Beauty or the Beast: life after ISO 9000

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ISO 9000 certification is just the beginning. There is a healthy life for your company's quality system after certification, and the disciplines developed under ISO 9000 will provide some of the basic building blocks that will improve this life.

ISO 9000 quality system standards are now the industry norm. Most companies are very familiar with these quality system models and are intimately involved with implementing and certifying their quality system to these standards. ISO 9000 has become so ingrained in our culture that companies all over the world now feel that certification to these standards has become a "means to do business."

There are companies, however, that feel these standards may create a "beast" within their organization. Many companies involved in the process are wondering what specific benefits they will get from a system designed to these standards. They are also asking, "OK, so now we're certified . . . what happens next?"

I believe there are enormous advantages to ISO certification but that certification is just the beginning. There is a healthy life for your company's quality system after certification, and the disciplines developed under ISO 9000 will provide some of the basic building blocks that will improve this life.

The ISO 9000 standards were published by ISO (International Organization for Standardization) in 1987. Since that time, some 80 countries have adopted these quality standards as their national quality system models. It is estimated that roughly 60,000 companies around the world have had their quality system designs registered to one of the three compliance standards in the ISO 9000 family.* These companies include not only manufacturing facilities but also the service sector, with doctors, lawyers, and other service organizations obtaining certification.

Buckman Laboratories obtained its first ISO 9002 registration for its South African manufacturing facility in 1988, shortly after the standards were published. The original intent for obtaining this certification was to continue to qualify for government contracts. Following the certification, however, this facility noticed significant improvements in the plant, including a dramatic reduction in the number of nonconforming products. Because of the benefits identified with the ISO 9002 quality system design, Buckman became involved in a corporate-wide move to qualify all its manufacturing facilities under the ISO 9002 standards. Our facility in Ghent, Belgium, was certified in May 1991. Our U.S. facilities in Memphis, TN, and Cadet, MO, were certified in February 1992. Our Brazilian and Canadian facilities were certified earlier this year, and our plant in Mexico is now scheduled for certification later this year. More importantly, our certified plants undergo periodic surveillance audits each year, and all have maintained their registration.

Following certification at our U.S. plants, we began to see improvements in our ability to manufacture products that met our specifications the first time around, or what we call Right the First Time production. We also realized that the disciplines and structures developed under our ISO system could serve as the basis for even more improvements in our quality system. In the remaining text, some of the benefits of ISO 9002, as well as some of the continuations from the basic ISO 9002 structure, are reviewed.

ISO certification provides benefits

The ISO 9000 standards constitute models for a quality system. It is quite possible to design a quality system to the ISO 9000 standards and never have it certified. There are, however, benefits to be realized from completing the final steps and obtaining certification.

Certification requires periodic surveillance audits. Through these audits, independent auditors review your quality system to ensure that it meets the intent of the standards. They also ensure that you are following your documented procedures. This process of auditing and maintaining your ISO registration helps assure that quality will continue as an important and visible function within the organization. Everyone knows that procedures must be performed as documented because an independent, outside organization will come into the facility and audit the quality system. Without ongoing certification,

*CEEM Information Services, Fairfax, VA, July 1994.

some departments, or individual employees, may be tempted to cut corners. As part of a certified quality system, however, they know that procedures must be documented and quality records kept, and that the price of omission could be the loss of registration.

Another benefit is a reduction in customer audits. Traditionally, customers wanting to know the type of quality system controls in place at their supplier's facilities audited the plants against predetermined criteria. With the increased awareness and acceptance of the ISO 9000 standards, more customers are evaluating their suppliers against these standards. For those suppliers with certified quality systems, their customers need not audit them because an independent company does it for them.

Documentation, nonconformance, and corrective action

Besides benefits gained from getting your quality system certified to an ISO 9000 standard, there are also significant benefits most companies will realize as part of the design of the quality system itself. There are many benefits, but for the purposes of this discussion we will concentrate on three: documentation, nonconformance, and implementation of corrective action.

The documentation requirements under ISO 9000 provide the foundation that allows a company to always understand its processes. The standards require a company to create and write procedures on a variety of areas, yielding a complete written record of how the company operates. This documentation also provides a vehicle to stabilize continuous improvement efforts. A change in procedure must be followed by a change in the documentation. Once the documentation has been changed, the procedure must be carried out in the manner documented, or the company will not be in compliance. If 10 people are performing the same task, and an improvement to the process is made, the changes in the documentation will assure that all 10 people shift to the new methodology. The documentation provides a roadmap that everyone can read, solidifying all changes that are made.

Because the standards require documentation and quality records, these materials are available if your customer has a question about the way your company operates. If a question is ever raised, the documentation and records are there to show exactly what is done.

Most of the improvements under ISO 9000 begin with the elements of nonconformance and implementation of corrective action. The standards say that products must be approved before they are sold. If a product does not meet the requirements or specifications originally established, then it must be segregated. The company must then determine the reason for the nonconformance and implement corrective action. This simply means that when a company makes something that does not meet requirements, they have to do something about it so it does not happen again. In the past, records may not have been kept on nonconforming products, so there may not have been a way to track and measure the amount of nonconformity. Even if records were kept, most companies did not force themselves to determine true root causes and implement corrective action for each product nonconformance. Under the ISO 9000 standards, companies are forced to keep records on nonconforming products and, more importantly, to determine the root cause and take corrective action.

The idea of nonconformance under the ISO 9000 standards also includes a provision for internal audits. This aspect looks at the systems used throughout a company. The benefit of an internal audit is that it provides a review of a company's procedures and processes and helps to keep the company compliant with the standards.

With each of the nonconformance systems, ISO requires corrective action. When a nonconformance is identified, the standards force you to perform an analysis to determine the root cause of the problem. Once the root cause is identified, you must take corrective action to eliminate it. Once completed, you must then review the action to determine whether it was effective. Detailed records of this process must also be kept that will, over time, show a very clear picture of a company's improvement efforts.

Nonconformance and corrective action, as mandated under the ISO 9000 standards, are the single most important elements in the development of a culture of continuous improvement. It assures basic improvements in manufacturing products to specification, and it guarantees that a company will continue to meet the intent of the ISO 9000 standards.

We have looked at some of the benefits that can be expected from the ISO 9000 standards. Life must, however, continue after ISO, and a stream of additional benefits can be realized by adopting the disciplines of documentation, nonconformity, root-cause analysis, and corrective action to other areas of your quality system.

Companies must grow beyond ISO 9000 standards

Looking beyond the standards caused Buckman to realize that procedural and process nonconformance was only discovered during internal audits. For our quality system to be successful, we identified the need for a more comprehensive system that would give everyone a method to eliminate nonconformance identified within their area. This system would allow everyone to communicate quality nonconformity as they saw it.

To put this informal audit system into operation, we took what we had learned from the ISO 9000 standards—nonconformance, root-cause analysis,and corrective action—and applied it to our own internal program. This program, called the Corrective Action Request (CAR) system, was designed to give everyone, including customers, a voice in identifying and correcting quality nonconformity (**Fig. 1**).

Under the CAR system, sales associates, internal employees, and customers can fill out a CAR form describing a problem. The form is then logged at the Quality Assurance (QA) De-

1. Buckman's Corrective Action Request (CAR) form provides the method for employees and customers to describe a problem.

CORRECTIVE ACTION REQUEST- CAR #: CA9 - -

ROUTING : _____ —> QA Dept. —> TO: _____ —> _____ —> QA Dept. —>_____ —> _____ —>_____ —> _____

SUMMARIZE NONCONFORMANCE *(Completed by associate requesting corrective action. Continue on back if additional space is required.)*

SIGNATURE_____ DATE_____

INVESTIGATION/CORRECTIVE ACTION *(Completed by associate performing investigation & C/A. Continue on back if additional space is required.)*

WHAT WAS THE ROOT CAUSE OF THE PROBLEM?

WHAT WAS THE CORRECTIVE ACTION TAKEN?

SIGNATURE_____ DATE_____

CORRECTIVE ACTION ACCEPTED? *(To be completed by the QA Department.)*

SIGNATURE_____ DATE_____

CORRECTIVE ACTION EFFECTIVENESS *(To be completed by the original issuing party.)*

WAS THE CORRECTIVE ACTION EFFECTIVE? (Please check appropriate box) YES - ☐ NO - ☐

COMMENTS: (Please add comment if necessary. Continue on Back if additional space is required.)

SIGNATURE_____ DATE_____

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partment and is sent on for investigation and corrective action. The corrective action taken is reviewed by the QA Department, and, once resolved, the CAR is initially closed. After a period of time, the CAR is reviewed with the issuing party to assure that the action taken did eliminate the problem. This final review step ensures problems are eliminated. If, during the review, it is determined that the nonconformity was not eliminated, the process is repeated.

Some areas covered under the CAR system include supplier nonconformance, requests for documentation changes, internal procedural errors, and those situations where we have not met a customer need. Once identified as a nonconformance, the same corrective action procedures defined under the ISO 9000 standards are applied.

Keys to improvement

The disciplines involved in maintaining ISO 9000 registration become ingrained in a company's operations. Consistent evaluation of nonconformance and implementation of corrective action become the normal method of operation. Because these disciplines are effective and become a part of the company-wide culture, companies can apply these methods to a variety of other areas where improvements are required.

Statistics are an area in which the disciplines learned under an ISO 9000 system can be applied. This is accomplished through definition of a statistical nonconformance system. One of the classic problems with statistical process control (SPC) is that it generates dozens of charts, many of which are never used, analyzed, or understood. Evaluating a process using SPC for out-of-control or special-cause situations, a "nonconformance system" can be created. If a process goes out of control, as defined statistically, this can be regarded as a nonconformance to the system. Nonconformance leads to root-cause analysis, followed by implementation of corrective action. The same discipline learned under ISO 9000 thus can help companies take action against special-cause situations and ensure continuing quality improvement.

I believe that you cannot improve things you do not measure, so defining goals is critical for quality improvement. With initial ISO 9000, these goals begin with manufacturing to your specifications and eliminating nonconformances identified during internal audits. Over time, these goals must grow beyond the requirements of the standards. Another nonconformance system that can be developed uses the Malcolm Baldrige National Quality Award criteria. By evaluating your company's quality system against these criteria, goals are set based on the results of the evaluation. Once these goals are set, you have the foundation for another nonconformance system. If you do not achieve your goal, implement corrective action.

Additional examples of areas where corrective action can be applied are customer satisfaction surveys, internal employee surveys, or lost customer analysis. Any system, in fact, to which a goal can be attached can be considered as a nonconformance system. Once the goal is established, the same basic discipline learned from ISO 9000 can be applied to achieve continued quality improvements. These improvements will far exceed the basic product (specifications) and process (internal audits) improvements obtained from the original ISO 9000 quality system design.

The ISO 9000 standards will provide an environment for looking at problems and for solving those problems so they will not reoccur. They teach us to look at the operations of our company, taking a systematic approach to eliminating nonconformity. They also provide the structure and discipline to continually modify the procedures that will ensure the growth of our quality system. As time progresses, we must create or adjust our definition of nonconformity, which will, in turn, take us farther down the quality improvement road.

Beauty or the Beast? Fortunately, there does not have to be a beast waiting for us after ISO 9000 certification. There can, in fact, be a very real opportunity to apply the lessons learned from ISO 9000 to additional parts of our business. Through these lessons, we can reap the benefits of continuous quality improvement.

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