ISO 9001 was founded in 1987 as an internationally accepted quality management certification system to define, identify and confirm quality benchmarks within organizations. But since then, it has become much more. Today, ISO 9001 is helping thousands of companies worldwide manage their processes to become more efficient and cost-effective.

Progressive companies are finding the ISO 9001 process can offer real strategic value, especially if it is aligned with corporate goals and objectives. For these companies, the ISO 9001 auditing process is more than running down a checklist—it is a true business asset.

To apply this model successfully, you need to work with a certifying organization that understands your business and mirrors your commitment to quality and continual improvement.

**Insight Auditing® from TÜV SÜD America**

As the ISO 9001 auditing process has evolved over the years, so has TÜV SÜD America. We’ve taken the process to new heights with Insight Auditing. It’s more than a process; it’s an attitude. Our auditors are experienced, well-trained and insightful. But above all, they’re passionate about their work. They come to your facility with a fresh eye and out-of-the-box thinking.

They take the time to listen to you and understand your business—so they can add value beyond the auditing process. TÜV auditors strive to work as business partners with you. At each engagement, we “read between the lines” of the audit to uncover observations that can lead to increased efficiency, reduced costs and increased speed to market.

Quick History of ISO 9001

The International Organization for Standardization (ISO) was founded 1946. Based in Geneva, Switzerland, it created the first international standards for manufacturing, trade and communications. ISO 9001 was initially published in 1987 and specifies, in broad terms, the necessary components of a quality management system and, in detail, the basic requirements of the quality function for all industries.

Today, more than 90 countries are members, with the U.S. representative being the ANSI-ASQ National Accreditation Board (ANAB). There are over 700,000 ISO 9001 certified companies around the world (including more than 50,000 in North America), all demonstrating a commitment to continual improvement in quality.

The most recent change to the ISO 9001 standard is ISO 9001:2000. This new standard is now in place and includes improvements in three key areas:

• Creating a common structure based upon a process model.
• Creating a method to demonstrate continual improvement and customer satisfaction.

ISO 9001 was founded in 1987 as an internationally accepted quality management certification system to define, identify and confirm quality benchmarks within organizations. But since then, it has become much more. Today, ISO 9001 is helping thousands of companies worldwide manage their processes to become more efficient and cost-effective.

**TÜV is accredited to provide third-party certification services by:**

1 ANSI-ASQ National Accreditation Board (ANAB)
2 German Accreditation Council (DAIT/GA/ZLG)
3 Verband der Automobilindustrie (VDA-QMC)
4 Standards Council of Canada (SCC) – including recognition as a qualified ISO 13485 Registrar under the Canadian Medical Devices Regulations
5 JAS-ANZ Accreditation

TÜV SÜD America also holds a host of additional domestic and international accreditations.

TÜV is an OSHA-approved NRTL (Nationally Recognized Testing Laboratory) and SCC accredited lab providing electrical, mechanical safety, electromagnetic compatibility (EMC) testing and regulatory solutions for a variety of industries, such as aerospace, medical, telecommunications and high tech to name a few. Combining management systems auditing, factory inspections and conformity assessment activities can reduce overall compliance/audit costs.

**Use Our Mark to Make Your Mark**

Your customers are often required to provide visible proof of certified quality systems and safety-tested products. Our unique TÜV-Mark demonstrates your strong commitment to quality. Its global recognition will help you reach out to the marketplace. Our single-source certification solutions can save time and reduce cost. Contact us today to learn more.

**POS4005 PEABODY  3/19/08  3:26 PM  Page 3**
Improvement. Now you have the foundation to integrate your quality process into your company’s overall business plan. You can also use this certification as springboard toward more advanced high-performance business models such as Six Sigma or the Malcolm Baldrige National Quality Program Criteria.

So where do you begin? Call TÜV SÜD America today. We’ll show you how to get started on the road to ISO 9001 certification and how our Insight Auditing approach can bring your quality management system to a new level of effectiveness.

History of TÜV
TÜV’s roots are in Germany. Founded in 1870, it has grown into an international organization. TÜV SÜD America covers North America and provides service throughout the NAFTA region for Auditing, Inspection and Testing, as well as our subsidiaries TÜV SÜD América de México and TÜV SÜD Canada Inc.

TÜV SÜD America, founded in 1987, is a global provider of management system certification services to virtually all industries. TÜV Management Service is a leading Registrar in North America, Europe and Asia. We have more than 750 experts in more than two dozen locations across the U.S., Canada and Mexico. We are accredited by both North American and international bodies to perform quality management system assessments.

TÜV SÜD America is headquartered in Peabody, Massachusetts, with auditing staff available at over a dozen offices throughout North America.

TÜV also has international operations throughout the world including: Austria, Bulgaria, Canada, China, Czech Republic, Denmark, Egypt, France, Germany, Hong Kong, Hungary, India, Italy, Japan, Korea, Mexico, Philippines, Poland, Qatar, Romania, Russia, Slovakia, Slovenia, Spain, Switzerland, Singapore, Taiwan, Turkey, the United Kingdom, United Arab Emirates and more.

TÜV Network of Services
TÜV SÜD America has an established array of services to help you improve your internal management systems and gain market recognition for your significant accomplishments.

TÜV Management Service conducts the following audits (numbers to the right of each audit correspond to available third-party certification service(s) from list at right):

- ISO 9001 management system. (1, 2, 4 & 5)
- ISO/TS 16949 for automotive suppliers. (3)
- AS9100 for aerospace suppliers. (1)
- ISO 13485 for medical devices. (2 & 4)
- TL 9000 for telecommunications. (1)
- ISO 14001 environmental management system. (1 & 2)

TÜV’s Management Service also provides the following audits:

- BS OHSAS 18001 health and safety.
- ESD S20.20 for electronics industry.
- ISO 27001 for information technology.
- SQF/ISO 22000.
- ISO 14001 environmental management system. (1 & 2)

The initiation of ISO certification may have started because of troubles conducting business internationally or from certification demands from a customer. Once the spirit of quality management and continual improvement is embraced, organizations experience a wide range of unexpected benefits beyond certification and extending throughout their organizations.

- Improved customer satisfaction.
- Increased profits.
- Enhanced marketplace recognition.

Success Story 1: The 10% Solution

Working closely with Bartley Machine and Manufacturing, TÜV auditors had the flexibility to run ISO audits in a way that uncovered opportunities for metrics, inspection and training improvements. The result was a 10% overall improvement in product quality.

Insight Auditing Increases

The Many Benefits of ISO 9001 Certification

The difference in ISO auditing is found when the chemistry between your ISO auditors and staff creates a bond that becomes more than the sum of its parts. Not only are problems solved and opportunities uncovered, there is added value extending to areas you may not expect. Implementing our Insight Auditing process within the context of an ISO 9001 certification can also verify your organization’s quality process is aligned with your business strategy. This alignment is critical to ensure your organization functions smoothly and processes complement the company’s overall mission and vision.

The initiation of ISO certification may have started because of troubles conducting business internationally or from certification demands from a customer. Once the spirit of quality management and continual improvement is embraced, organizations experience a wide range of unexpected benefits beyond certification and extending throughout their organizations.

- Improved customer satisfaction.
- Increased profits.
- Enhanced marketplace recognition.
Step 1 — Management Commitment

A commitment from senior-level management must be a driving force in this critical initiative. Again, this is not simply running down a checklist; this is a commitment to the culture of quality. Employees must understand and embrace the corporate vision. Management must reinforce and demonstrate their commitment by providing necessary resources and on-going support for the process.

Now is the time to make sure the ISO 9001 initiative is aligned with corporate goals and strategy. Establishing clear and quantifiable business objectives will help keep the process on track and people focused on the appropriate goals. As part of our Insight Auditing approach, we also audit how your business strategy is integrated into your operational processes.

Commitment also involves assigning responsibility and authority for quality initiatives, planning, problem identification, solution implementation and control. One person should have ultimate responsibility for the project. The ISO 9001 “management representative” must report directly to top management.

Step 2 — Planning (No One Plans to Fail, But Sometimes We Fail to Plan)

Implementing ISO 9001 focuses on establishing the quality mission, policies and procedures that form the foundation of an effective and quantifiable quality management system. Achieving certification can seem a bit overwhelming. Like most larger-scale initiatives, there are a number of steps to take prior to the certification to minimize cost, reduce risk of failure and maximize value.

Step 1 — Management Commitment

A commitment from senior-level management
we’ve added a process to help your team at this stage. We review the quality manual and the supporting procedures. Most auditors only review the quality manual. We can discover a significant amount of documentation-related problems at this stage. In some cases we make 10-20 observations during this review. You can use the supplied report to make any necessary changes before the audit. This saves time, money and reduces the stress surrounding the audit.

In addition, TÜV reviews your organizational profile, which is an outline of your organization’s operating environment. This profile includes a description of your organization, customer and market requirements, supplier and partnering relationships, competitive situation and strategic context of your operations. This review allows our audit team to better understand your business before we come to your site, so our Insight Auditing can begin long before we audit your facility.

During the entire discovery evaluation process the audit plan is being developed. Our auditors gather all pre-audit and relevant data and construct more than a checklist. The Insight Auditing approach to creating the audit plan is designed to reflect your company’s audit priorities and help align your overall business goals/goals/objectives with the quality initiative.

Phase 3 — Audit
After all the planning and preparation comes the actual audit.

The length of the audit depends on the size of the business. A small business may be audited by a single auditor in one day. A large organization may require a team of auditors working over several days. If a number of facilities perform identical tasks, we use sampling techniques to minimize the number of locations visited. Audits are typically performed by:

- Touring your facility and observing ongoing operations.
- Interviewing employees working at various levels in your organization.
- Reviewing documentation and evaluating quality records.

The audit team collects evidence that your company has implemented a quality management system in compliance with the ISO 9001 standard and that your practices match the descriptions captured in your quality documentation.

TÜV’s Insight Auditing process then takes it one step further. The quality management system is then evaluated against your business objectives, strategies and vision statement. All must be aligned to ensure overall success and continuous improvement.

During the auditing process our auditors will probably ask a number of intriguing questions. During the closing meeting you’ll see the value of these questions and Insight Auditing. Our auditors are sensitive to the needs of your business and the integrity of the ISO 9001 process. In addition to the ISO requirements, we’ll also present a series of observations. We can’t consult but we can point out areas for improvement. Our auditors are trained to look beyond the numbers and uncover findings you can use to increase efficiency, process effectiveness and quality. This is what Insight Auditing is all about.

A closing meeting is conducted at the audit’s completion and all identified problems are reviewed. The audit team will also share its level, it also ensures the process stays on track with the strategic business goals of your company.

The task force is responsible for creating the implementation plan. This includes roles, responsibilities, deliverables, time lines and budget. The implementation time line should include:

- Building a project support team that includes all applicable departments.
- Documenting the initial tactics to help reach quality process goals.
- Creating a general training program to educate all workers about the new quality initiative.
- Establishing internal auditor training.
- Reviewing and implementing new process documentation.
- Scheduling internal self assessments.

News about change can be disturbing to uninformed employees. Keep the lines of communication open about your ISO 9001 activities. You need to help employees understand the value of this effort. They need to hear this from all levels of your organization.

Step 3 — Documentation
If you’ve been in business for a long time, you probably have a lot of documentation. Chances are much of it is uncontrolled, inadequate or even obsolete. If you’re a start-up you probably don’t have much documentation. In either case, ISO 9001 documentation standards are very clear. This is an area that requires attention to detail, commitment to effective implementation and to maintenance.

One good way to start this process is to separate your documentation into tiers, with each tier representing a different level of detail.

Tier One: Quality Manual. Required by ISO 9001, this manual identifies the strategies and policies of your organization and relates, on a macro-level scale, how your organization will address the requirements of the standard, and answers the question, “Why does your business do what it does?”

Tier Two: Processes and Procedures. Next, your organization will need to identify the processes under which your company operates. Often, these processes can be separated into two groups: “key” processes (sometimes referred to as “customer-oriented” processes) and, support processes (e.g., organizational processes supporting key processes such as human resources, training, preventive maintenance, document and data control, etc.). Some processes, depending upon their criticality to your organization or whether they are addressing specific requirements of ISO 9001:2000, may have to be documented in a formal procedure. Other processes simply may be described in the Quality Manual with sufficient detail to ensure the process is capable of being understood and effectively implemented. Either way, processes and procedures should detail such aspects as what should be done, when and where it will be done and who will do it.

Tier Three: Work Instructions. Work instructions provide details on how specific tasks or operations, as identified in Tier 2 Processes and Procedures, are to be performed. The need for work instructions can be based upon the complexity and/or criticality of the task at hand and the qualification and competency of the workforce.
Tier Four: Quality Records. To some extent, your organization will have to add a fourth tier to include forms, charts, illustrations or checklists used on a daily basis. These documents are generically referred to as Quality Records as they demonstrate evidence of activities performed or results achieved.

Organizational processes and documented procedures are a critical part of an ISO 9001 quality management system. They define the correct and proper operation of a company from a quality perspective and are applicable to all operations within your organization, to include product development, service provision, production and delivery systems. An independent ISO 9001 Registrar (quality auditing organization) verifies that processes and procedures are followed and that the quality management system is effective in achieving your organizations' objectives.

It may appear that ISO 9001 generates a huge amount of documentation, however, many companies find that it actually reduces their dependence on paper. As not all processes are required to be documented in procedure form, and the determination of the need for documented procedures and work instructions is based upon many different factors, processes may also be “documented” in the form of flowcharts, visual aids, data bases, and other media forms.

Finding Outside Help For Your ISO 9001 Audit

If you’re ready to start the process, there is plenty of support available to you. ISO 9001 seminars are available from TÜV SÜD America and other organizations. These will give you a better appreciation of the ISO 9001 process and how it can help your company.

There is a tremendous difference between reading the ISO 9001 requirements and knowing how to establish and implement the systems that meet the requirements. Consultants can offer a variety of assistance on ISO 9001 quality awareness training, system evaluation, documentation writing/review and internal auditor training.

One sign of an experienced consultant is someone who actively engages all appropriate levels of personnel in the process. Experience within your marketplace, specific international knowledge and the right “chemistry” are other considerations.

Using a consultant will increase your cost. However, the guidance and experience of the consultant may reduce the time it takes for you to achieve your ISO 9001 certification.

Registrars (like TÜV SÜD America) are not allowed to consult. We cannot advise you on how to solve a problem. We do highlight where problems exist. The strict separation of auditing and consulting is a fundamental ethical requirement of all ISO 9001 Registrars.

Selecting the right Registrar for your situation is critical. Cutting corners at this stage could jeopardize your entire quality initiative. You need to find a Registrar that will work with you as a partner, take the time to learn your organization’s needs within the context of your ISO 9001 effort and reflect your passion for quality.

Insight Auditing® from TÜV SÜD America

ISO 9001 is strict and exacting. It should be more than a checklist of what is done or not done to requirements. Used properly, it can be empowering and dynamic, providing information that can help drive organizational improvements. Over the years, TÜV has refined its approach helping companies maximize the value of ISO 9001 certification. Our auditors are trained to think outside-the-box to maximize the value of the ISO 9001 certification process.

We call this the IDEAL Process. The four phases of this process include:

**Phase 1 — Information Gathering**

The process begins with an informational meeting between your company and the TÜV team. We summarize our role and explain the auditing process.

Most importantly, we listen. We listen to your company’s needs within the context of ISO 9001, this will help educate your management and staff on what is about to occur. You’ll become more familiar with our auditors and our Insight Auditing approach and we’ll learn more about the processes within your company. Your auditor will point out any areas of concern.

During this meeting we’ll answer any questions about our services and explore how we should set the foundation for a lasting relationship. During our initial series of information meetings we will identify any specific issues that need to be resolved prior to the actual audit.

One important consideration in the information phase is the opportunity for a pre-audit. It is not a formal requirement for certification. A pre-audit is a high level evaluation indicating where your company currently stands in compliance with ISO 9001. If you are new to ISO 9001, this will help educate your management and staff on what is about to occur. You’ll become more familiar with our auditors and our Insight Auditing approach and we’ll learn more about the processes within your company.

Your auditor will point out any areas of concern. Addressing issues at this point reduces risk of nonconformance during the actual audit. This early observation can be immediately implemented into your management system, so you can benefit from our insights before the actual audit even starts.

**Phase 2 — Discovery Evaluation**

Most Registrars call this phase “documentation review,” performing a quality manual review prior to the audit. At TÜV SÜD America, we conduct a more thorough “discovery evaluation” of your documentation. Over the years we’ve found many audit nonconformances result from documentation problems and the procedures relating to documentation. So...