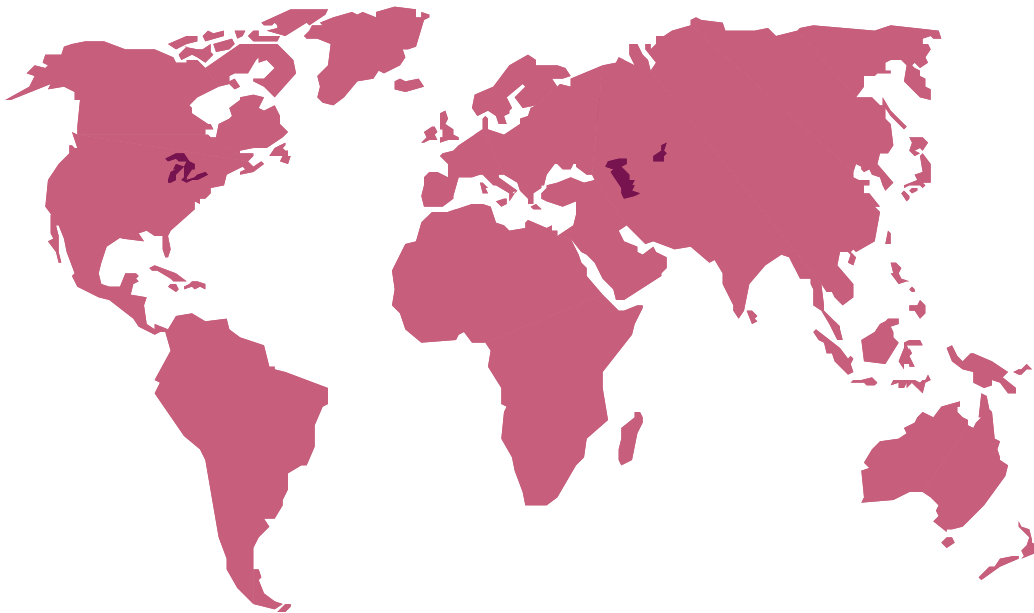


ISO 9001

Downright Basics



ISO 9000 Overview

October 1997

Each Company is an
Individual which **Must**
guide the **Tailoring** of
compliance to Its specific
Systems, Product(s), and
Company Goals.

Foreward

During 1992 I was asked to take a look at a 'standard'. It turned out to be the ISO 9000 series of documents. I scrutinized the documents. Not much here I told myself. The basics were evident almost every place I have worked. The documents didn't seem very demanding or explicit. ISO 9001 was the most comprehensive, yet it only specified that elements basic to a minimal Quality Assurance program be in place. But there was one overlying theme - documentation must exist to support systems and processes. This was not particularly exciting to me. Working in military electronics manufacturing, the intensive documentation was a given.

At that point I joined the documents with a matrix I had developed earlier in a systems integration effort. The matrix expanded slightly, however most of the ISO 9001 elements were already customer requirements. I kept coming back to the documentation theme. I spoke with numerous people about the ISO 9000 documents. Most were ignorant of their existence. The ones who knew of ISO 9000 and had the actual documents all had differing criticisms. Most said things like "Well, ISO 9000 doesn't really relate or compare to". I spoke with one fellow and as we were talking, he brought up the subject of traceability. The fellow told me he believed ISO 9001 would force him to serialize each item his company produced. I told him I read the paragraph (ISO 9001, para. 4.8) to say traceability is required to the extent the process and product warrant traceability. Obviously a metal stamper putting out several thousand parts a day is not going to serialize every part.. It would serve no purpose. A stamp (ink or metal impression) of a lot number would be appropriate, but not individual serialization. We bet a beer on it. My friend called the next day and said when he reread the paragraph, 'to the extent the process and product warrant traceability' was the key. I won a beer.

Since that initial exposure to ISO 9000, I have seen terror in peoples eyes. Though the document is short, people I spoke with seemed to have lost their ability to read and interpret. It was as if people would pick up ISO 9001, for example, and close their eyes before they began to read. The document took on a mystical air. What is it? What will it make us do? All of a sudden it appeared an alarm had gone off. I heard ISO 9000 this, ISO 9000 that.. My amazement grew as I watched ISO 9000 become a growth business. People were running to seminars, hiring 'Top Guns' to evaluate and instruct them, and generally running amuk (as far as I'm concerned, amuk is the best description) in their pursuit of 'compliance'. I spoke with people who attended seminars - some came out with a 'revelation'. Others left the seminar in utter confusion, looking for a 'consultant'. And consultants there are - about everywhere today.

So - what is this mysterious document? What does it really ask? What does it require? I'll try to put it in perspective here.

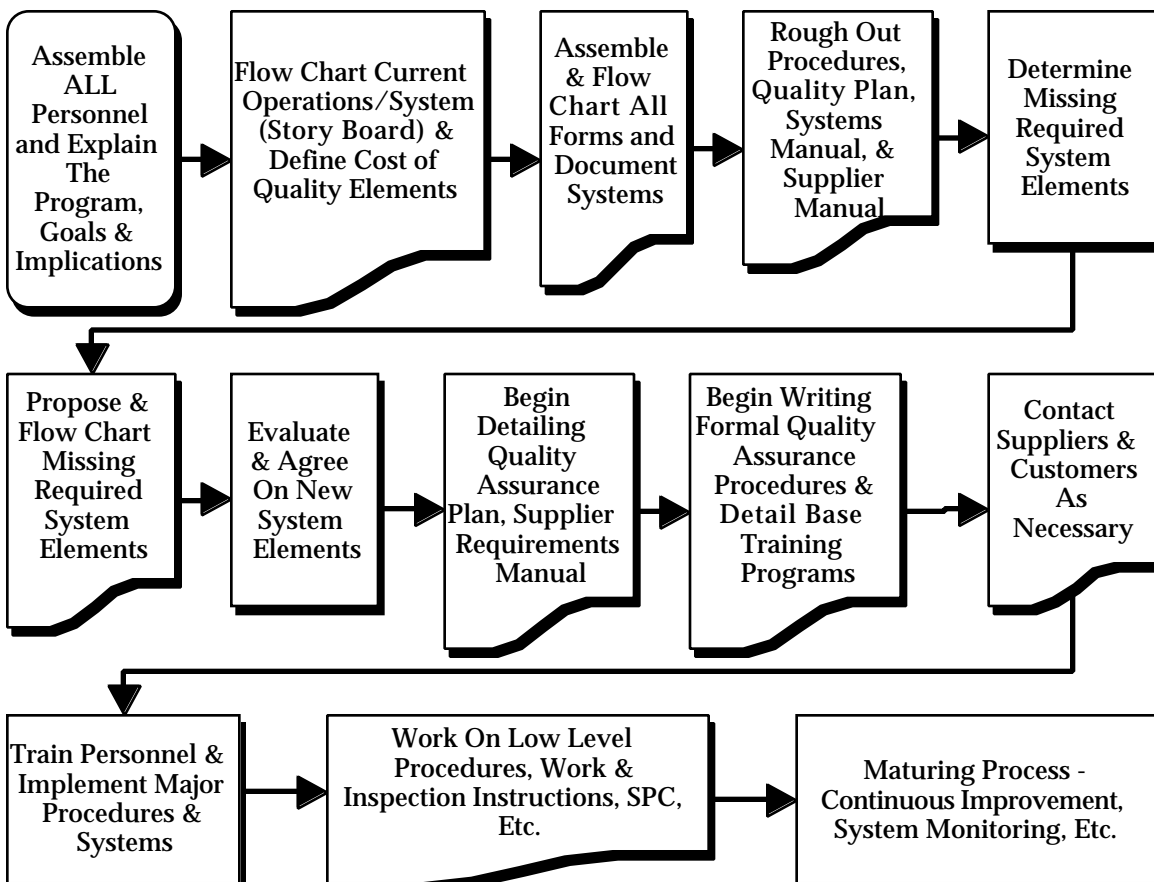


The **Key** To ISO 9000 Compliance Is **Matrixed, Integrated, Living Documentation**

Yes, minimal quality assurance systems and several minor related elements are necessary. For the most part, the required elements are good business practices anyway. Their form is not dictated. The main thrust of ISO 9000 is to force companies to be Consistent through 'Living' Documentation. It forces a company to define its self, its systems, and its processes. The article from Fortune accompanying this diatribe is the best explanation of its relation to Quality in general and what ISO 9000 is and isn't in a nut shell.

That's it! That's all there is to it believe it or not. Well, then again my statement should be tempered. The effort required to reach compliance depends entirely upon the state of the individual company. Many companies have all their systems documented but the documentation is not matrixed and timely. Some companies have absolutely no documentation (Frank knows exactly how to do that job...) and they produce products of excellent quality and value. Some companies have excellent documentation which was written 5 years ago, looks professional, yet has never been updated to reflect changes over the years. Everyone knows the procedures are there, but no one follows them. In one plant someone told me he 'doesn't prescribe to that procedure'. He knew he had a better way to do it, but rather than change the existing procedure, he did it his own way.

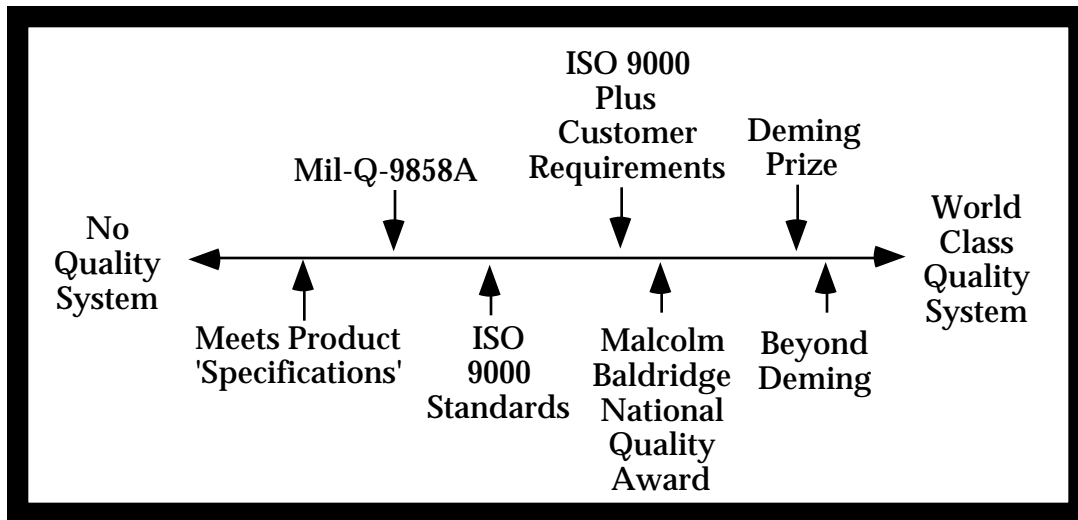
Keeping documentation current is not as formidable a task as it was even a couple of years ago. Relatively cheap technology, networked PCs, allow a company to keep documentation simple and current (Living). For example, one no longer needs a special group to produce work instructions with illustrations. Scanners can input sketches, prints, etc. with ease quickly. Distribution can be by electronic mail or masters may be kept on a network server for reference by personnel. The system still has to be overseen by someone, however if set up correctly minimal time need be spent on 'maintenance'.



**A company does not have to be a behemoth to afford
and implement a good system.**

**It does take a commitment by both management to fund
and provide continuous support for success and by
each individual employee**





What Is ISO 9000?

The ISO 9000 standards are *international* standards. We have an equivalent set of standards in the United States called the ANSI/ASQC Q90 Series of documents. The European ISO 9000 specifications are the same as the United States ANSI/ASQC Q90 specifications. Both sets of standards are identical - in fact they are word for word almost exactly the same. But what are they and why do they exist? Why are they so important all of a sudden? Up until a year or so ago few people knew they existed. What happened?

These **standards** have been in existence for several years, but they are now becoming very important as the nations of the world try to come up with **equivalent, consistent standards** which **everyone** can follow. The ISO-ANSI/ASQC documents are an attempt by the European community and the United States to provide common standards.

Why Now, So Suddenly?

This is not really 'all of a sudden'. We have been watching for years as Japan and other countries have embraced Quality Assurance and provided reliable products we want, often at prices lower than we can produce them for here in the United States. The drive for common standards has actually been on for over 15 years. The ISO 9000 documents are dated 1987 - they were published as standards over 5 years ago. The fact is, many companies are just now considering compliance because world markets, as well as markets internal to the United States, are demanding compliance as a basic element for doing business. Many companies are finding their customers are requiring an ISO 9000 compliant system as a condition of doing business. Compliance can be initially somewhat expensive, so many companies have held back believing compliance might not be worth the effort. But as more and more companies require ISO 9000 systems as a minimum of their suppliers, more and more companies are seeing compliance as necessary to sell their product. In short, if a company doesn't comply, fewer people will buy their product.

Why Common Standards?

As the world 'shrinks', it becomes more important for common rules and standards to exist. As an example, we can use two states. You live in Indiana and want to buy something from Utah. There are Federal regulations and standards which define safety standards for both states. This protects people in both states by defining 'common' safety requirement for products each produce. With 'common' safety standards, you can confidently buy something made in Utah and know it is safe (as defined by regulations/ standards). In fact, the ISO 9000 series was initially conceived to assure safety compliance in a unified Europe.

The ISO standards attempt to provide common definitions, directions, intentions, techniques and requirements for basic Quality Assurance Systems in manufacturing and other business systems. But they aim not only to provide these basics, they also provide a method to evaluate systems and processes while providing data which will allow for the identification of problems, as well as cost reductions. They do not yet address Continuous Improvement, but the revisions next year do.

The focus and purpose of the standards is ultimately to:

CONTINUALLY MEET CUSTOMER NEEDS AND WANTS

PROVIDE CUSTOMERS WITH WHAT THEY EXPECT

**PROVIDE CONFIDENCE TO A COMPANY
THAT IT IS PROVIDING THE BEST POSSIBLE PRODUCT**

**PROVIDE CONFIDENCE TO A PURCHASER
THAT THEY ARE GETTING THE BEST POSSIBLE PRODUCT**

So we can see two things. The standards have been around for a while and they are an attempt to provide a common basis on which to design a basic system. But what is the focus? What is the Bottom Line?

The Bottom Line is:

For compliance with ISO 9000, a company must have a documented Quality Assurance program with a demonstrated management involvement - Total Quality Management. The key word here is documented! Written policies and procedures are the significant part of the program, although it is written with guidelines. A company must have a somewhat detailed, defined Quality System, yet the main thrust is that company systems are written - which is not as easy to put together as it looks on first glance. Policies and procedures are more difficult to write than they appear to be on the surface. They must be clear, concise and fully inter-related. Some people will say writing a good, matrixed Quality Assurance Plan, company Policies, and Procedures is a true art. This has long been seen in Military Manufacturing Systems and is now significant in automotive and other progressive businesses.

For a company which has no documented systems, the first move is to flow chart systems and integrate systems within the flow charts. Next comes flow charting and integrating required systems which do not currently exist. Then comes writing procedures which describe the details of the flow charted systems. This is more time consuming and expensive than most people initially think. It is a lot like writing a book - a detailed book.

The ISO 9000 series contains five actual documents - ISO 9000, 9001, 9002, 9003, and 9004. The actual documents can be ordered (the American version is the ANSI/ASQC Q90 Series) from the ASQC, 611 East Wisconsin Avenue, Milwaukee, WI. 53202 (414-272-8575) for about \$50.00.

Lets look at some of the *basic reasoning* behind the Quality Systems elements of the standard guidelines contained in ISO 9001:

First it says there must be a **written Quality Policy** which defines a company's objectives and commitment to Quality. By requiring a written policy, it makes a company think about its goals and forms a promise. Just as if I write you a letter and tell you I will do something, a *written* statement helps define what I am saying. In addition, it tends to make what I say more *definite* - more of a *promise* than if I just say I will do something.

Next, the standard says the **company** must be



organized and defined. This part of the specification forces a company to define responsibilities. It defines responsibilities by position, not name. For example, a Quality Assurance Manager is responsible for certain things. The position is a defined element of a 'company tree' which not only shows the position, but who the position answers to, as well. And the position the QA Manager answers to is responsible for performance. A "Company Tree" delineates responsibilities

Just as you see more and more and more of this type of sign, you will see more and more international standards and specifications to provide international compatibility and understanding.

from the top down.

The next part of the specification says the company must have a **defined, documented Quality System**. Just like defining the company organization, the Quality System must be documented to define who is responsible for what. The reason for this is to provide assurance that a company produces items which conform to specified requirements. Specified requirements? When a product is designed there are requirements stated. For example, when a door panel is pressed it must be made of a certain material. It must conform to certain standards set by the designer such as having no scratches or dents. These requirements are not just for the operations necessary to make the door panel, however. It must be pressed, packaged and shipped in a way to arrive at the customers facility with no dents or scratches. So handling, storage and shipping are included in the plan. The main point is that an over all plan must exist to encompass events from receipt of material to shipping.

Document Control is the next part of the specification. This section says simply that all documents which affect manufacture of a product must be controlled. What are documents? They include procedures, specifications, drawings, forms and tags and other manufacturing paperwork. Why control? Control keeps old drawings, forms, and such from being inadvertently used. Lets say you buy something which requires assembly. If the company which makes that item does not have control over the instructions it includes to guide you in assembling it, it could send you old, outdated instructions or even instructions for another item. Which would not make you happy. It is the same with documents used inside a company. They must be controlled to assure that the latest, correct paperwork is being used. In manufacturing, work instructions, prints,

inspection instructions and other product related documents must be controlled.

Purchasing Yes, even purchased material used to manufacture a



product must be controlled. As an example, lets say you want some meat for a cook-out. You go to the store and buy what you want. You assume the store has bought inspected meat which is fresh, disease free, and if the label says it's beef that it is beef and not horse meat or something else. Maybe you order ground round. You don't want to be sold cheap hamburger and pay for ground round. The same idea is important in manufacturing. If a customer wants a company to make something, they specify what materials to use. It is necessary to be absolutely sure that what the specification calls for is what is ordered.

Process Control. The goal is consistency. The specification says processes must be defined and carried out under controlled circumstances. What this means is when we make something, we must do it the same way every time. Lets take the cook-out example from earlier. You want to make potato salad to go with the meal. While you might not use a

written recipe, you try to use the same ingredients every time if you want the potato salad to taste the same as last time you made it. If you find a taste you really like, you will probably write down exactly what you put in it and how you made it - a certain number of hard boiled eggs, a certain amount of mustard, etc. You may cook the potatoes for a certain amount of time and boil the eggs for a certain number of minutes. The same is true in manufacturing. To make the same thing exactly the same way every time, you have to have detailed, defined, documented controlled processes. Presses are set up the same way every time, pressures are the same, etc.

Inspection and Test is the next topic of the specification. This part is pretty self explanatory - it states that everything produced must have an inspection and, when applicable, a test plan to assure (verify) that product is being constantly produced in accordance with the specification. This includes material coming in for processing as well as what is being produced. Above we spoke about purchasing, about how we want to be sure what we buy is what we ordered and what we are told by the supplier is true. In the same way, we want to be sure what we produce is all made the same and is what we say we will be selling to others. And we want *objective evidence* which verifies this. Lets say we make a part for a car. If the process gets off of center - say a punch on a die breaks and we don't notice it - we want to have a definite way to keep a **documented** check that every thing is going well and nothing has broken or changed. We do this by planning an inspection procedure **prior** to production and following it strictly through out the production process.

Inspection, Measuring and Test Equipment Simply put, this says that instruments we measure with - specifically tools we use in production to inspect or test with - are calibrated to the same *international* standard. This

the arena of production knowing how to do ones job is seriously important. If an employee is expected to perform a function, he/she must know how - which is the reason for training.

Is it all this short and simple? Well, not exactly, but it is this straight forward. Remember that most everything you now do will not change. There may be a few things you will do that you do not do now.

When you review the requirements put forth by most major companies (including Ford, General Motors, LTV, etc.) you will find they are basically the same as the ISO 9000 specifications. In fact, most major companies have requirements far in excess of those detailed by the ISO 9000 documents.

Please remember

-

This overview is meant only to provide a basic picture of the
ISO - ANSI/ASQC 9000 documents.



The following is an article scanned from Fortune. It is the best, most concise 'description' of ISO 9000 I have read. It cuts to the quick and relates a number of current 'hot buttons' and 'buzz words'.

Fortune
6/28/93

THE HOT NEW SEAL OF QUALITY

Brace yourself for ISO 9000, the certification many people don't understand. If your operation hasn't qualified, it may need to soon. ■ by *Ronald Henkoff*

WHAT IS ISO 9000—dial-a-horoscope? A foreign sports car? A new galaxy? No, try again: ISO 9000 is a standard of quality management, hugely popular in Europe, that is rapidly taking hold in the U.S.—and around the globe. If, like many business people, you don't know the first thing about ISO 9000, or if you think this is just another trendy program with a goofy acronym, then listen up. Your customers are calling.

Du Pont, General Electric, Eastman Kodak, British Telecom, and Philips Electronics are among the big-name companies that are urging—or even coercing—suppliers to adopt ISO 9000 (say it ICE-o nine thousand). GE's plastics business, for instance, commanded 340 vendors to meet the standard by June. Declares John Yates, general manager of global sourcing: "There is absolutely no negotiation. If you want to work with us, you have to get it."

"It" is a certificate, awarded by one of many independent auditors, attesting that your factory, laboratory, or office has met quality management requirements determined by the International Organization for Standardization. In the U.S. the number of certificates issued has more than quintupled in just the past 14 months (see chart).

The ISO 9000 standards, spelled out in a slender paperback volume (available in the U.S. for \$235 from the American National Standards Institute, 11 West 42nd Street, New York, New York 10036; 212-642-4900), do not tell you how to design a more efficient washing machine or build a more reliable nuclear missile. But they provide a framework for showing customers how you test products, train employees, keep records, and fix defects. Think of ISO 9000 not as another variant of total quality management but as a set of generally accepted accounting principles for documenting quality procedures. With certificates issued worldwide estimated at more than 30,000, the

standard is rapidly becoming an internationally recognized system, comprehensible to buyers and sellers.

Says Richard Thompson, vice president and general manager of Caterpillar's engine division, whose Mossville, Illinois, plant was among the first American diesel engine factories to win the certificate: "Today, having ISO 9000 is a competitive advantage. Tomorrow, it will be the ante to the global poker game."

So frothy is ISOmania in the U.S. that auditing firms, known officially as quality systems registrars, are doubling and tripling their staffs in a frantic effort to keep pace with demand. Often offshoots of product safety testing firms such as Underwriters Laboratories, registrars are frequently booked solid six months ahead. The drive for ISO 9000 registration—which can cost a company as much as \$200,000 per site—has spawned a new industry of consultants, trainers, and conference organizers.

HOLD ON to your checkbooks. Despite the hoopla, ISO 9000 remains dogged by controversy and confusion. Most industrialized countries have set up accreditation bodies to vet registrars. But accreditation is a nicety, not a prerequisite for setting up shop as a registrar, and even if a registrar has passed muster in one country, its certificates may not be recognized overseas. Says Stephen Halliday, a lecturer at Buckinghamshire College Business School in Britain: "You and I could start a company this evening, and by tomorrow we could be awarding certificates."

In the U.S. the biggest problem surrounding ISO 9000 is ignorance. Nearly two-thirds of executives at midsize manufacturers have either never heard of ISO 9000 or think it will have no impact on their companies, according to a poll by management consultant Grant Thornton. Other managers cling to the wrong-headed impression that ISO 9000

is a legal requirement for doing business in the European Community. It isn't, though it is steamrolling through Europe. In Britain about 17,500 certificates have been issued, vs. just 1,300 in the U.S.

Founded in 1947, the International Organization for Standardization is a non-profit group that comprises industrial standard-setting bodies from 92 countries (the U.S. is represented by the American National Standards Institute). The organization sets but does not enforce international norms for everything from paper sizes to screw threads to film speeds.

ISO is not an acronym—not in any language. It is an official nickname, derived from *isos*, a Greek word meaning equal, as in isobar, isometrics, and isosceles triangle. ISO 9000, published in 1987, is actually a series of five related standards (numbered 9000 through 9004) that has been adopted by 60 countries—including the U.S., Japan, Canada, and the 12 members of the EC.

Businessmen, not bureaucrats, are the force driving ISO 9000. Purchasing agents like the certification because it helps them cut through the worldwide clangor of competing quality plans, gurus, audits, and awards. Says Jim Holz, director of suppliers quality assurance at Bell Canada, that country's largest telephone operating company: "Saying you have a total quality management program doesn't mean a lot to me unless you have a way of benchmarking it to a standard that I can understand."

But ISO 9000's biggest virtue, its universality, is also its greatest vice. By setting norms that are attainable across a broad range of industries and cultures, ISO 9000 falls far short of the quality that world-class corporations demand of themselves and their suppliers.

ISO 9001, the most detailed standard in the series, consists of just seven pages of often vague directives ("The supplier's management shall define and document its policy and objectives for, and commitment

to, quality"). Its governing principles can be summed up in three words—documentation, documentation, documentation. To become registered, a business must prove it is following its own procedures for inspecting production processes, updating engineering drawings, maintaining machinery, calibrating equipment, training workers, and dealing with customer complaints.

But ISO 9000 makes no demands or assurances about the quality of a company's products. And the standard virtually ignores the mantra of modern quality management, continuous improvement. Companies don't have to show that they know how to reduce cycle time, cut inventories, or speed up delivery. Nor do they have to demonstrate that their customers are happier than they used to be, or even that their customers are happy at all.

Complains Richard Buetow, director of corporate quality at Motorola: "With ISO 9000 you can still have terrible processes and products. You can certify a manufacturer that makes life jackets from concrete, as long as those jackets are made according to the documented procedures and the company provides the next of kin with instructions on how to complain about defects. That's absurd."

Even Motorola, one of the first major companies to win a Baldrige award, is pursuing ISO 9000 registration for many of its plants around the world. Why? Because customers are asking about it. Says Buetow: "We're doing it for insurance." If you're a Motorola supplier, however, an ISO 9000 certificate won't even buy you a cup of coffee. Adds Buetow: "We would never stop auditing a company with ISO 9000. It's just a fraction of what we're looking for."

Perhaps, in a more perfect world, the Baldrige award criteria—which do demand quality products, satisfied customers, and continuous improvement—would become the international quality standard. But few companies are actually ready, or willing, to play in that league. Only 76 companies applied for the 1993 award, down from a peak of 106 in 1991. And even a Baldrige award is no guarantee of commercial success. Wallace Co., a small pipe and valve distributor, won the prize in 1990 and filed for Chapter 11 the following year.

Many managers insist that ISO 9000 is worth chasing, not simply because their customers are demanding it but also because it helps them run their businesses more efficiently. A company can spend up to 18 months—and seven man-years—getting a single site ready for an audit. Registrars descend for up to a week, quizzing managers as well as randomly selected factory workers. The process doesn't end when the certificate is issued. The registrars return every six months to make sure the company hasn't let standards slip.

Prepping for an ISO 9000 exam is like going through a giant spring-cleaning exer-

cise. Companies find the darnedest things: operating manuals so obtuse that nobody understands them, training records so incomplete that supervisors don't know the skills of their own employees, and engineering drawings that have been obsolete for months still in use on the factory floor.

In its drive to win—and maintain—registration, Caterpillar Engines has undergone a massive tune-up. In the past when customers complained that an engine wasn't performing well, engineers might order a design change. But the company had no systematic way of checking that factory workers were using the new specs. Says Larry Fischer, manager of quality technology at the sprawling Mossville, Illinois, diesel plant: "A guy could get a blueprint and stick it in his drawer and forget it was there." Today Cat regularly audits all employees to make sure they are using only the latest documents. That helps avoid mistakes that used to be caught only in final testing bays, or, worse, when the engine reached the customer.

But wait a minute. This doesn't sound like TQM. What about doing it right the first time, checking your own work, and inventing new ways to do your job better? What about empowerment? Fine ideals, say the proponents of ISO 9000, but they need to be tempered with an old-fashioned concept: discipline. Says Richard Haworth, CEO of Haworth Inc., a leading manufacturer of office furniture: "You can't just let a group of people do what they want when they want. An environment of empowerment without any guidelines is not going to create a lot of consistency."

Haworth speaks from experience. For nearly a decade his privately held company, based in Holland, Michigan, experimented with quality management. Says chief operating officer Jerry Johannesson: "We floundered from guru to guru, from book to book, from magazine article to magazine article. We used the right buzz terms, but we weren't getting the message across to our employees." That began to change, he adds, when Haworth applied for a Baldrige award (which it did not win) and an ISO 9001 certificate (which it did).

Now every manufacturing work area at Haworth's five West Michigan plants is adorned with multicolored placards that describe in words and pictures exactly what employees are supposed to do—helping to ensure that all follow company processes consistently, as ISO 9000 requires. In the past an operator on the day shift might have driven in a screw with five pounds of pressure, while his counterpart on the night shift used ten pounds. Now there is no room for argument. Having crystalline processes will also help Haworth, with plants in five European countries, standardize production practices worldwide.

Despite its emphasis on documentation, ISO 9000 can actually force a factory to

dramatically reduce paper flow. Workers at Rockwell International's Allen-Bradley plant in Twinsburg, Ohio, which makes circuitboards, programmable controllers, and other electronic devices, used to have to cope with a blizzard of manuals, work orders, and memos, most written in engineeringese. Procedural changes arrived almost daily in the form of computer printouts stuffed into envelopes. Says plant manager Anthony Pajk: "We were doing a great job of putting in new procedures but not a great job of taking old ones out." Overwhelmed workers evolved their own methods for doing things, often taping up crude crib sheets on their work benches.

In pursuit of ISO registration, Pajk pulled seven assemblers off the floor—some for as long as seven months—and placed them on teams with engineers and supervisors. Their mission: to devise procedures comprehensible to everyone. Now the envelopes have been replaced by an electronic mail system that delivers new instructions and purges old ones. When an assembler has a problem with a new procedure, the engineering department has seven days to find a fix. Some complaints used to go unanswered for six months. The new system helped Twinsburg win an ISO 9001 certificate, one of the 21 held by Allen-Bradley around the world. Productivity at Twinsburg has improved 21% since last year, cycle time has dropped 18%, and product defects have fallen 32%.

ISO 9000 is not a solution. It is, at best, a catalyst. Square D, a part of France's Groupe Schneider, makes circuit breakers and other electrical and electronic equipment, and it used ISO 9000 as part of a three-year effort to standardize quality management systems in its 29 U.S. plants. But W.F. Fightmaster, vice president for quality, is not one to overplay its importance. Says he: "There are some people who believe that once you have ISO you have a quality system. That just isn't so. It's less than one-seventh of the system." The other pieces include training and empowering workers, benchmarking competitors, and setting—and achieving—tough goals for continuous improvement.

The ISO 9000 bandwagon is rolling. The idea of a common quality system has strong appeal. Last year 30 customers came to audit Caterpillar Engines, each spending one to four days touring plants and quizzing managers. Says Cat's Larry Fischer: "Each customer requires us to do things a bit differently. That's where ISO comes in. Let's all adopt the same standard." Given ISO 9000's many imperfections, business will need to tread carefully. The ISOman cometh, but whether he delivers a quality revolution or just a bucket of cold water will depend largely on what else companies have in their larders. ■