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ISO 9001: 2000

Is it an improvement?

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ISO 9001:2000

— the updating of an industry tool

In 1987, the ISO 9000 (ISO) certification was introduced to industry, much of which was less than thrilled to have one more potential program to incorporate. It was not a quality system unto itself, but a series of universal standards that specify quality systems.

The mantra of ISO 9000 believers was simple: “Say what you mean, mean what you say and be able to prove it,” but there was no getting around the considerable logistics involved with the voluntary project. Detractors liked to point out that the process was both expensive and paperwork-heavy, and worse, that a company could be in complete ISO 9000 compliance yet still manufacture a shoddy product.

That, as the saying goes, was then. Today, the ISO 9000 series has become a fact of life for many companies. Only now, they have less than a year to

comply with an updated version of ISO 9000 known as ISO 9001:2000, the single standard which is replacing the 1994 versions of ISO 9001, ISO 9002 and ISO 9003. It is designed to be more practical and effective, but the reality will take a little longer to judge as companies that are already ISO 9001:1994 certified have until December 15, 2003, to “migrate” to ISO 9001:2000.

ISO 9000 is on an upswing. According to the Geneva-based organization, at the end of 2001, more than 510,000 ISO 9000 certificates had been awarded to 161 countries and economies, an increase of nearly 102,000 certificates from the prior year, by far the highest increase recorded in all 11 cycles of the survey carried out since January 1993. Of those new ISO 9000 certifications, 44,388 were for ISO 9001:2000, which

represents 43 percent of certificates awarded in 2001 and nearly 9 percent of the overall total.

This feature looks at some of the requirements of the new ISO 9000 standard, including comments from three companies that explain their experiences as well as some statistics provided by ISO.

The main copy that starts below stems from an edited and expanded technical paper by Doug and Carole Anton, AEM Consulting Group, which specializes in consulting ISO 9000 certification. It includes their comments, experiences and expectations.

Maximizing the value of ISO 9000 certification

The trend in today’s global marketplace is a growing demand for registration to the internationally recognized ISO 9000 standard. Companies that are not ISO-certified may want to start thinking about getting certified.

Doug and Carole Anton, AEM Consulting Group, say that they recognize, however, that many companies view the certification process with skepticism, anticipating a costly waste of time they must endure in order to please customers. “What they fail to realize is that ISO 9000 certification done right is an opportunity to lock in real, continual improvement to a company, raise customer satisfaction, and increase profitability.”

The secret of taming the compliance beast, the Antons say, lies in the way companies approach the certification process. “Some view ISO 9000 certification as nothing more than a trophy hunt. These companies go through the motions of the process with little thought to its long-term consequences. Then there are those who are committed to making quality a centerpiece of their company-wide mission. For them, the process of certification is a long-term investment in their company’s future.”

Regardless of which approach a company chooses, ISO 9000 is here to stay, the Antons insist. Therefore, it makes sense for a company to get as much value as it can from the resources it commits to the process.

“What can “value” mean in terms of numbers? According to one of our client companies, their ISO 9000 regis-



Doug and Carole Anton, AEM Consulting Group. Photo by Gary Choppe.

tration efforts resulted in a 65 percent drop in customer returns, a 15 percent increase in on-time delivery and a 21 percent increase in inventory turns. There are never any guarantees, but the possibilities for a committed company are unlimited.”

The Antons note the five following ways to make ISO 9000 a worthwhile investment. With these conditions in place, they insist, the process of ISO 9000 registration will yield not only a framed certificate, but also a quality system that contributes to the bottom line.

- *Include only value-added processes.* ISO 9000 provides the structure for standardized work processes and procedures. This is a valuable aspect of ISO—when applied correctly. The key is to avoid documenting a picture of operations to please the auditor at the expense of processes that contribute to the company’s success. Weak implementation creates a monster that employees will have a difficult time maintaining, the Antons warn. “One company’s president, who was frustrated with the lack of progress towards ISO, finally halted operations for a week and ordered employees to write procedures. The result was successful registration, but the system created was a hodgepodge of forms and paperwork that strangled day-to-day activities. Since registration is for a three-year period with surveillance visits by the registrar every six months, the company had no choice but continue feeding the beast it had created. Just as with products, lousy design always results in additional headaches down the line.”

- *Aim for simple and concise documentation (more is not better).* Documenting the company’s quality system is usually considered to be the most excruciating part of the registration process. However, documentation done properly allows companies to move beyond mere compliance and achieve excellence as well as greater profitability. The process of documentation begins by recording current operational processes. Then, the company analyzes, improves and assesses those processes to the ISO 9000 stan-

(continued)

An ISO 9000 believer for all the right reasons

In 1997, Chase & Sons, a manufacturer of rubberized fabric used in products that include tapes for power and communication cables, recognized the need to upgrade its quality system, said Ed Silva, the company’s QA manager.

That decision to seek ISO 9000 certification was not based on pressure from customers, but because the company felt it would be beneficial for the business, Silva said. The company, which has approximately 100 employees at three manufacturing sites in the U.S. and Canada, became ISO 9000 certified in February 1998, and has since become updated to new ISO 9001:2000.

Has the effort been worth it? Silva said that the answer has been a definite “yes,” at least for Chase & Sons. “Specifically we have seen a profound reduction in our customer complaint frequency and credits, down 68 and 40 percent, respectively, over the past five years,” he said. The requirements have been a useful tool. And not overwhelming to use and to maintain, he insisted. The company became more efficient as it employed ISO 9000-based comprehensive Standard Operating Procedures in all manufacturing areas, he said. Those detailed work instructions, diagrams and flow charts reside in the company’s computers, and are easily accessed by employees, making the ISO 9000 “tools” practical, he noted.

The transition to the new ISO 9001:2000 requirements did take an effort. “The toughest part of the transition were identification and measurement of the quality objectives, most particularly those involving customer satisfaction,” Silva said. “Many ideas had to be abandoned because there was no practical way to quantify them. If you cannot measure it, you have no way to determine how you are performing against a target or norm, thus making

the objective meaningless. However, once you adjust your focus and recognize the emphasis on customer satisfaction and process relationships (most easily satisfied by flow charts), it became a lot less stressful dealing with the first transitional surveillance audit. The more difficult job was our initial certification process, because it represented a huge culture shock to nearly everyone. A great deal of time and effort

was spent trying to overcome the inertia of over 40 years of ‘old school’ thinking. Now it has become more of a way of life as opposed to a simple tool, therefore maintenance is almost routine.”

Asked whether ISO 9000 pays for itself, Silva responded that, “the fixed costs for regularly

scheduled outside audits are more than offset by our reduced complaint/credit ratios. Not having that outside authority to answer to would, in my opinion, result in gradual regression of our quality program.”

Silva added that, “Is ISO 9000 for everyone? Probably not, but it was the right move for us, for all of the right reasons.”

Silva’s advice to companies pursuing ISO 9000 is:

- Not to panic and feel as if all your documentation needs a major overhaul. In most cases only minor tweaking is needed to comply and although the new standard requires documented procedures for only six elements, we found it beneficial to keep most everything we had in place.

- Use flow charts in place of verbal instructions where possible. It satisfies the requirements, is easier for registrars to follow during audits and it simplifies revisions.

- Make certain that upper management “buys into” the process.

—Mark Marselli



Ed Silva, QA manager, Chase & Sons.

dard. Finally, the company documents the streamlined processes. This is not the end, however. Writing down procedures is a powerful tool for pinpointing where there is room for improvement—continual improvement.

- *Integrate all ISO 9000 activities into the company's day-to-day business.* Companies should drop the term "ISO 9000 quality system" from their manuals and simply call it their "business system." In today's hectic environment, it is challenging enough to keep one system going. Imagine how much more energy a company needs to manage two systems.

When ISO 9000 is seen as a separate entity it competes for scarce resources, the Antons observe. "In fact, there is a common fear among companies facing the prospect of becoming certified that registration means having to hire a permanent employee just to oversee the ISO 9000 quality system. This fear is needless for companies that take an integrated approach to registration. An Underwriters Laboratories, Inc. (UL) lead auditor once stated that companies holding 'ISO 9000 meetings' are a red flag to her because this signals they have not integrated the ISO 9000 requirements into their day-to-day business activities."

- *Make sure senior executives are committed and involved.* Some of the best ISO 9000 successes have been in companies where a senior executive serves as the "management representative." In this type of situation, management studies and understands the ISO 9000 standard, then interprets and applies it to the company's unique situation.

In one such success story, a company named its executive vice president as the management representative, the Antons recall. "He kept his copy of the ISO 9000 standard, which was full of his highlights and notes, with the company's business system manual. He understood the standard and the corresponding sections of the company's business system that addressed the

requirements. Because his position allowed him to see the big picture of his company, he could readily discern all the ways in which his company was already compliant with the standard as well as what areas needed improvement."

When a company designates as its management representative a lower-level manager in a more specialized position, that person will possess a much narrower scope of company knowledge than a high-level executive, the Antons say. "It is the top executives' extensive knowledge of the company that helps prevent third parties, such as customers or the ISO 9000 registrar, from erroneously asserting that the company is not compliant in a certain area."

"If a company intends to use a process management approach, ISO 9000 is a great methodology."

— Doug and Carole Anton, AEM Consulting Group

- *Engage a registrar with excellent credentials and auditors.* To become ISO 9000 certified, companies engage the services of a third-party registrar, which determines if the company meets the standard. Some experts maintain that the third-party registration scheme is an inherently flawed one, pointing out examples such as Firestone, a company with one of the worst quality-control disasters in automotive history. Prior to that debacle, a registrar had deemed Firestone worthy of QS 9000 certification, which is widely acknowledged as one of the most challenging of all the industry-specific variants of the ISO 9000 standard.

The ideal registrar has seasoned auditors with excellent business skills and verified credibility with the company's key customers, the Antons say. "If in the U.S., it should have accreditation with the U.S.-based Registrar Accreditation Board (RAB) as well as its counterparts in other countries

where the company does business. The right registrar is not necessarily the cheapest, nor is it the one that will rubber-stamp a company through the registration process. One company in a high-tech aerospace industrial park tells of a shop down the street that sells copies of their quality manual with an ISO 9000 certificate. That kind of certification may be cheap and easy, but it would have little currency with a customer like Boeing."

The ISO 9000 return should be measurable

As in any long-term business investment, the greatest returns from ISO 9000 registration go to those companies that invest wisely, plan ahead and are the most informed, the Antons say.

"ISO 9001:2000 should provide an ROI of not more than one to two years, otherwise why would anyone do it? If a company intends to use a process management approach, ISO 9000 is a great methodology. Because the new revision is more common sense based, it should cost approximately 25 percent less than the

older versions. Also, prices for third-party registration are coming down probably due to the competitive nature of the registration business."

Properly done, the new revision requires less time, more in the six- to eight-month range, the Antons note. "This is because of the process focus of the standard, which requires an understanding of how a company's system and processes mesh with ISO. You no longer fit the company to the ISO 9000 requirements; instead you take credit for current processes meeting the requirements."

For companies that have implemented ISO 9000 correctly, cost effectiveness has always been the case, the Antons say. "The new revision makes cost-effectiveness easier to attain. The key is to spend adequate time on the design of the system and processes. Just as with products, good design enables the implementation to go much smoother, which costs less and takes less time. Properly applied, ISO

Working with multiple certifications can equal improvement

For many larger companies, certification can mean more than one type. Bill Wilson, director of quality for General Cable Corporation, reports that his company is certified to both TL 9000 as well as ISO 9001:2000.

The TL 9000 certification is required for some of General Cable's Communications Business customers.

"ISO 9000 and TL 9000 standards have provided a format to develop the quality system structure for General Cable," Wilson explained. "The new standards have been used as a basis to developing process flow diagrams for each of our business systems within the standard operating procedures."

The standards, Wilson observed, help because it makes General Cable focus even more in the areas of customer communication, design and continuous improvement.

"Our goal is to not only meet the standard requirements but to continual-

ly improve in each area of our business," Wilson said. "Formal processes and procedures had to be incorporated to adhere to the standard. This has been looked at as an opportunity to improve and link together our business functions throughout the corporation," he observed."

As Wilson explained, ISO 9000 is not stated in contracts, "but many of our customers do business with General Cable due to us having registration." He judged that "the cost of the registrations has been somewhat offset by the improvements we have made to our internal procedures and processes."

Wilson added that, "Without the requirement to upgrade, I feel that General Cable would still have made the continuous improvement strides anyway, but the standards helped to push the improvements."

Asked what he would tell companies

seeking ISO 9001:2000, Wilson said that he recommends getting "as much upfront training to the new standard for the internal auditors and for the quality managers responsible for the upgrades."

Wilson noted that General Cable made sure each of its plants were prepared, which he described as a necessity for both achieving and maintaining compliance as well as for getting meaningful results from having the program.

"We had each of our quality managers attend a three-day training session covering the changes from the old standards and auditing to the new standard," Wilson said. "Each of our 21 North American manufacturing facilities has since rolled out training for their individual internal auditors," he said.

AVOID EXCESSIVE DOCUMENTATION



ISO 9000 should help, not complicate. AEM's **ISO 9000:2000 Survival Software Templates** utilize the unique Scripted Flowchart Process. They make documentation easy to use and understand. To learn more about ISO, the Software Templates, or AEM, contact Doug or Carole Anton:



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Comments on the new standard sent to ISO 9000

The following comments, a list of pluses and minuses made by a mix of accreditation and certification bodies and other user organizations, appeared in an ISO publication, *ISO Management Systems*.

Pluses:

“The process approach helps organization eliminate complicated QMS documentation.”

“The degree of top management involvement becomes clearer because senior managers’ responsibilities and roles are emphasized in the QMS.”

“Sales and marketing departments accept the new standard better than the previous one.”

“I met several managers and company representatives who were skeptical about ISO 9000:1994 after three to four years’ experience with the old standard. They have fundamentally changed their views...since understanding the key elements and framework of the new standard.”

“The standard provides the opportunity to view the complete management system. It is more closely aligned to the day-to-day practice of the general manager. All the requirements in the standard are ‘common sense’ and very close to ‘normal’ business.”

“The revision of the ISO 9000 family of standards has introduced a new dynamic in the approach to quality

systems and in certification processes. The open revision process offers benefits to all interested parties, and the possibility of ‘one time’ analysis and comments on successive drafts.”

Negatives:

“Many organizations have problems in understanding and complying with the requirements ... because they see it as a quality assurance standard.”

“Only six mandatory documented procedures are required ... The remaining process operating documentation needs are mainly dependent on the complexity of the process and competency of the operator. This could result in dispute between auditor and auditee as the deciding criteria are very subjective.”

“Auditors face greater challenges and (must) be more competent/qualified.”

“There is an impression among organizations that the new standard is more suitable for ‘service sector’ companies.”

“The lack of an updated auditing standard corresponding to ISO 9001:2000 has limited the effectiveness of auditors ... in helping organizations realize the added value ...” update.

9000 provides the means to understand a company’s system and processes. This knowledge allows employees to assess needs and prioritize improvements to provide goods and services better, faster and cheaper which is the name of the game. When done this way ISO 9000 works effectively with lean manufacturing, six sigma and MRP/ERP.”

The Antons say they believe that, for perhaps half of registered companies, “ISO 9000 is mostly an exercise or trophy. Worse, it can actually cause

further consternation than is usually encountered in companies. Companies that are successful with ISO 9000 set measurable objectives and expectations and use it as means to an end not vice versa.”

Comparison of new ISO 9000 requirements

ISO 9000:1994 certification required a company to keep and maintain a detailed documented process of what it does, from start to finish. It did not tell

a company how to make its products nor did it replace an existing quality system.

As with any system, there were pluses and minuses, and the ISO 9001:2000 version, which took effect December 15, 2002, but has a one-year period for companies to comply, was revised to be more practical. So, how is the new version most different?

Here are four major changes, as described by the Antons.

- *A change to being system-and process-orientated.* The standard now requires you to understand and control your system and processes from initial customer requests to shipping a product or delivering a service. Prior revisions looked at specific activities like contract review, design, purchasing and process control. Now, the standard puts these activities into a contiguous process: product realization. This requires much more thought on the

... and the WAI Connection survey says

Asked if they would push a button that eliminates the entire concept of ISO 9000, have to think about it because it has been a matter of pluses and minuses or leave it alone because the program has been a plus for their company, the results were about as evenly split as they could be.

Of the 89 people who responded to the poll in the free electronic newsletter sent bi-monthly to WAI members, 33 percent said they would end ISO 9000, 34 percent said they would have to think it over and another 34 percent said they would keep it.

linkage between these functions.

- *Reduction of required procedures (six) and records.* This shifts the focus from looking good on paper to proving that the system meets your needs and conforms to the ISO 9000 requirements. The typical approach to the 1994 revision was to fit a company into 20 elements resulting in 20 separate procedures. The 2000 revision provides for a more flexible approach that allows a company to describe its system with a mixture of procedures and records. Our clients usually end up

with 7 to 13 documented procedures.

- *Proof of performance.* Under the 1994 revision, even if a company was registered to ISO 9001, it could still provide substandard products/services and maintain their registration. This was a major criticism of the old revision. Companies must now measure and provide records of customer satisfaction; i.e., on-time delivery, ppm defects etc.

- *Demonstration of continuous improvement.* Before continuous

improvement was implied, now a company must demonstrate continual improvement.

The 1994 version of ISO 9001 did not explicitly require a company to make continual improvements in their system. Compliance alone with existing quality measures satisfied some users of the standard and their registrar.

The 2000 version not only mandates a documented continual improvement process, the company must also provide evidence (records) that their system and processes are improving (better, faster, cheaper) over time. This is another reason that ISO 9001 registration can no longer just be a one-time, put the certificate on wall, trophy hunt. The system must continually provide better results.

And what about QS 9000?

QS 9000 remains a much more daunting standard, the Antons say. "The main difference is that QS requires a company to do specific things like control plans (or FMEAs) while ISO 9001 gives complete latitude on how a company accomplishes the requirements," they say.

"QS 9000's days are numbered as the automotive industry intends to retire it by December 2006," the Antons noted. "Meanwhile its replacement, ISO/TS 16949 – 2002 was released in 2002 and remains a significantly more challenging standard in the same manner as QS."

No matter what the type of certification a company is seeking, a major key to success is a commitment to the goal, the Antons insisted. As the process goes forward, a company should begin to see the advantages, some of which can be subtle but valuable, of using ISO 9000 as a tool, they said.

Doug and Carole Anton of AEM Consulting Group, Inc., are manufacturing industry consultants and the authors of the *ISO 9000:2000 Survival Guide* (available at WAI Bookstore) and the *ISO 9000:2000 Survival Software Templates*. They can be contacted at 800-950-7123; fax 541-488-0220; e-mail: anton@aemconsulting.com; www.aemconsulting.com. ■

FQAs on ISO 9001:2000 from the ISO web site

These edited FQAs and other questions/answers can be found at <http://www.iso.org/iso/en/iso9000-14000/iso9000/faqs.html>. Further information can be found by visiting the ISO web site at www.iso.org and reviewing the wide assortment of information there.

Will the year 2000 revision affect my organization's current quality system registration/certification?

Yes. The strategy adopted by your organization to meet the requirements of ISO 9001:2000 should include an appropriate timing for upgrading your organization's registration/certification. It is expected that the process of upgrading registration/certification will be a smooth transition that is incorporated into the applicable Registration or Certification Body's regular audit routine.

Where can I obtain information on the revised standards?

There are a number of sources of information on the revision of ISO 9000 quality management system standards, including, of course, this web site, which carries detailed information on the revised standards and is updated on a regular basis. ISO Central Secretariat in Switzerland is also maintaining a web site at www.iso.ch that carries general information on the revised standards.

Will my organization need a full reassessment for the revised standards?

This is primarily an issue between your organization and your registration/certification body. It is expected that conformity to the new ISO 9001:2000 standard will be evaluated by certification bodies during regular surveillance visits, and that full reassessment will only take place once current certificates expire.

Will my organization have to change its quality system and, if so, when?

It is not the intention that you should have to change the whole structure of your system or re-write all your procedures; however, the revised standards include some new requirements and you should consider addressing them in your system at an appropriate opportunity. By December 15, 2003, all organizations wishing to retain accredited certification will have to have migrated their quality management system to being compliant with ISO 9001:2000.

What will happen to my organization if it is currently registered/certified to ISO 9002:1994?

The organization is not obliged to include within the scope of its certification all the products that it provides. (Note that the ISO 9000:2000 definition of "Product" includes services!). However, for those products that are included in the certification scope, all applicable requirements of ISO 9001:2000 will need to be addressed. The standard allows for the exclusion of some requirements (via clause 1.2 "Application"), but only if it can be shown that these requirements are not applicable to the organization.

Exclusions are limited to Section 7 ("Product Realization"), and requirements may only be excluded if it can be shown that they do not affect the organization's ability to provide product which meets customer and applicable statutory/regulatory requirements.

If design activities are required to demonstrate your organization's capability to meet customer or statutory/regulatory requirements for products covered by the quality management system certification, then these design activities must be included in the scope of your registration/certification to the ISO 9001:2000 standard.

Can organizations remain certified/registered to the 1994 version of ISO 9001, 9002 and 9003?

Organizations may choose to continue or even seek new certification/registration to the 1994 versions of ISO 9001, ISO 9002, and ISO 9003, but any accredited certificates issued or renewed will, however, only remain valid until December 15, 2003.

If design activities are not required to demonstrate your organization's capability to meet customer and applicable statutory/regulatory requirements, or if your product is provided on the basis of established design, you will still be registered to ISO 9001:2000. In this case, you will need to justify the exclusion of the design and development requirements in your quality manual.