management sees value in maintaining the system.

The dreaded “program-of-the-month” syndrome: Here today, with much sound and fury—and, after a slow, embarrassing fade-away—gone tomorrow.

Your ISO 9000 system won’t fade away as long as top management remains committed to it. Top management will remain committed to it as long as they see that it is returning some sort of benefit. That benefit may take one of two general forms:

1. Current business stays as a result of the ISO 9000 system.
2. New business comes as a result of the ISO 9000 system.

PITFALL

Improvement programs fade away when tangible benefits are not recognized by management.

Net result: Organization achieves incremental cost savings as a result of the ISO 9000 system. Since most companies get into ISO 9000 due to customer pressure, the first benefit is the most operative one. The second benefit is speculative. The net result, surprisingly, is genuine—ISO 9000 registrants, with virtually no exception, realize proven cost savings—but, like mating elephants, it is accompanied by much roaring and screaming, and takes two years to see the results.

THE REINFORCEMENT MECHANISMS

1. Surveillance assessments.
2. Management reviews.
3. Internal audits.
4. Measurement and analysis.

Top management will stay committed to the system if only to maintain existing business and, hopefully, obtain new business. This requires that the organization remain registered. For the organization to remain registered, it must undergo and pass surveillance assessments, usually every six months. This is probably the most potent of the four reinforcement mechanisms of ISO 9000—the attributes that keep the system from fading away as another program of the month.

The second reinforcement mechanism is the Management Review process required by the Standard (Question 31). Management reviews require that senior management review the ISO 9000 system from top to bottom—its implementation, its suitability, its effectiveness, its results. Management must do this on a scheduled basis. Records must be kept to prove that it is done. The reviews have the effect of forcing management to pay attention to the system. The reviews are also an educational process for management. Over time, they see how useful the ISO 9000 system can be as a management and communications tool.

The third reinforcement mechanism is the internal audit process required by the Standard (Questions 68, 85, 86). Trained, independent employees audit the entire quality system on a scheduled basis and record the results. Corrective actions must be carried out and verified against deficiencies found during these audits. Internal auditing is not only an outstanding implementation tool. It also keeps the entire organization tuned in to the system and improving it on an ongoing basis.

OPPORTUNITY

The disciplined gathering and analysis of objective data about your process is the surest route to meaningful improvement.

The fourth reinforcement mechanism—and arguably the most important one—is the measurement and analysis processes required by the Standard (Questions 63–67). If you do a good job of establishing meaningful process and quality measures—and then gather, analyze, and react to the data on a disciplined basis—you will see how well the system is working for you. Word to the wise: *Establish the measures early in the implementation*, so you have a set of baseline measures to compare with subsequent results.

12. We're leaders in our market. Our customers love us. Our quality is unquestioned. What does ISO 9000 offer us that we don't have already?

CAPSULE ANSWER

ISO 9000 can help your company maintain access to key customers, improve performance, and achieve a new level of international credibility.

What does ISO 9000 offer? For one thing, it offers you continued business with customers who may be requiring you to register. That is a pretty strong benefit right there.

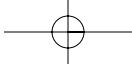
These customers may never question your quality, but these customers depend heavily on their main suppliers. They know they can improve their quality and through-put, if you improve yours.

- *Just because you are great does not mean you are as great as you could be.* ISO 9000 mandates a continuous improvement system. You can wriggle and fudge, but if you implement that system and work it conscientiously, you cannot help but improve. Continuous improvement is not just a buzz term. It is an imperative.
- *Just because you are great today does not mean you will be great tomorrow.* Has your industry changed? Has your organization changed? A well-implemented ISO 9000 helps your organization adapt to change. It brings independence of individuals and consistency of practices—two features that tend to resist declines in performance.

OPPORTUNITY

ISO 9000 implementation and registration are tangible and meaningful messages to customers that you are committed to their satisfaction.

What else does ISO 9000 bring you? When well implemented, an ISO 9000 quality system improves organization performance. That is, after all, the whole point. In cases where it does not, the fault tends not to be in the ISO 9000 process (its inherent deficiencies notwithstanding). When an ISO 9000 system does not provide substantial



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benefits and improvement in performance (Question 4), it is usually because management has consciously chosen to cut corners, blow smoke, stay uninvolved, and starve the system of all but the most essential resources. “We’ll do this stupid thing, but we’re sure not going to change the way we operate.”

ISO 9000 registration brings you one more thing that your organization may not have today: International credibility. ISO 9000 is deployed and practiced in nearly 100 countries around the world. In today’s ever-growing international economic climate, this is not a bad emblem to have, however narrow the scope of your market today.

