Business Performance Excellence

Through Total Quality Management

2nd Edition

Jack P. Pekar

ASTM INTERNATIONAL
Standards Worldwide

Business Performance Excellence through Total Quality Management—2nd Edition

Jack P. Pekar

ASTM Stock Number: MNL22-2nd

ASTM International
100 Barr Harbor Drive
PO Box C700
West Conshohocken, PA 19428–2959

Printed in the U.S.A.

Library of Congress Cataloging-in-Publication Data

Pekar, Jack P., 1940–

Business performance excellence through total quality management/Jack P. Pekar.
p. cm.

Rev. ed. of: Total quality management/Jack P. Pekar. 1995.

"ASTM stock number: MNL22-2nd."
Includes index.
ISBN 978-0-8031-7005-6
1. Total quality management. I. Pekar, Jack P., 1940– Total quality management. II. Title.
HD62.15.P46 2009
658.4′013—dc22 2009020940

Printed in Dayton, Ohio
November, 2009

Foreword

Committee F16 on Fasteners wants to do all it can to assure that the fastener industry is able to comply with the Fastener Quality Assurance Act (FQA) of 1990, which was last amended on June 8, 1999. F16 is comprised of fastener manufacturers, users, and distributors, all of whom have a large stake in this law. As a consequence, F16 requested and sponsored me to write a manual that would show our members how to comply with the law and remain competitive. But this book goes beyond assisting those in the fastener industry to cope with the FQA. It can be of benefit to any industry or enterprise because it is about Performance Excellence through Total Quality Management (PE/TQM). This revision puts more of a focus on criteria that shapes the guidelines for performance excellence defined in the Baldrige National Quality Program.

This book was written so that others may share what I have learned through 43 years in the quality profession. It is a book that presents principles and guidelines that, when applied, can be used to develop and implement a total quality management system. Today, more than ever, we in the business community face challenges at every turn from every corner of the world. Those businesses that survive will be those that demonstrate leadership innovation and apply a customer-centered and process-driven approach to their business practices.

Those who practice the teachings in this book have a better chance than most to achieve success. They may find the journey difficult and cluttered with obstacles that impede their progress, but, if they are true leaders, their message will be heard. They must not and cannot be discouraged for they must lead us to and through the new global market.

Contents

Introduction vii

Chapter 1—Management's Role 1

Chapter 2—Strategic Planning 6

Chapter 3—Continuous Improvement 17

Chapter 4—Quality Systems 24

Chapter 5—Quality Reporting 29

Chapter 6—Supplier Partnerships and Control 33

Chapter 7—Statistical Quality Control Six-sigma, and Lean Manufacturing 37

Chapter 8—Quality Manual Guidelines for ISO 9001 45

Chapter 9—Compliance with Public Law 101-592 49

APPENDICES

Appendix A: Synopsis of ASTM Standards F1469, F1503, F2282, and F2688 51

Appendix B: Supplier Quality Systems Survey 52

Appendix C: Attribute Gauge Analysis Form 57

Subject Index 59

Introduction

Because there is no single path to achieving performance excellence within an organization, there are no hard and fast rules to follow to become a world class company.[1] This is because all organizations have their own cultures, people, and technologies. What may work well for one company will not necessarily work for another. The only constants are basic criteria/guidelines for performance excellence, which, when followed, lead to success. These criteria/guidelines are as follows.

Leadership Commitment

The leadership of an organization must be committed to continuous improvement. This commitment must be visible throughout all layers of management. Management must "walk the talk." Only when management is committed to create a sustainable, high-performing organization with a business and customer focus will employees excel at what they do. It takes time to change work cultures and work habits, but with perseverance the message of enlightened management will prevail. Employees want to do a good job; all they need are the right tools and the right systems. These can be supplied only by management.

Customer and Market Focus

The organization must be customer-centered. Everyone in the organization must understand that without a customer-centered approach to business practices there would be no purpose to their work, no repeat business, and no positive referrals. What must also be understood is that the external customers are served by the internal customers (employees). There is, therefore, a need to focus on the requirements and expectations of both internal and external customers. One of the first steps management should take in this regard is to conduct surveys of the external and internal customers. The voice of the external customer will provide knowledge about the needs and desires of current and future customers. Employees (internal customers) should be apprised of the results of external customer surveys so they understand the needs of the market that they serve. A truly committed management team will also allow employees to see the results of internal surveys. This brings "the good, the bad, and the ugly" to the table for discussion. The good can be improved upon. The bad can lead to opportunities for improvement. The ugly must be addressed through open, two-way communication with cross-functional teams to find solutions. The voice of the internal customer may best be accessed through two survey tools provided by the Baldrige National Quality Program: Are We Making Progress? and Are We Making Progress As Leaders?

Workforce Focus

The organization must assess the current skill level and awareness of total quality principles of all employees. This assessment begins with top management and moves throughout the organization. Begin by training top management on total quality and performance excellence. Once top management is trained and committed to these criteria/guidelines, it will be easy to train those who follow. This training will pay high dividends at every level in the organization. Through training, be sure that all employees have the necessary skills and technical knowledge to perform their jobs effectively. Thus they may be counted on to be effective participants in contributing to the total quality and over-all improvement process. Information should be provided to employees describing external educational programs available to them through various professional organizations and colleges. By creating an awareness of these opportunities, the organization demonstrates its commitment to continuous improvement of employee skills.

Soon after the commencement of training, management must provide opportunities for employees to apply what they have learned. They need to test their skills. They will not and should not be content with the way things are. Every aspect of their job should be evaluated and measured against the new paradigms. This will bring new challenges to their managers. The managers, in turn, through their own training, will now be equipped with the attitudes and analytical skills to consider their suggestions. They will no longer feel the threat of losing control.

Measurement, Analysis, and Knowledge Management

In order for management or employee improvement teams to determine if they made process improvements, they need to know where they were when they began. If we do not have historical data to let us know, we must at least determine where we are through a short-term study.

The first step is to define the organization's critical performance indicators (CPIs), which are defined as those measures that contribute to customer satisfaction. There are several tiers of indicators in any organization, and they can be broken down as primary, secondary, and tertiary. Examples of first-tier CPIs include On-Time Delivery, Customer Satisfaction Indicators, and Cost of Quality. Second-tier CPIs are measures that contribute to the first-tier CPIs. Examples of second-tier CPIs for On-Time Delivery may be quote turn around, manufacturing lead time reduction, and supplier performance. Third-tier CPIs are the employee involvement action items. Examples of third-tier CPIs for manufacturing lead time reduction could be (1) set up reduction and (2) scrap and rework reduction. CPIs are discussed in detail in Chapter 2. In general, the organization needs to measure, analyze, review, and improve its performance through the use of data and information at all levels and parts of the organization.

Strategic Planning

It is the responsibility of senior management to understand the organization's competitive environment, their key strategic challenges and advantages, and their system for performance improvement. Senior management along with their management team need to focus on actions that include on-

[1] Portions of this Introduction were taken either in whole or in part from an SME technical paper by the author entitled, "Continuous Improvement—Managing Yesterday, Leading Today." Reprinted with permission of the Society of Manufacturing Engineers, Copyright 1993, from the Cold Forming '93 Conference.

going improvements in productivity that may be achieved through eliminating waste, improving customer satisfaction, maximizing return on investment, and improving quality through a strategic action plan. This plan should include Six-sigma and lean manufacturing principles, or variations of these principles. One tool for this assessment is the Organization Profile analysis available through the Baldrige National Quality Program. This document is free and can be obtained from NIST.

The completion of this assessment sets the context for the way your organization operates. It will clearly define your environment, key working relationships, strategic challenges and advantages, and provide you direction in guiding your performance management system.

Process Management

The organization needs to understand its business processes, and then design, manage, and improve them to deliver customer value and consistent organizational success and sustainability. One of the more useful tools to assess your business and its current state is to conduct an analysis of your organization. The Organizational Profile work sheet serves very well in providing you with the current state of your business. Once an understanding of the organization's business processes are known, they may be managed and improved upon through such documents as ASTM F2688-08[2] (Standard Guide for System-Based, Customer-Centered Quality Plan for Manufacturers), ISO/TS 1694[3] (Quality Management Systems—particular requirements for the application of ISO 9001:2000 for automotive production and relevant service part organizations), ISO 9001[4] (Quality Management Systems Requirements), and ASQ 9001 (Quality Management Systems). The application of statistical process control (SPC), Six-sigma, and lean manufacturing in the organization's processes will facilitate the effective elimination of waste and create processes that are truly efficient.

Recognition and Awards

Everyone appreciates a pat on the back after they have achieved a noteworthy goal or successfully completed a difficult or important task. This encourages further participation by the employee and shows other employees that their efforts are appreciated. When a team has met an established goal, the entire team should be recognized.

The form of recognition should fit the accomplishment; in other words, the value of the recognition should be commensurate with the value of the accomplishment. Also, when recognition is given, it should be consistent. To assure consistency, a panel of management and nonmanagement employees should be established to set up a recognition program to acknowledge those individuals and/or teams who meet company objectives.

Communication

The organization must communicate with the work force, their suppliers, and their customers. I cannot provide enough differentiation among this trilogy to say one is more important than the other. All participants in this trilogy of communication must interface for an organization to be truly successful. Within the organization, employees at all levels need information about continuous improvement projects so they can become aware of progress, their contribution, and the effect these projects have on critical performance indicators. Business goals must be communicated to suppliers. Suppliers should be viewed as extensions of the organization who contribute to the overall success of continuous improvement. They should be part of decisions to utilize purchased services.

Suppliers are specialists in their fields of expertise; therefore, their input should be required when decisions are made to use them. World class purchasers understand the difference between price and value. As purchasers (customers) we expect, and should demand, products that contribute to our success. The voice of the customer must be heard. Customers are the reason we are in business. Without customers, no provider of goods or services could survive. To understand customers' needs, we must listen to their messages. Invite existing and potential customers to your facilities and ask them to apprise your management team of their business objectives. Ask how you can assist them in achieving their goals.

Results

An organization must make it a point to examine the effectiveness of performance and improvement in all eight of the previously mentioned criteria on the path to Performance Excellence: Leadership Commitment, Customer and Market Focus, Workforce Focus, Measurement, Analysis, and Knowledge Management, Strategic Planning, Process Management, Recognition and Rewards, and Communication.

[2] Annual Book of ASTM Standards, Vol 01.08.

[3] Available from Automotive Industry Action Group (AIAG), 26200 Lahser Rd., Ste. 2000, Southfield, MI 48034-9738.

[4] Available from the American National Standards Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036.

Acronyms

ANSI	American National Standards Institute
ASQ	American Society of Quality
ASTM	American Society for Testing and Materials
BNQP	Baldrige National Quality Program
CMM	Coordinate Measuring Machine
CPI	Critical Performance Indicators
DMADV	Define, measure, analyze, design, verify (used in Six-sigma applications)
DMAIC	Define, measure, analyze, improve, control (used in Six-sigma applications)
E&I	Empowerment and Involvement
FAC	Fastener Advisory Committee
FMEA	Failure Mode and Effects Analysis
FQA	Fastener Quality Act
HRC	Hardness Rockwell C
JIT	Just in Time
LPA	Layered Process Audits
NIST	National Institute of Standards and Technology
NVLAP	National Voluntary Laboratory Accreditation Program
P&IC	Production and Inventory Control
PE	Performance Excellence
PE/TQM	Performance Excellence/Total Quality Management
PIE	Plan, Initiate, Evaluate
QFD	Quality Function Deployment
R&R	Repeatability and Reproducibility
SCD value	Severity rank times the Capability rank times the Detection rank
SEM	Scanning Electron Microscope
SME	Society of Manufacturing Engineers
SPC	Statistical Process Control
SPQP	Service/Product Quality Planning
SQC	Statistical Quality Control
TCQ	Total Cost of Quality
TQM	Total Quality Management

1

Management's Role

THE PRIMARY ROLE OF MANAGEMENT IS TO PRO-vide employees with the leadership necessary to meet the goals of the organization. This leadership must reflect the principles of total quality management. These principles were presented in the Introduction: Leadership Commitment, Strategic Planning, Customer and Market Focus, Workforce Focus, Measurement, Analysis, and Knowledge Management, Recognition and Rewards, Process Management, and Communication.

Leadership Commitment

Management must first examine how they manage. Is their style tailored to encourage input from other managers and departments? Or is their style that of not allowing other departments or disciplines to influence their decisions? In other words, do they operate as team leaders or as silos? When I refer to managers operating as silos, I mean that they stand alone within the organizational structure by excluding input from other managers or departments. This concept is explained further below.

Silos

Management in the past relied on experts in given disciplines to develop systems and procedures to guide the organization. These experts headed up their own departments (silos) and had specialists working for them who created the culture and systems for the *silo master*.

The silo master made it clear to all other silo masters in the organization how his department functioned and that there would be no interference from other groups or departments. This allowed the silo master to keep control of his territory. This also assured that the other department managers did not fully understand the requirements for positive interaction between groups or departments within the organizational structure. Here is a classic example of how silos can thwart satisfying customer requirements. The marketing group receives an order from a customer and tells the design group what the customer wants. The design group gives their interpretation of the customer's needs to the manufacturing engineering group. Manufacturing engineering tells manufacturing what process to use to create the product that will satisfy the needs of the customer. Manufacturing does their very best to manufacture the part according to criteria supplied by manufacturing engineering. The quality department inspects the final product and decides it is manufactured incorrectly. Rework is performed and the part is shipped to the customer. The customer rejects the part because it does not meet his requirements! (See Fig. 1-1.) None of the various department heads worked with others as a team to determine customer needs.

Management needs to break down silos in their organizations because they create waste, redundancy, and poor quality. We are getting better today at breaking down silos and allowing interaction through cross-functional team management. Management should evaluate themselves to determine if their management style is autocratic or team oriented.

Autocratic Management

I remember when I first started working. I was told that in order to succeed and to keep my job, I had to remember two rules. Rule 1: The boss is always right. Rule 2: When the boss is wrong, remember Rule 1. Those were the days when standard operating procedures/systems developed by the "boss" were more important than people. Employee involvement consisted of doing only what the boss told you to do, whether it made sense or not. Management felt that empowering the worker took control away from management. Standard operating procedures/systems developed by those who perform the work or task with management approval, provide a far better approach to conducting business.

Switching to a management style that encourages employee involvement and empowerment is a tough transition for many. Unless special training is provided for middle and first-line management, the transition may never take place. And, unless upper management invests and participates in this training, the organization is bound to fail. It will be overtaken by other organizations who have invested in their most valuable resource, their employees, and are cashing in on that investment. Employees of an enlightened organization contribute every day to improved operations and systems.

Once management has committed itself to breaking down silos, it must embrace the concept of Team Management.

Team Management

Gone are the days when managers are expected to be proficient in only one discipline. Today managers must be part of a management team, and they must have a working knowledge of their peers' responsibilities. For example, the quality manager needs to understand how design engineering, manufacturing engineering, purchasing, sales, production control, customer service, and every other department functions. And every other manager should know the roles of the others.

This is not to say that they need to be as well trained in the other disciplines as their peers, but they must understand how the entire organization functions. We want to break down silos so we can move freely throughout the organization. This creates another dilemma because now we

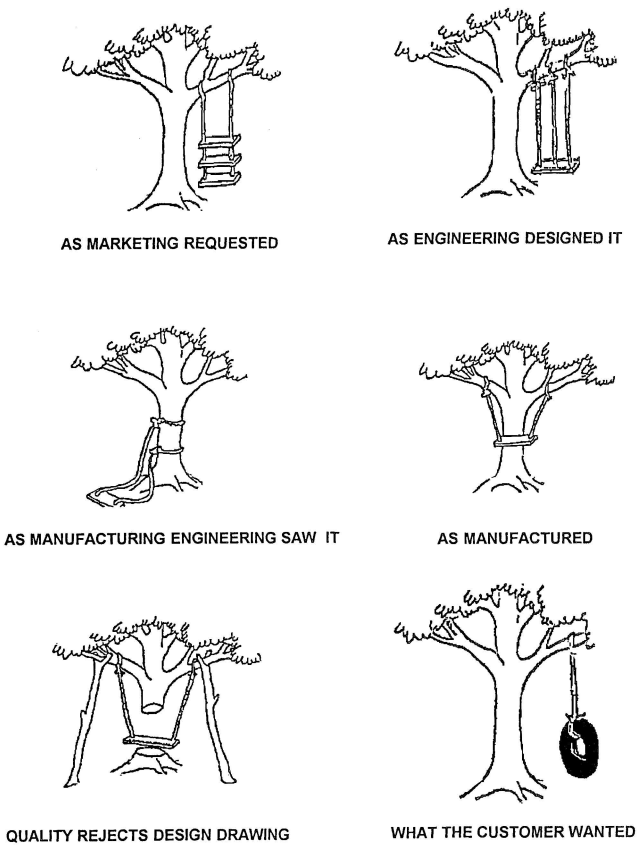

Fig. 1-1—Customer requirements.

need to allow managers who are outside our responsibility to be permitted, even welcomed, to handle situations that structurally may belong to us.

It is time for the goose story. We, as managers, should take a lesson from the goose. I am sure you have observed geese in flight. They fly in a pattern that forms a horizontal V. There is a good reason why geese fly in a V pattern. The lead goose breaks the air current and creates an uplift behind him that the other geese can take advantage of. The second tier of geese likewise does the same for the third tier and so on and so forth for the entire flock.

The lead goose eventually tires of butting his head against the wind, so he drops back in the formation. Here is when something interesting takes place. Another goose from the flock moves to the front to assume the lead. This goose does so until he tires. Then he drops back and another goose moves in to lead. Geese in a flock are willing to follow the lead of whoever is leading at the time because they all have a common goal.

We can learn a lot from the goose! Geese have learned how to work as a team. All in the flock are willing and able to lead when necessary. The leader who drops back is not intimidated by another taking his place. He understands that for now it is best that someone else assumes leadership.

Customer and Market Focus

Management must develop an attitude that puts customer needs and market conditions in every decision made. The customer is the reason we are in business. Without customers there would be no job to perform, no requirements to be met, and no reason anyone would wish to purchase your company's stock.

As explained in the Introduction, there are two kinds of customers: *internal* and *external*. External customers provide income for the organization through purchasing goods or services. Internal customers (employees) satisfy the requirements of the external customers and the requirements of others in their own organization. Both are important and need to be understood for an organization to succeed and prosper.

External Customers

The expression "The customer is always right" is not always true; however, one right of the customer is always true: "The customer has the right to purchase from whomever he wants." With this in mind, we should make every attempt to make sure the customer wants to buy from us.

To assess the needs of your customers, utilize input from all customer contact personnel. In an organization that follows PE/TQM principles, input can come from the sales representative, your marketing group, the quality department, manufacturing, customer service, and engineering. The method in which the input is provided can be *reactive* or *proactive*. Both sources should be looked upon as opportunities for satisfying your customers' needs.

Reactive input is in the form of customer complaints or from interpreting customer purchase orders or sales inquiries. When customer complaints are received, either as written complaints or in the form of returned goods, some organizations react as fire fighters and focus on the hot spot. They sometimes ignore the system that created the problem in the first place. When a purchase order or sales inquiry is received, often organizations interpret their customers' requirements through the mirror of their own paradigms.

Proactive input is solicited through visits to the customer's place of business, visits to your facility by your customer, customer satisfaction surveys, and by cross-functional teams consisting of employees from customer and supplier facilities. All these activities should be part of management's strategic business plan. The strategic business plan will be discussed further in Chapter 3.

Internal Customers

In a PE/TQM environment, the attention paid to employees is as important as, if not more important than, the attention paid to the customer. The employee is the internal customer of the organization—the individual who can make things happen. His or her understanding of the organization's goals and commitment to customer needs must be complete. This can be assured by following a three-step process that includes (1) an employee survey, (2) an employee training program, and (3) regular communication sessions to continually reinforce the organization's goals and customer needs.

Employee Survey

The employee survey should be designed to provide an assessment of how the employee feels about the company and how he perceives his role to the customer. An example of a survey I used successfully is provided in Fig. 1-2.

The PE/TQM steering committee (discussed in Chapter 3) should review and analyze employee survey results and

(1) How do you perceive your role in service for customers?
_____ Directly Involved
_____ Indirectly Involved
_____ Not Involved

(2) How do feel about service you receive from related departments?
_____ Satisfied
_____ Not Satisfied
_____ No Opinion

(3) Do you have enough authority to make improvements to better serve our customers?

If No, Suggestions: _____

(4) Do you receive everything you need from the previous operation or department to do your job well?
Yes No (circle one)

If no suggestions: _____

(5) If you could make one change in either your department or the company as a whole, what would you change to improve service for our customers?

(6) If you could rate overall the products and services provided to our customers, what would that rating be?
_____ Superior _____ Good _____ Average _____ Poor _____ Other

Please explain: _____

Fig. 1-2—Employee survey.

determine the training program required to bring employees up to speed on company goals. Training can be conducted by inside experts or by using outside resources. There are advantages and disadvantages to both approaches.

The advantages to using inside experts are cash flow containment and assurance that the training is tailored to existing company paradigms. The disadvantages of using in-house experts are having to overcome existing negative perceptions of the expert, if there are any, and removing the expert from his duties to provide preparation and training.

The advantages of using outside sources for training are many. Among them is the natural perception that an outside consultant knows more about a subject than inside people. This advantage can create a more receptive learning environment for the employee. Another advantage is that no time is taken from anyone's schedule for preparation of lesson plans. Two major disadvantages are expense and the fact that the outside resource is not familiar with your company culture.

Both options of training must be evaluated by the PE/TQM steering committee, and selection of training resources should be made on the best fit analysis. The key is to assure that whatever training source is utilized that the source emulates the goals of the organization.

Activities concerning customers need to be communicated to everyone in the organization in a timely manner. Most information can be distributed on a monthly basis, but special news should be disseminated as required. An ideal method of sharing news is through a company's information technology systems (computers, message boards. etc.) that provide information on employees, customers, and continuous improvement activities.

Workforce Focus

Continuous improvement cannot occur within an organization unless training is part of management's agenda.

Leaders in respective departments should take the initiative to conduct an analysis of each employee's ability to perform his or her job. This is often referred to as a *needs assessment analysis*.

The needs assessment analysis should be performed on the job function, not the individual performing the job. Suppose the job is to prepare an accurate product certification document. A flow diagram on completing a product certification is shown in Fig. 1-3.

The focus should be on preparing an accurate product certification, not on the skills of the final product auditor, the material handler, or the typist. Study each step in the flow diagram for the job and determine exactly what is required for that step to be successful. For example, let's look at the step: Inspect All Critical Characteristics Per Sample Plan.

To be successful at this step, each preceding step must have been performed correctly and accurately. All critical characteristics must be identified on the inspection plan or engineering drawing. The sample plan should be available and germane to the product being inspected. The test equipment and inspection equipment should be in full calibration and acceptable for the tolerances being examined. The individual conducting the task must be qualified for the task.

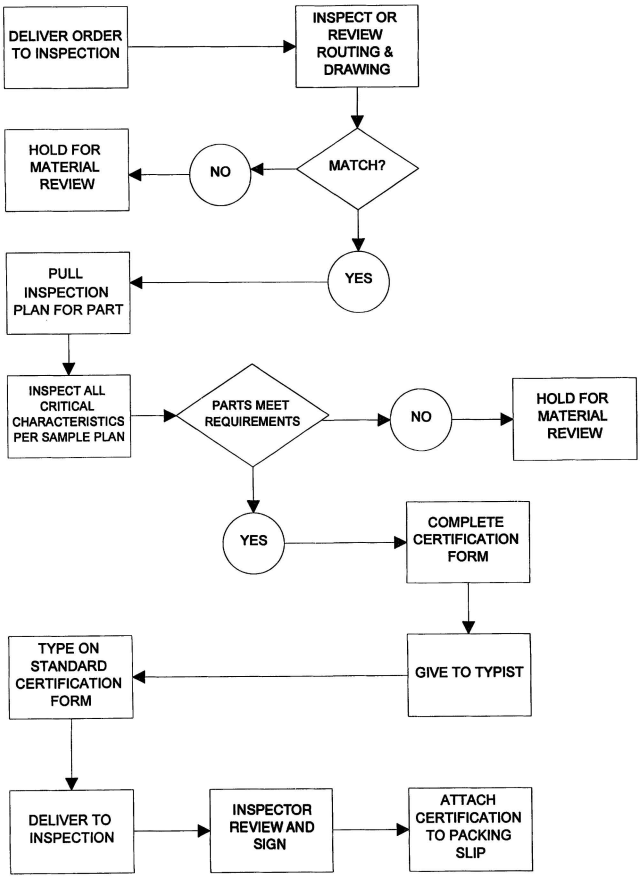

Fig. 1-3—Product certification flow chart.

Any deficiency found in any of the subgroups contributing to the successful completion of the main task of *inspecting all critical characteristics per sample plan* may require training for the individual doing the inspection or correcting some upstream activities.

Empowerment and Involvement

One of the more responsible acts management can perform is recognizing that their employees can make significant contributions to the success of the organization. If management provides the tools and training, a great deal can be accomplished through employee empowerment and involvement (E & I). However, the employee must be properly prepared for such responsibilities.

The first employees that should be prepared for Employee E & I are managers and supervisors. The concepts of PE/TQM must be provided through several training sessions and should be reinforced through appropriate actions from senior management. One of the better methods of demonstrating senior management's commitment to Employee E & I is by forming management teams and allowing these teams to evaluate and suggest how to improve current systems. It is through these management teams that lower-level employee teams are created.

The teams formed at all levels will concentrate on improving the organization's critical performance indicators (CPIs). CPIs are tracked and evaluated through measurement parameters established by management E & I teams.

Measurement, Analysis, and Knowledge Management

Management should establish measurements to track progress on CPIs. The unit of measurement should fit the indicator being evaluated and should be understood by those who contribute to the improvement process for that indicator. For instance, the cost of quality CPI should be measured in dollars and compared to several key values, such as cost of sales or cost of manufacturing. Another example is on-time performance.

This CPI can be measured in several ways, which should all relate directly to customer requirements. For example, this CPI can track orders shipped to customer-required dates (external customer measure), or it could track design engineering input to manufacturing engineering (internal customer measure), or it could track quote turnaround from your suppliers (a measure of your needs as a customer of your supplier).

CPIs will be discussed further in Chapter 2 when methods of continuous improvement are explored.

Recognition and Rewards

Management has the responsibility to provide the work force an environment that is safe and environmentally clean. This environment should also lay the foundation for supporting the employees' quality of work life. Once this foundation has been established, management must develop a recognition and rewards program designed to improve and maintain employee job satisfaction.

A three-tiered system should be developed, which includes (1) day-to-day recognition, (2) informal recognition, and (3) formal recognition programs. The best way to get started is to create a steering committee made up of staff management. This committee can define the scope of the program and establish guidelines to be followed by employee teams established to implement the program. Employee teams should include participants from all levels of the organization.

The steering committee can set the scope of the program to include as many systems as they feel the company can support and effectively manage, but some systems should always be included because of their proven effectiveness.

The following systems, when properly structured and administered, are very cost effective and contribute directly to a company's profitability through various improvements. In no particular order, these proven systems are *pay-for-performance, perfect attendance, service awards*, and *continuous improvement programs*. Pay-for-performance recognizes employees for their performance on the job and should include such criteria as quality of work produced, productivity, attendance, initiative, job knowledge, and safety. An attendance policy should establish rules to define when employees are to be on the job and when they are excused from their job. This may seem like a basic idea, but it is surprising how many companies do not have an established and documented policy on absence from the job. When there is no written policy, there is no consistency, and this leads to dissatisfied employees who see management as untrustworthy or at the very least prone to favoritism. A service awards policy recognizes employees for their length of service with

the company and can be very rewarding in enhancing employee esteem and fostering employee loyalty.

Strategic Planning

Strategic planning is discussed in Chapter 2.

Process Management

Process management is incorporated in Chapters 3–7 as we examine Continuous Improvement, Quality Systems, Quality Reporting, Supplier Qualification, Statistical Process Control, Six-sigma, and Lean Manufacturing.

Communication

Communication is one of the most important guidelines for both management and employees. It is a two-way street, and both should strive to keep the airwaves open. Even though communication is a two-way street, it must start with management. Management should set the standard by creating an environment conducive to openness without fear of reprisal or ridicule. At all times communication must be polite and conducive to enhancing self-esteem. The best way to get started is as with all the other guidelines: establish a steering committee to set the policy and the guidelines for implementation. Then create the opportunity for employee involvement teams to get the program underway.

Some of the more common and effective programs include company newsletters (electronic or paper), staff and employee meetings, and an open invitation from management to allow employees at all levels to hold informal conversations or brainstorming sessions in employee lounges during breaks.

2

Strategic Planning

ONCE MANAGEMENT'S ROLE AND COMMITMENT to quality are defined and established, the top executives of the organization should establish a *quality policy*. The quality policy should state the organization's commitment to (1) continuous improvement and (2) customer satisfaction. These seem like basic organizational goals, but, unless stated, the rest of the organization will not be aware of them or will not have a clearly stated policy from which to develop their own planning for improvement.

Quality policies can be from one paragraph to a full page. The policy's length is not as important as its contents. For lasting impact on employees and customers, it is best to keep them short. After all, it is easier to recall one paragraph than an entire page. An example of a quality policy could be: (*insert company name* here) is committed to continuous improvement and providing products and services that meet or exceed our customers' requirements.

Although short, this policy is very much to the point. It says a lot about the philosophy of the company's top executives. It says, "The most important goal of this organization is to satisfy the customer and to find better ways to manufacture products and/or provide services." I do not want to become too involved with what *quality* means in this quality policy statement. There are as many definitions of this word as there are words on this page. The following are a few definitions of the word *quality* that should provide a basis for developing many more.

Quality is:

1. When a product is consistently represented.
2. An attitude of excellence with an objective of error-free performance shared by all employees.
3. Achieved through dedicated and skilled employees, modern facilities controlled manufacturing processes, continuing education, and a positive work environment.
4. Directly related to superior value and performance and is provided to customers in terms of productivity improvements, reduced operating costs, and outstanding service.

For the rest of this book, quality is simply defined as: providing goods and services that meet or exceed customer requirements. To provide goods and services that meet this definition, the executives of the organization must have a quality strategic plan (referred to as the strategic plan in this discussion). The organization will/should have other strategic plans for such business activities as Product, Marketing and Sales, Engineering, Manufacturing, etc. to lead the company along this path. The plan should contain both long-term and short-term objectives. The window for long-term objectives should be no more than 4 years and preferably 3 years. The world changes so fast that planning more than 4 years ahead is not practical. Markets change at an almost constant pace. Customers' requirements do the same.

A long-term strategic plan should consist of four main programs. There should be: (1) a program for futuristic quality planning, (2) a program for service and product improvement, (3) a program for employee involvement and education, and (4) a program for business systems. These programs require a mission statement so that the goals of the program are understood. As with the quality policy statement, the mission statements for these programs should be short and to the point. This gives precise direction to steering committees implementing these programs. Mission statements for the programs I recommend are:

1. *Futuristic quality planning*—Develop and drive business decisions that utilize quality tools and concepts to assure the successful introduction and implementation of new products, processes, and services to our customers.
2. *Service and product improvement*—Develop and implement programs to improve office and manufacturing operations, processes, and systems leading to improvements and consistency in service and products, and reductions in internal waste.
3. *Employee involvement and education*—Utilize the inherent knowledge and expertise of our employees to identify and participate in opportunities for improvement, and provide appropriate education as needed in support of these goals.
4. *Business systems*—Develop and manage the business systems required to assure quality, improve operations, and support our internal and external customers.

These programs require further definition to understand how they are applied to effect continuous improvement.

Futuristic Quality Planning

Futuristic quality planning is necessary to assure successful applications of new systems, processes, and products. Futuristic quality planning applies equally well to existing processes or products because it perpetuates continuous improvement. This planning program almost always requires the use of cross-functional teams. The core members of this team should consist of people who have the necessary authority to make decisions that support the program. During the course of planning activities, it will often be necessary to recruit employees who have special insight or knowledge of the process being evaluated.

It is best to use a structured approach for this planning process. This will assure consistency of purpose and allow easy inclusion of participants who have had experience on other quality planning teams.

A method I have applied over the years fits the needs of both service and product manufacturing. Both activities require futuristic quality planning to assure efficiency of operations and customer satisfaction. Service/product quality planning (SPQP) is a structured approach that can be applied to any business activity. It does not matter if we are working in a manufacturing or service environment. It does not matter if we are looking to improve office systems or manufacturing processes. The principles are the same:

(1) flow chart the process chain for the activity or product;
(2) assess the current method and effectiveness of quality control;
(3) do a failure mode and effects analysis of high-risk process steps; and
(4) develop a control plan to assure quality.

The SPQP process is designed to improve the quality of current services and products. When new services or products are under consideration, another quality tool should be applied to achieve maximum customer satisfaction. This other tool is quality function deployment (QFD). QFD is a very structured and extensive analysis of customer requirements and needs. The study and application of QFD warrants a book of its own and will not be covered in this manual.

We can still develop a strategic plan for customer satisfaction using only the tools contained within SPQP when applied toward new services or products if the customer is permitted to participate. I feel that most readers of this book are more interested in finding methods to improve current services, processes, or products. The study of QFD is recommended for marketing functions and design engineers. The steps and tools required to prepare an SPQP are as follows:

Phase 1: Flow Chart

There are universal rules to follow when preparing a flow chart. A square box should be used to describe each major process step involved in creating the service or product. Arrows should be used to show the direction each process step takes as the total process evolves. Diamonds should indicate decision points along the process chain. Either inside or adjacent to the diamond is usually a question. Process flow lines (arrows) from the diamond points are used to act upon the answer and lead to the next process step. Other universal symbols are used to reduce the amount of text contained in a flow chart. One example is an inverted triangle to indicate that an evaluation or an inspection must take place at a particular process step.

An example of a flow chart using these symbols is shown in Fig. 2-1. This is a flow chart for heat treating a threaded bolt in a molten salt bath. This flow chart has ten process steps. Each individual process step could be expanded to describe the actions necessary to complete its task, but generally this is not necessary unless that particular step needs to be improved upon. This process has two decision points controlled by the furnace operator. A "yes" answer by the furnace operator allows the process to continue, but a "no" answer requires assistance from quality control.

Phase 2: Flow Chart Analysis

After the process is defined so that each major process step is identified, the next phase is to assess the contribution each

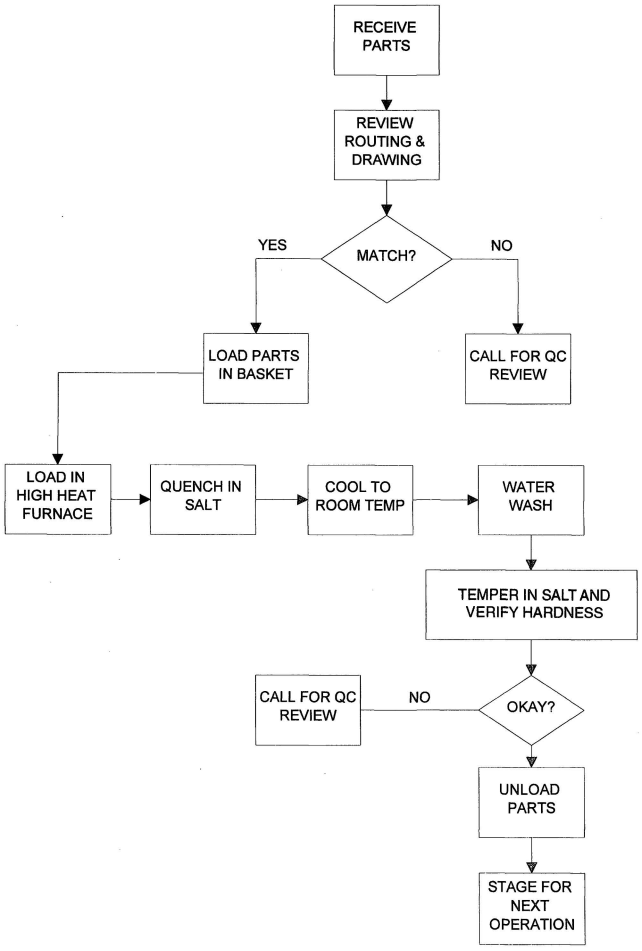

Fig. 2-1—Basic salt bath heat treat process flow.

step has in reaching the desired end result of the process. In this case, the end result is a bolt (or a processing lot of bolts) meeting all metallurgical and design requirements after the salt heat-treating process.

Let us review the process step LOAD PARTS IN BASKET (see Fig. 2-1). This step requires the furnace operator to verify several facts to assure compliance with meeting all quality requirements of his work order. These quality requirements are the contributions that this step has in satisfying the metallurgical and design requirements for salt heat treating.

The operator has to assure that all paperwork received with the product matches. This includes drawings, manufacturing routings, the heat treat process sheet, the quality assurance control plan, etc. The operator must assure that when the parts are loaded into the basket the parts are positioned so that there will be an even transfer of heat during the heat-treating operation. The operator must assure that the parts are positioned to minimize distortion. And the operator must assure that if there are parts from other orders in the same basket, these parts will have weight and mass similar to the parts for the current order. All aspects of this one step, LOAD PARTS IN BASKET, can be evaluated as to its overall effectiveness.

In the flow chart analysis, we evaluate each step in a process as to the severity of failing to perform the step correctly,

TABLE 2-1—Service/product quality plan—severity assessment guidelines.

Rank	Description	Result
5	Safety related characteristic	Failure to satisfy this requirement could result in unexpected and/or catastrophic failure, leading to personal injury or property damage.
4	Critical characteristic	Failure to satisfy this requirement could either result in a significant loss in performance or cause the end user to produce a product that does not conform to his or her customer's requirements or would prevent or significantly hamper a following operation from performing its function.
3	Functional characteristic	Failure to satisfy this requirement could prevent the product from being assembled and used as intended, lead to more variability in performance than is normally anticipated, or be perceived as poor quality by the final customer, or a subsequent operation would have some difficulty in its process due to the nonconformance.
2	Nonfunctional characteristic	Failure to satisfy this requirement will not have any appreciable impact on performance. Most cosmetic requirements shall be considered nonfunctional characteristics unless there is a history of customer complaints. Cosmetic requirements that have resulted in complaints will be considered a functional characteristic. Subsequent operations would see no appreciable difference in performance.
1	Process characteristic	Failure to satisfy this requirement has no impact on the finished product or the manufacturing process.

Note: *The severity assessment* rates the overall importance of each potential product nonconformance to the process and final customer.

the capability of the process itself to perform the step correctly, and the probability of knowing when the process is not performing as expected. We assign values to the severity, capability, and detection criteria to weigh the results so it is possible to prioritize required actions when the failure mode and effect analysis (FMEA) is prepared. The guideline values for severity, capability, and detection are presented in Tables 2-1–2-3, respectively.

To see how these guidelines apply, let us continue to work with our example for heat treating. In Step 3 (see Fig. 2-1) of LOAD PARTS IN BASKET, the SPQP team made the following decisions as shown in Table 2-4.

1. For "paperwork matches," the team chose a severity rating of 3 because they felt that incorrect information as to material type, for instance, would prevent the product from responding as expected in the high-heat furnace. A capability of 3 was chosen because past experience has been positive with hardly any cases of mixed paperwork. For detection, the team chose 1, because mixed paperwork is very easy to detect when it occurs.
2. For "parts are positioned to assure even heat transfer," a 4 was chosen for severity because failure to satisfy this requirement could result in nonconformance to metallurgical properties. A 3 was chosen for capability because the baskets are designed with a partition that properly spaces the parts for even heat transfer. When it came to detection, the team picked 2 because if the op-

TABLE 2-2—Service/product quality plan—capability assessment guidelines.

Capability assessment	For manufacturing processes with documented process capability data	For manufacturing processes without documented process capability data
1	$Cpk > 2.0$	N/A
2	$1.67 < Cpk < 2.0$ or $Ppk < 2.0$	N/A
3	$1.33 < Cpk < 1.67$ or $1.67 < Ppk < 2.0$	Although documented process capability data are not available, past experience with this process on similar products was very positive.
4	$1.00 < Cpk < 1.33$ or $1.33 < Ppk < 1.67$	Very few known problems occurred when using this process on similar products in the past.
5	$Cpk < 1.0$	Either this process is known to be a source of scrap and/or discrepant material when used on similar products or there are no historical data for this process.

Note: This assessment uses the formula min. $[(\bar{x}-LSL)/3\sigma, (USL-\bar{x})/3\sigma]$ for both *Cpk* and *Ppk*.

TABLE 2-3—Service/product quality plan—detection assessment guidelines.

Detection assessment	The detection assessment rates the probability that the current inspection and SPC system will find a nonconformance should it occur.
1	A nonconformance will almost always be detected. Either the process automatically detects a failure or a high capability has been established and SPC is appropriate, understood, and used to run the process.
2	There is a good chance of detecting a nonconformance. SPC is generally understood, and usually reacted to in a capable process, or some form of 100 % inspection is used.
3	The current system may detect a failure. SPC is in place, but not fully understood, or reacted to. Sample inspections are done throughout the run.
4	A nonconformance will probably not be detected. Control charts are done incorrectly or are incomplete; or inspections are limited, such as setup only.
5	There is absolute certainty that a nonconformance will not be detected. No inspection is done.

NOTE: "Detection" must take place before reaching the next applicable process/customer. Inspection by the next process or final inspection is not appropriate in determining this rating.

TABLE 2-4—Load parts in basket.

Process step	Controlled characteristic	SCD	Severity	Capability	Detection
Load parts in basket	Paperwork matches	9	3	3	1
	Parts are positioned to assure even heat transfer	24	4	3	2
	Parts are positioned to minimize distortion	24	4	3	2
	Parts have similar mass and cross sectional area	24	4	3	2

erator put more than one part in a partition it would most likely be detected.

3. For "parts are positioned to minimize distortion," the team gave a severity rating of 4 because failure to satisfy this requirement could result in a dimensional defect. The capability was 3 because of operator experience with the effects of incorrect positioning. The selection of 2 for detection was assigned because a double check of position prior to moving the parts to the high-heat furnace is performed by another operator.
4. For "parts have similar mass and cross-sectional area," ratings of 4, 3, and 2 were assigned for severity, capability, and detection, respectively, based upon the quality history and experience of the operators involved.

This process is completed for each step in the process of salt heat treating. The end result is a compilation of values that allow management to prioritize the analyses and improvements to be made by the SPQP team. An example of the completed process flow analysis for salt heat treating is provided in Fig. 2-2. In this example, one can see that the SCD values (severity rank times the capability rank times the detection rank equals the SCD value) vary from one step to the other and within each step depending on the controlled characteristic. Management must decide which controlled characteristics require further evaluation through a FMEA. Companies usually do not have unlimited resources and must limit the number of projects through the use of a Pareto analysis.

Before going further, I feel it is beneficial to provide definitions of *Pareto analysis* and *Pareto chart*.

Pareto analysis: Analysis of the frequency of events described on a Pareto chart that contribute to an outcome. In the quality profession, outcomes could be rejects, scrap, and other contributors to cost of quality such as incorrect invoices, purchase orders, missing information, etc.

Pareto chart: A simple statistical tool that ranks contributing factors to an outcome according to either cost or frequency of occurrence. This allows for easy prioritization of contributing factors for analysis, thereby keeping cost of analysis low by focusing on the *vital few* and temporarily not analyzing the *trivial many*.

In our example, management decided to perform a FMEA on all controlled characteristics that had an SCD value that exceeded 50. The candidates for FMEAs are shown in Table 2-5. In general, management would also consider any controlled characteristic that had a 5 for either capability or detection regardless of the SCD's value rank.

Phase 3: FMEA

The FMEA is a document designed to accept change. It acts as a futuristic planning tool by identifying potential causes of failure that should be considered in the development of control plans, and audit checklists under layered process audits (LPA). As new controls are implemented, the FMEA is revisited and revised to reflect new process capabilities. FMEAs can be developed for processes or products. In our example, we are creating a Process FMEA for the salt heat treating process. A FMEA is an analytical technique utilized to assure to the best of its ability that all potential concerns (failures) are identified and addressed through some control mechanism. The group best suited to develop a FMEA is manufacturing engineering or a similar group or individual that understands the process (manufacturing or service). The Process FMEA identifies failure modes, explores the effects of the failure on customers, determines the potential causes of those failures, looks at current controls to avoid or identify the failure, and suggests actions to improve control.

The team assigned to complete the FMEA should consist of those closely involved with the process being evaluated. As mentioned earlier, for a manufacturing operation such as heat treating, the best person to lead the team is a manufacturing engineer. For our example, other potential members are the plant metallurgist, laboratory technician, furnace operator, and supervisor of the heat treat department. An example of the FMEA format is shown in Fig. 2-3.

Let us work through an example of completing a FMEA. Each column contains information that leads to information/action for the subsequent column. Our team came up with the FMEA shown in Fig. 2-4 for Process Step 4: High Heat Furnace. The following logic is applied to fill the columns with information:

Process

In this column, list the process step that creates the controlled characteristic under analysis. For our example, the first entry in this column is High Heat Furnace. This process step is the first process step of the process flow analysis that had an SCD value that exceeded 50. To complete the FMEA, the next entries from Table 2-5 would be Cool, Temper, and Hardness Test.

Controlled Characteristics/Fail Mode

In this column, list the controlled characteristic and the anticipated failure mode. For the process step, High Heat Furnace, the controlled characteristic is Part Microstructure. The potential failure modes are: incorrect atmosphere, incorrect furnace temperature, and incorrect time at temperature.

Effects

In this column, list the effects the failure mode would have on the controlled characteristic. In the case of our example, all failure modes identified would cause the wrong micro-

SERVICE / PRODUCT QUALITY PLAN

Phase I - Process Flow Analysis

Product Line: Salt Bath Heat Treat

Manufacturing Location: ABC Company

Original Issue Date: January 1994

Approved By:

Process Flow Diagram	Controlled Characteristics	Original Severity	Original Capability	Original Detection	Original SCD	Revised (9/30/93) Severity	Revised (9/30/93) Capability	Revised (9/30/93) Detection	Revised (9/30/93) SCD
1) Receive Parts	1) Parts are ready for Heat Treat.					4	3	1	12
2) Review Routings and Drawings	2) Parts match metallurgical requirements of the routing and drawing.	4	3	4	48	5	3	2	30
3) Load Parts Into Rack or on Wire and Match Paperwork.	3) - Paperwork for each load match.	3	3	1	9	3	3	1	9
	- Parts are positioned to ensure even heat transfer	3	3	3	27	4	3	2	24
	- Parts are positioned to minimize distortion.	4	3	4	48	4	3	2	24
	- Parts have similar mass and cross sectional area.	3	3	3	27	4	3	2	24
4) High Heat Furnace	4) Part microstructure					5	3	5	75
5) Quench	5) Part hardness					3	3	5	45
	Part microstructure.					5	3	5	75
6) Cool	6) Part microstructure.					5	3	5	75
7) Water Wash	7) Parts free of salt.	2	3	1	6	3	4	2	24
8) Temper	8) Part hardness					5	5	3	75
	Part microstructure.					5	3	5	75
9) Clean	9) Parts free of Heat Treat scale.	2	3	2	12	3	3	1	9
	Parts free of Heat Treat salts.					3	4	2	24
10) Hardness Test	10) Meet part hardness requirement.	4	3	2	24	5	5	3	75
11) Unload Parts From Rack or Wire and Match Paperwork.	11) Parts are free from:								
	- Damage					3	3	2	18
	- Distortion					3	4	4	48
	- Cracks					5	3	3	45
	- Salt					3	4	2	24
	- Paperwork matches parts in individual orders.					4	3	1	12
12) Stage For Subsequent Operations, Black Oxide or Further Processing.	12) Parts are as represented.					3	3	1	9

(Salt-ht1A)

Page 1 of 1

Fig. 2-2—Process flow analysis.

TABLE 2-5—Salt bath heat treat Phase 1 results: Operations in the process that exceed 50 in the SCD rating.

Operation	Characteristic	SCD Rating
Step 4: High heat furnace	Part microstructure	75
Step 6: Cool	Part microstructure	75
Step 8: Temper	Part hardness	75
	Part microstructure	75
Step 10: Hardness test	Meet part hardness requirement	75

structure, leading to product failure at a subsequent operation or in product application.

Likely Causes

At this juncture, we examine the likely cause(s) of the identified failure modes. The likely cause of incorrect atmosphere is contaminated salt. The likely cause for incorrect temperature is a defective furnace thermocouple. The likely cause of incorrect time at temperature is an incorrect setting of the furnace timer.

Current Control Methods

In this column, list the present method of controlling the likely cause(s) of the failure mode(s). In our example, the furnace salt is evaluated every 6 months by the chemical company that the supplies the salt. The maintenance department changes the furnace thermocouples every 2 weeks. The removed thermocouples are returned to the thermocouple supplier to be calibrated and rebuilt as required for future use. The furnace operators monitor the time at heat as indicated on the electronic furnace controller.

Responsibility (Resp. and Date)

In this column, list the person(s) held accountable for applying the current controls. For our example, the heat treat supervisor is held accountable for having the furnace salts evaluated every 6 months, the maintenance department is accountable for changing the furnace thermocouples every 2 weeks, and the furnace operators are accountable for monitoring the time at heat.

Recommended Actions

This column is used when the team identifies an opportunity for improvement on one of the current methods of control. In our example, the team felt that the 6-week interval was too arbitrary and not based on historical data. This meant that during some 6-month periods, the salt bath was almost certaintly out of control or specification and this would not be known except by sporadic metallurgical failures. So the team decided to apply statistical process control (SPC) to the salt bath analysis. A program was established to analyze the bath every week and chart the main variables of the bath on an individual's chart. The bath could then be rejuvenated/replaced based on out-of-control data. In the long run the team felt that money could be saved using this approach by eliminating metallurgical rejections necessitating rework or scrap. The chemical supplier was providing the bath analysis free of charge and was more than happy to acquire statistical data on the life cycle of his chemicals for marketing purposes.

Date

In this column list the name of the individual responsible for the recommended action(s) and the date the action(s) are expected to be implemented or completed.

All FMEAs should be put on a review program to evaluate and ascertain the currentness of the document. One of the better methods is to put document numbers on the SPQP and add them to the company calibration software system. This way, a one year "calibration" cycle can be programmed, and the review process cannot be overlooked. The review does not require a team; all that is required is that the individual making the review be knowledgeable of the process under review. The individual can always solicit, as necessary, the opinion of others in the organization for expert or specific assistance.

Phase 4: Control Plan

The final phase of a SPQP is the development of a control plan. As with the FMEA, a control plan can be designed for a process or for a product. The decision to make a process or product control plan is usually determined by the type of organization. An organization that provides a service, such as a machine shop manufacturing components for a larger manufacturer or a company that provides office cleaning services, would most likely employ a product control plan so that they are confident of satisfying all their customers″ unique requirements. On the other hand, a manufacturer of standard ASTM A325M structural bolts or a bank clearing customer checks would find the process control plan more apropos. In either case, the control plan format is the same and is shown in Fig. 2-5.

The control plan, as the FMEA, is divided into columns with headings to provide a natural sequence of events enabling users of the control plan a concise and clear guide for controlling the quality of the process or product. We will now work our way through a process control plan for heat treating an ASTM A325M structural bolt with a salt-bath furnace.

Process Point Control

This column contains the same information in the same sequence as the same column in the process flow analysis for the salt heat treat process. It is a listing of all steps required in the process of heat treating via this method in the exact order the steps are performed.

Controlled Characteristic

This column contains the same information in the same sequence as the same column in the process flow analysis for the salt heat treat process. All characteristics controlled at the process step in the same row must be listed in this column.

Control Methods/Sample Plan

In this column the method of controlling the characteristic along with the specified sampling method is detailed. Several methods of control are available including first article verification, in-process inspection to a sample plan based on lot size or production rate/hour, statistical process control, and 100 % inspection. The method of control is based upon the capability of the process step to maintain design criteria.

SERVICE/PRODUCT QUALITY PLAN

Phase II - Failure Mode and Effects Analysis

Pg___ of ___

Product Line: _____ Current Revision/Date: _____

Manufacturing Location: _____ Approved By: _____

Original Issue Date: _____

Process	Controlled Characteristics/Fail Mode	Effects	Likely Causes	Current Control Methods	Resp. and Date	Recommended Actions	Date

Fig. 2-3—Failure mode and effects analysis.

SERVICE/PRODUCT QUALITY PLAN

Phase II - Failure Mode and Effects Anaysis

Pg 1 of 3

Product Line: Salt Heat Treat

Manufacturing Location: ABC Company

Original Issue Date: January 20,1994

Current Revision/Date: _____

Approved By: _____

Process	Controlled Characteristics/Fail Mode	Effects	Likely Causes	Current Control Methods	Resp. and Date	Recommended Actions	Date
High Heat Furnace	Part Microstructure 1) Atmosphere Wrong 2) Temperature Wrong 3) Time Wrong	Wrong Microstructure Leading to potential product failure	1) Salt contaminated 2)Wrong control settings 3)Thermocouples defective.	1) Salt evaluated every 6 mths. 2) Operator monitors temp. & time on controller instruments for each furnace. 3) Thermocouples are changed every 2 weeks.	Supervisor Operator Maintainance	1) Evaluate salt analysis to determine optimum frequency of evaluation. Use control chart method take data weekly.	Supervisor Begin 02/14/94

Fig. 2-4—Failure mode and effects analysis.

SERVICE/PRODUCT QUALITY PLAN

Phase III - Control Plan

Pg___ of ___

Product Line: _____

Date: _____

Manufacturing Location: _____

Process Point Control	Controlled Character.	Control Methods/Sample Plan	Method of Evaluation	Resp.	Reaction of Plan to Out of Control or Specifications.

Fig. 2-5—Control plan.

SERVICE/PRODUCT QUALITY PLAN

Phase III - Control Plan

Pg ___ of ___

Product Line: _____

Date: _____

Manufacturing Location: _____

Process Point Control	Controlled Character.	Control Methods/Sample Plan	Method of Evaluation	Resp.	Reaction of Plan to Out of Control Specifications.
Temper	Part Hardness	x + R Chart, 5 pieces per furnace load per order.	Newage Digital Hardness Machine.	Furnace Op.	Implement Procedure QA 017
	Part Microstructure	1 coupon per shift/furnace/material grade is submitted to the metallurgical laboratory for analysis.	metallograph	Laboratory Technicians	All parts processed after the last acceptable micro must be held for metallurgical evaluation. Any product found out of compliance is handled in accordance with procedure QA 017 and QA 018.

Fig. 2-6—Control plan.

Method of Evaluation

In this column we describe the process, equipment, or instrumentation used to evaluate each controlled characteristic. Methods may include visual inspection with or without a microscope, a metallograph, a pair of dial calipers, a scanning electron microscope (SEM), a hardness testing machine, etc. Of importance here is the requirement that for whatever method of evaluation we employ, an evaluation of the repeatability and reproducibility of that method be determined. One method of conducting an evaluation of the repeatability and reproducibility of an evaluation method is described in ASTM Standard Guide for Conducting a Repeatability and Reproducibility Study on Test Equipment for Nondestructive Testing (F1469).

Responsibility

In this column, list the person(s) or department held accountable for evaluating the controlled characteristic. In the case of multiple persons having responsibility for the evaluations, avoid the use of personal names; instead, refer to the job title. This practice allows wider use of the control plan and eliminates the need for revisions when an individual is no longer performing the task detailed in the plan.

Reaction of Plan to Out-of-Control Specifications

In this column we specify what to do if during the course of evaluation we find the characteristic either out of control or out of specification. This is an important consideration, and the team developing the control plan should be very specific so that the person/department making the evaluation has clear instructions on how to handle the situation.

Failure to properly handle an out-of-control or out-of-specification characteristic could result in allowing the situation to continue or even permit a defective product to reach the customer. It is recommended that the team refer to standard operating procedures that describe in detail how to deal with these situations. Any referenced procedure should be available and completely understood by the individual/department that must act upon the problem.

A partially completed process control plan is shown in Fig. 2-6. So that we know how it is constructed, we will go through the process step, Temper.

The columns entitled Process Point Control and Controlled Character in the Phase III Control Plan shown in Fig. 2-6 list the process step and the controlled characteristics, respectively, for the temper operation. Two characteristics are affected by the temper operation: one is "part hardness," and the other is "part microstructure." A separate line is used for each of these characteristics.

In the Control Methods/Sample Plan column adjacent to Part Hardness, the team put the phase "X & R Chart, 5 pieces per furnace per order." This lets the furnace operator or anyone viewing the control plan know that statistical process control is to be applied to this characteristic at this process step. It also specifies the type of chart and the frequency and size of subgroup sampling.

In the Method of Evaluation column, the team inserted the name of the instrument required to check part hardness, in this case, a Newage digital hardness machine.

In the column entitled Responsibility, the team inserted the job title, Furnace Operator. In all cases, when assigning accountability for action, name the individual performing the task. With this directive comes responsibility from management. Management must insure that the person understands what is required and is properly trained to perform the task.

The column entitled Reaction of Plan to Out-of-Control Specification must provide enough information for the person designated with responsibility to take appropriate action. In this case, the team chose to reference a procedure that details how to deal with nonconforming material.

The controlled characteristic, part microstructure, is addressed in similar manner. However, due to the time and cost involved in preparing metallurgical micromounts, the team decided to check this characteristic only once per shift/furnace/material grade. This action was made possible because the team earlier initiated more frequent check analyses of the salt bath when an opportunity for improvement was taken on the FMEA. Although the SPQP program is very powerful, it does require a great deal of effort and resources to apply. This downside, however, is nothing compared to the business consequences of failing to plan for quality. Futuristic quality planning pays high dividends in terms of reduced scrap and rework. Other benefits include more satisfied customers both in terms of the sheer number of customers and in the degree to which your customers are satisfied. This alone should be enough incentive for the top executives of an organization to fully support such a program.

Once the full support of top management is acquired, the staff management should review their operations and make recommendations for application of the SPQP process. It is best to choose a process or product fairly well understood by all involved in the process flow and one that shows promise for improvement. By starting with a process or product that is going to show success, confidence in the program is instilled in those who participate and in those who are on the sidelines watching to see how it goes. After two or three successes, you will find a grass roots movement by others to apply this new technique to their own areas of responsibility.

The other three programs mentioned earlier in this chapter are best covered under *continuous improvement*, the topic of Chapter 3. In Chapter 3, we will discuss critical performance indicators (CPIs), and the plan, initiate, evaluate (PIE) processes for continuous improvement. These two programs include strategic methods for service and product improvement, employee involvement and education, and business systems.

3

Continuous Improvement

IN THE FIRST CHAPTER WE DISCUSSED MANAGE-ment's role in providing the leadership necessary for the company to meet its business objectives. One business objective of primary importance is *continuous improvement*. If a company is dedicated to continuous improvement, it will constantly improve its internal performance, customer service, and quality, moving it closer to performance excellence. Such improvement automatically strengthens the company's competitive position and its ability to respond to customer needs.

Continuous improvement begins with an understanding of where you are and where you want to be. Everyone wants to be the best in their field; however, our ambitions should be realistic and in line with our resources. Goals should be obtainable while providing enough challenge to allow employees the opportunity to extend their current abilities. To determine your current "state of the business," I recommend using the BNQP Organizational Profile available from NIST. This exercise "sets the context for the way your organization operates. Your environment, key working relationships, and strategic challenges and advantages serve as an overarching guide for your organizational performance system."[5]

While moving along the path of continuous improvement, keep in mind that the journey never ends! The present is now and the future is only the next step along the way. You cannot stop because, if you do, someone will pass you by. There is a saying from the Great North: "If you are not the lead dog, the scenery never changes." This saying applies to a company's journey along the path of continuous improvement. If you are not the leader in your industry, you will not see future opportunities until your competitor has passed that point, leaving only the spoils for you.

So, where do we begin to move along this path of continuous improvement? Similar to any journey, we have to determine where we are and where we want to go. Most companies have a pretty good idea of where they are through historical data that provide a measure of how well they are meeting the needs of their customers. These data include ratings on customer quality system surveys, customer returns, the number of service requests, employee absentee rates, efficiency ratios, the ratio of quotes accepted to those given, employee turnover, customer certification awards, cost of quality, JIT delivery performance, lost time injuries, and hundreds, even thousands more.

The data include information from internal as well as external customers. The two are equally important, since both contribute to the strength of the company. In the first chapter, we talked about utilizing surveys to assess the current pulse of the company. This is a good place to begin.

Top management should form a steering committee to evaluate all the summary information available from the data acquired from this historical data mentioned earlier. From that information, intelligent questions can be formed to ask employees, customers, and suppliers in the form of a survey. The purpose of this survey is to discover your strengths and weaknesses.

An analysis of the survey results should identify the critical performance indicators (CPIs) that drive your organization. If you recall, we earlier defined CPIs as those measures that contribute to customer (internal and external) satisfaction. It may not be surprising to find such factors as on-time delivery and cost of quality among the concerns of your customers and employees.

Once you have identified your CPIs, you need to know how to track and measure these indicators so that you may find out whether your efforts toward continuous improvement are effective. This requires a structured and systematic approach and a few statistical tools.

Structured and systematic means that procedures are established to assure that everyone knows what is expected and that they do things the same way. It is important that everyone work with the same set of data and that these data be factual. The statistical tools are basic problem-solving techniques employing the use of brainstorming, flow chart analysis, and cause and effect analysis. These are simple yet powerful techniques that anyone can apply. A more detailed study of these techniques is discussed in Chapter 7, Statistical Quality Control, Six-sigma, and Lean Manufacturing.

The next step is to create a flow chart of the process that affects the CPI. An example of a flow chart was presented in Chapter 1, Fig. 1-3. A flow chart is simple to construct and can be done by the employees who contribute to the processes that lead to the final output of that process. Let us say that one of our company CPIs was to ship the customer order on time. If we examine the processes (steps) that affect shipping the customer's order on time, we may find, depending on the size of the organization, that as many as 30 processes contribute to that CPI. For the sake of simplicity, let us cut the number of processes to a more manageable level for this example.

The first step is to assemble representatives from each department that have an influence on shipping the customer's order on time. In our fictional company, these representatives will come from the customer service, design engineering, manufacturing engineering, production control,

[5] Criteria for Performance Excellence 2008, NIST Gaithersburg, MD 20899-1020.

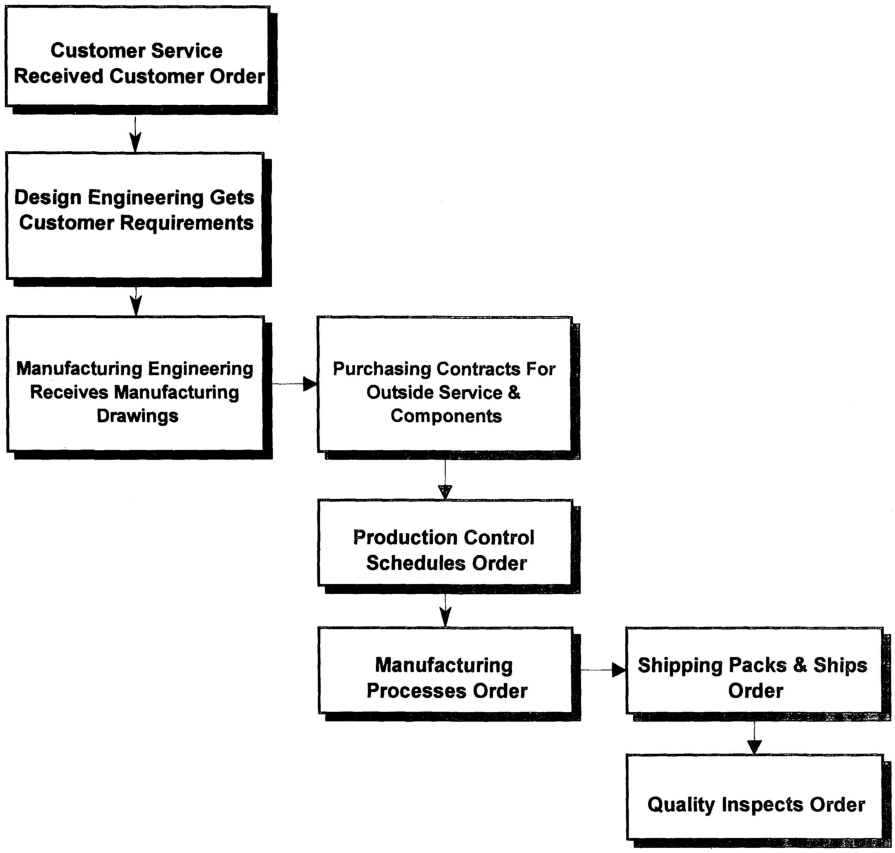

Fig. 3-1—Flow chart for processing a customer order.

purchasing, manufacturing, quality, and the shipping departments. The entire process is represented in Fig. 3-1.

Each of the steps in this Ship Customer Order On Time flow chart has flow charts of its own. For instance, the last step, Shipping Packs & Ships Order, requires several steps before the customer order is actually shipped out the door. Documents must be assembled, packing and shipping instructions read, boxes selected and assembled, labels prepared, the product containerized, and the method of transportation scheduled.

Every step requires time and employee input. Does each step contribute value to the product, and is each step necessary? These basic questions must be answered by everyone along the process chain. If a step is required, the next questions center on the overall efficiency of that step. Throughout this analysis, the collection and evaluation of data should be observed by the employee team from the process. Some of the best methods of presenting data are the simplest. The run chart is very effective in tracking progress over time (Fig. 3-2).

The on-time shipment chart in Fig. 3-2 shows improvement over a twelve-month period. The chart could very well have shown a downward or even a random pattern. It is important to know when to react to trends on run charts. It is a mistake to assign cause every time the chart makes a move in either the positive or negative direction. Normal forces of variation are ever present, and until a process is in control and control limits are calculated via statistical calculations of control chart data, any reaction to movement should be made with caution. Control charts will be discussed in more detail in Chapter 7.

Through an analysis of data collected, opportunities for improvement will become evident. Management must determine which opportunities to work toward first. These decisions are usually based upon cost effectiveness, quality improvement, or criticality of correcting an undesirable condition. Whatever the reasons for choosing a particular opportunity as a project for improvement, the process is the same.

The improvement process has been defined by more than one quality guru as the *plan, act, measure*, and *evaluate cycle*. I call the process plan, initiate, and evaluate (PIE) (Fig. 3-3). PIE methodology is closely aligned with the define, measure, analyze, improve, control (DMAIC) processes associated with Six-sigma.

Plan

The most important part of a project is the planning phase; this is certainly true for continuous improvement projects. The more robust the plan, the better the implementation and the results. When developing a plan, the team needs to consider all action steps in the process expected to lead to the improvement desired. Once all action steps are identified, the next step is to decide the sequence in which these steps should be implemented. After the sequence is determined, the time allotted to complete each step is calculated, and responsibility for each step is assigned. In general, during this

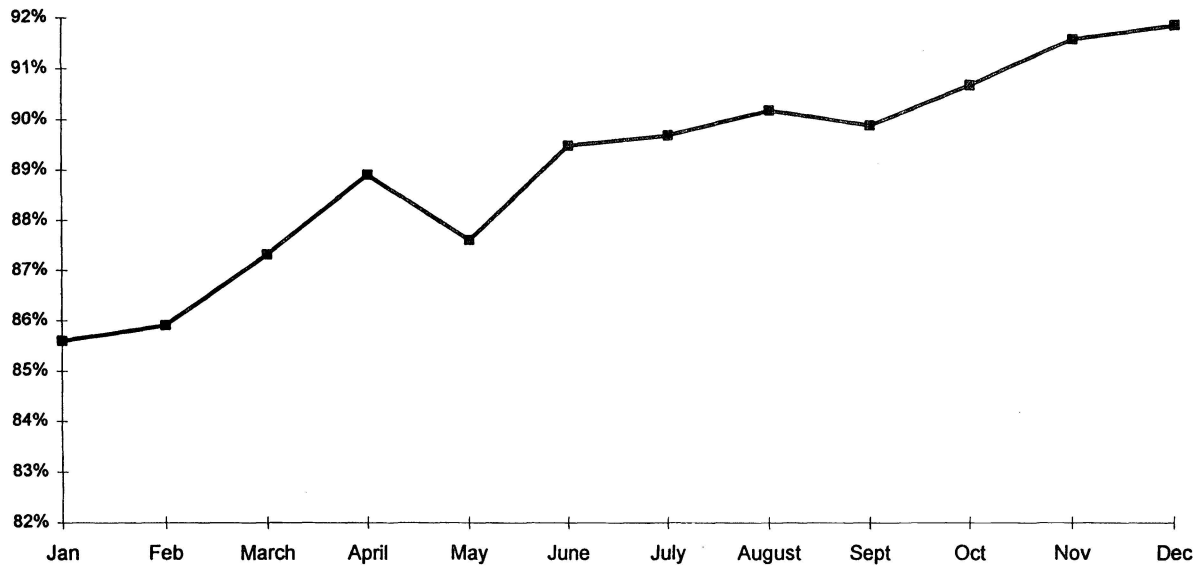

Fig. 3-2—On-time-shipments trend chart.

phase we define our goals based on customer demands and our organization's strategic goals. We do a thorough investigation of the key aspects of the current process that affect quality, and we analyze the data collected and observed to seek cause and effect relationships that contribute to process outcomes. These last three actions: define process goals, measure key aspects, and analyze data are the DMA in DMAIC used in Six-sigma.

This planning process can work only if a few basic guidelines are applied during this phase.

Planning Guidelines

- Obtain upper management commitment through sponsorship.
- Form the right combination for the team.
- Develop a vision and a policy statement for the team.
- Develop objectives and guidelines.
- Review current programs and projects.
- A closer study of each of these planning rules will make your planning easier.

Obtain Upper Management Commitment Through Sponsorship

Whenever a project is being considered, it is wise, indeed imperative, that the most senior member of the organization be firmly established as sponsor of that project. The project needs his endorsement and the understanding that his door is always open to discuss progress on the project.

Form the Team

This phase of planning should not be taken lightly. Picking names and then throwing these individuals together in a room does not create a team. Each function involved in the project should be represented, and these representatives should have good working knowledge of the area they represent. They must possess attributes that foster teamwork. These attributes include honesty, good communication skills, dependability, leadership, empathy, and a willingness to work with others and share.

Develop a Vision and a Policy Statement

The team needs to know when they have achieved their objective. The vision is where the organization wishes to be when all phases of the program are implemented and successful. The vision statement should be concise and easy to understand. It should be measurable and should fit with the organization's business policy. It becomes a policy statement when endorsed and signed by the senior manager at the facility.

Develop Objectives and Guidelines

The team must be provided with the objectives of their project and the guidelines to be followed to achieve those objectives. For instance, an objective may be to reduce the lead time in turning around a "request for quote" to a customer. A guideline (or restriction) may be that we are only interested at this point in reducing in-house lead time. We wish to tackle the outside sales and marketing function at another time.

Review Current Programs and Projects

After the team has been formed and several meetings have been held describing the project and its vision statement, policy statement, objectives, and guidelines, the team should

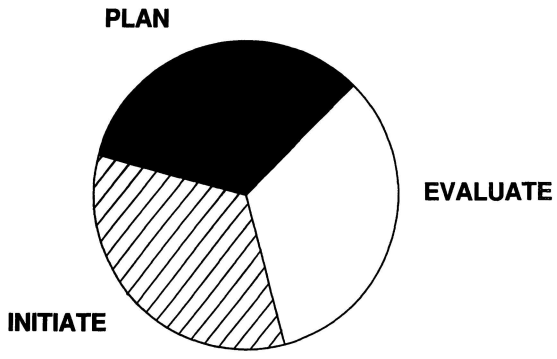

Fig. 3-3—PIE.

thoroughly review the project. The objective of this review is to determine if the team has everything at their disposal to initiate the project and to successfully achieve the vision. A list of needs should be prepared and submitted to the senior manager for his consideration and action.

The two previous examples provide a good starting point for describing how we can work with CPIs and the PIE method to achieve continuous improvement. Management provides the resources for service and product improvement, employee involvement and education, and process management, discussed in Chapter 2, to gain the fullest benefits of these terms as follows:

Initiate

The next step in the PIE process is initiating actions identified in the planning phase. In my example for the planning phase, it was important to demonstrate how plans are initiated through the use of identifying and tracking CPIs. We also explored how to expand upon acquired data to further analyze avenues to improvement.

What is important to remember in initiating action to act upon a plan is to involve the people who make things happen. It may be necessary to provide training for selected individuals or groups of individuals to prepare them to contribute to the success of the program. This investment in people is an investment in bottom line improvement, as detailed earlier in this chapter.

Involvement is a two-way street. In addition to involving employees, supervisors and managers must be active members of the action teams. Managers and supervisors make for good team facilitators to assure that the team stays the course. The teams must be ever mindful of the vision statement and plan objectives. Once the team has achieved the goals of the project, three steps should be taken.

First, the team should be congratulated, and depending on the significance of the achievement, rewards should be awarded. Second, the team should be disbanded; otherwise, teams could go on meeting forever with no agenda. This is not only a waste of resources, but prevents them from pursuing new opportunities for improvement. Third, the CPIs improved upon should be monitored for a period of time to assure that the gains are held.

Evaluate

Total quality management is about measurement and evaluation. The only way to know if improvement is taking place is by measuring where we are and comparing it to where we were and where we want to be. If we develop a plan for improvement, initiate action to improve, and do not measure the outcome of our actions, we are unaware. We do not know if we are improving, remaining constant, or losing ground.

During the initiation phase of the improvement project, evaluation should be frequent, sometimes daily. As the program continues for 6 months or more, less frequent studies can be made on results. When a project is deemed complete, the frequency of evaluation will vary with the dynamics of the CPI. I recommend, at a minimum, that monthly summary reports be analyzed to look for changes due to business swings on first-tier CPIs.

This simple philosophy, when adopted by management, will almost always guarantee success: Make *continuous improvement a way of life in your organization*. This applies to all managers in the organization. Obviously, the most senior manager should share this philosophy, but so should all department heads and supervisors because their organizations are those pursuing performance excellence. Demonstrate to all members of your organization that you expect improvement. We need to demonstrate that we will not be satisfied with the status quo. Encourage your people to ask, "Why can't things be better?," "How can I improve this process?," etc.

When problems or issues arise, treat them as opportunities to improve upon the situation. Every solved problem contributes to improvement. We should be on the lookout for problems because we improve our competitive advantage by identifying and solving them.

Pay attention to W. Edwards Deming's point of driving out fear. At all levels of the organization, people should be able to discuss problems and mistakes. The messenger should never be shot. We are all human and subject to the actions of the systems in place. If there is a problem, chances are the system is at fault because the issue was never addressed or because a change has occurred external to the system.

To the fullest extent possible, base decisions on fact, not intuition. Look to data and assure that these data are true.

Decisions based on intuition are almost always wrong at the operations level. For higher-level continuous improvement, intuition sometimes cannot be avoided and oftentimes is the basis for decisions that move an organization to the next level of achievement. Marketing sometimes must make decisions based on customer innuendo, but a shop foreman or office manager should rely on data.

Utilize statistical methods to evaluate and study processes.

Once processes are under statistical control, the need for extensive inspection is eliminated. You will still need to carry out audit inspections (or verifications), but total inspection time should be reduced. Concentrate on doing the job right the first time. Do not rely on inspecting quality into the job after it is complete. The process of quality by inspection only perpetuates the hidden "rework and remake" departments of your organization.

PIE Expectations—Service and Product Improvement

Service and product improvement comes from initiating new programs or techniques and monitoring the CPIs associated with the process undergoing change. The advantages of service and product improvement are many and varied as shown below:

- Reduced scrap
- Less rework
- Improved capacity
- Fewer returned goods
- Less service calls
- Improved earnings through lower cost of quality
- Improved earnings through more efficient operations
- Satisfied customers
- Satisfied employees
- Gaining a competitive advantage over your competition

Engage Your Workforce to Achieve Organizational Success

Employee involvement and education is one of the main ingredients in creating continuous improvement when using the PIE methodology. The objectives for actively seeking employee involvement are described below:

- To bring, to the fullest extent possible, common values and procedures to the workplace.
- To produce cost effective, highest-quality products and services for world markets and meet customer expectations.
- To have employees participate in the decision process to:
  - Provide capable systems and manufacturing processes.
  - Define and enumerate clear expectations in terms of operations and quality.
  - Provide a means to measure progress.
  - Identify a means to correct any situation not meeting expectations.
  - Create the environment for all employees to work together toward the accomplishment of organizational goals.
  - Emphasize the need to achieve "total" commitment to quality and productivity by all employees.
- To create an action plan developed through representation of all employees.
- To motivate all employees to have ownership of the process of continuous improvement and an understanding and commitment to the organization's goals.
- To achieve total commitment to customer service, whoever that customer may be.
- To assist in the creation of an interesting, challenging, enjoyable, and safe work environment.
- To develop a system of communication and feedback to solve organizational problems and to keep employees informed by:
  - Intra/inter department communications.
  - Management-level communications.
  - Employee-to-employee communications,
- To have sufficient knowledge of company operations, customer needs, and individual job responsibilities.
- For all employees to have a better or complete knowledge of the working part of the company's product or service to assure a better assessment of acceptable quality.

It is difficult to dispute the advantages employee involvement brings to an organization, yet many company executives still feel threatened by employees who "know too much." The truth of the matter is that the more employees know about their business contribution, the better they are able to contribute to the overall success of the organization.

Process Management

New processes are created and existing ones refined through the CPI and PIE programs. Not often do new processes work perfectly the first time, but how many times have you heard somebody say, "But we always did it like that!" Why are some people so afraid to change the way things are done? The answer lies in the company's management style. A management philosophy should embrace W. Edwards Demings 14

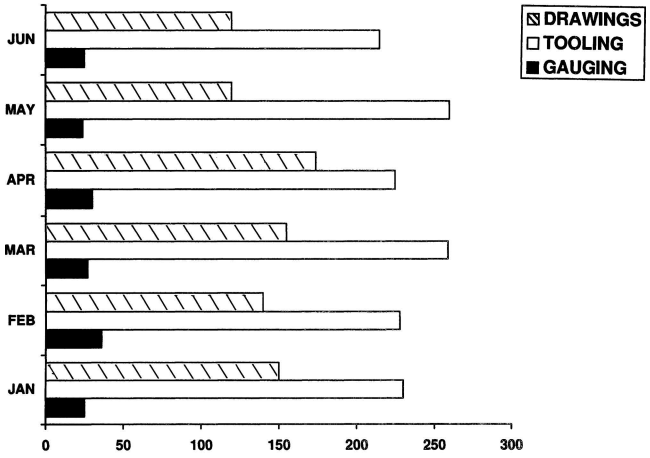

Fig. 3-4—Set-up CPI analysis.

Points of Management Obligations.[6] His 14 management obligations are paraphrased below:

1. Create constancy of purpose toward improvement of product and service with the aim to become competitive, stay in business, and provide jobs.
2. Adopt the philosophy: We are in a new economic age created by global competition. A transformation of management style is necessary to halt the continued decline of industry.
3. Cease depending on inspection to achieve quality. Eliminate the need for inspection on a mass basis by building quality into the product in the first place.
4. End the practice of awarding business on the basis of price tag alone. Purchasing must be combined with design of product, manufacturing, and sales when dealing with chosen suppliers. The aim is to minimize total cost, not just initial cost.
5. Improve constantly and forever every activity in the company to improve quality and productivity and thus constantly decrease costs.
6. Institute training and education on the job for everyone, including management.
7. Institute supervision. The aim of supervision should be to help people and machines do a better job.
8. Drive out fear so that everyone may work effectively for the company.
9. Break down barriers between departments. People in the research, design, sales, and production departments must work as a team to tackle usage and production problems encountered with the product or service.
10. Eliminate slogans, exhortations, and targets for the work force that ask for zero defects and new levels of productivity. Such exhortations only create adversarial relationships; the bulk of the causes of low quality and low productivity belong to the system and lie beyond the power of the work force.
11. Eliminate work standards that prescribe numerical quotas for the day. Substitute aids and helpful supervision. (Such aids would be CPIs.)

12a. Remove the barriers that rob hourly workers of their

[6] "Out of the Crisis," Massachusetts Institute of Technology, Center for Advanced Engineering Studies, 1986.

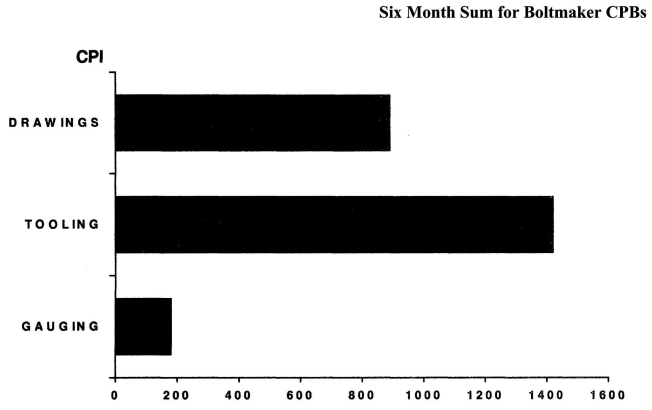

Fig. 3-5—Six-month Pareto analysis for boltmaker CPIs.

right to pride of workmanship. The responsibility of supervisors is to change the goal from sheer numbers to quality of the product or service.

12b. Remove the barriers that rob people in management and in engineering of their right to pride of workmanship. This means, among other changes, the abolition of the annual or merit rating and of management by objective.

13. Institute a vigorous program of education and retraining. New skills are required for changes in techniques, materials, and service.
14. Put everybody in the company to work in teams to accomplish the transformation.

I find it interesting and prophetic that Deming's 14 Points of Management Obligations are as true today as they were back in 1986.

Let us work through an example of how CPIs can be used to bring about awareness and thus improvement.

Let us take another look at the run chart we created for on-time shipments.

Our management team has decided that our on-time-shipment performance may not continue to improve unless a greater emphasis is placed on that goal. At a meeting that included all staff management, a decision was made to create an employee team to study and find ways to improve our on-time-shipment performance. A representative from the management team was selected to serve on this employee team as a facilitator. The management team also set objectives for the employee team. Among these were an overall improvement of on-time-shipments to 96 %. The management team felt that, with concerted effort by the employees and with full support of management, this goal was obtainable. During the last quarter, the company achieved an average of 91.4 %, and the last two months nearly 92 %. During the last 12 months, each month was an improvement over the previous month's performance with only two exceptions.

The goal of 96 % represents a 5 % improvement over the last quarter results. A 5 % improvement can be significant or insignificant. It all depends on the time block during which management wishes this goal to be reached and on the level of difficulty of change to reach each milestone. As discussed earlier, by the time management has come up with the vision, most obstacles have been thought out and addressed, making it possible to reach that vision through the talent pool that makes up the improvement team. For our example, let us say the vision is to reach a level of 96 % on-time shipment in 6 months. The vision has been approved, and the general manager has affixed her signature to the vision statement securing her support and making it management policy.

With our team in place and the objectives and guidelines understood, responsibilities are established to carry out the project. It is important to point out that the team was made aware that, even though the goal is to improve on-time shipments, there is a broader objective—to improve on-time performance in each process step along the process chain from receiving the order from the customer to shipping the order out the door. Even with this expanded objective, you can see that management put in some guidelines or restrictions. For this project, we are not concerned with the process chain between the customer's request for quote and the moment the customer receives our quote. Management, at this time, is also not interested in the process from the time the order leaves the facility to the time it reaches the customer's dock. These two process chains certainly contribute significant time to the overall process, but there is little this facility can do to influence these process steps, with the possible exception of design engineering the concept. Let us go back to the flow chart shown in Fig. 3-1 for processing a customer order.

The team formed to improve upon this process consists of talented employees from each of the departments represented in the process chain. Working together, they conclude that each department in the chain needs to track the amount of time an order spends in their area. This may differ for different departments. For example, the time spent in the quality department can be measured in hours, whereas the time spent in the manufacturing department should be measured in days. Also, it is clear that some departments require further breakdown in their contribution. For instance, in manufacturing there are possibly several cost centers that make up the entire department. In manufacturing an ASTM A325M[7] fastener, for instance, we could have wire annealing, wire draw, boltmaker, heat treat, and hot dip galvanizing all contributing time to the process. And let us not forget the queue time between operations; sometimes these delays take more time than value-added steps. Even these subprocesses need steps of their own to make them effective. Let us look at the boltmaker step in manufacturing the ASTM A325M fastener. Steps in this process may include gathering process drawings, tooling, and inspection gauging. All aspects of the process are under investigation when our task is to improve our on-time-shipment CPI.

At this point it is usually important to have each team member construct a detailed flow chart of their department's process. They may wish to enlist help from their department and form an ad hoc team to give a full evaluation of each process step performed in their department. They would be the ones closest to the action and should know the ins and outs of their operations better than anyone. The ad hoc team would try to identify opportunities for improvement and eliminate redundant or unnecessary steps. After a new section of the process is selected for evaluation, a CPI can be chosen and data collected and tracked. As a change is made

[7] Specification for Structural Bolts, Steel, Heat Treated 830 MPa Minimum Tensile Strength (Metric).

Quality Technician Development
Issued by: Joe Quality
Issue date: Jan. 5, 1994

STEP	Process/Activity	Responsibility	J	F	M	A	M	J	J	A	S	O	N	D
1	Define job description for a Quality Tech.	Quality Manager		Þ										
2	Provide job desc. to the inspectors	Quality Supervisor			Þ									
3	Assess current skill level of inspectors	Quality Engineer				Δ								
4	Advise each inspector of their skill level	Quality engineer					Δ							
5	Consult with each inspector	Quality Supervisor					Δ							
6	Develop training modules-internal	QA Staff				Δ								
7	Develop training modules-external	Community college				Δ								
8	Commence training	Quality. Staff & Community college						Δ						
9	Evaluate effectiveness of training	Quality Supervisor & Quality Engineer						Δ						
10	Certify inspectors as Quality Technicians	General Manager & Quality Manager						Δ						

Fig. 3-6—Project timetable.

to the process, it can be determined if that change has an effect by seeing a shift in the CPI.

Let us take a closer look at this example. Assume the team for the boltmaker department decided they would track how long it took the boltmaker operator to acquire tooling, gauging, and process drawings to run an order. They decide to do this for a 6-month period to see if any one category might benefit from more attention. The results of their 6-month study are shown in Fig. 3-4.

If we rearrange the above data to include only the CPIs and occurrences, it becomes evident that the time spent waiting for tooling is an opportunity for improvement. The result is Fig. 3-5.

Now the boltmaker team has an area of focus to isolate reasons for delays in getting tooling to the boltmaker. They will choose to select CPIs that contribute to having tooling available. Examples may be tool location, setup time, or tool availability. The process goes on until all causes are identified and presented to management for resolution.

There are times when an identified opportunity requires extra planning to initiate change. Let us look at another example. This one was identified by the quality department. The representative from that department found that orders were sometimes delayed at final inspection because the inspector on duty was not always familiar with the product or the inspection techniques necessary to determine if the product met requirements. A separate employee involvement team was established to develop the plan to improve the knowledge of inspection techniques of the inspectors. The team was comprised of the inspection supervisor, several inspectors, a design engineer, and a quality engineer. After several brainstorming sessions, the team came up with a progression of steps that would lead to a well-informed and educated quality technician. Note that the team felt so strongly that the training to be provided to the inspectors was so much beyond the current job description that a new job title had to be created. After all steps in the process were finalized, the team created a project timetable for developing quality technicians. The project timetable they came up with is shown in Fig. 3-6.

This project timetable represents an overview of the project to train inspectors to be certified quality technicians through the American Society of Quality (ASQ), Milwaukee, WI. Each and every step in the process has its own project timetable detailing the progression necessary to complete that objective and the individual responsible to make it happen. Some of these activities may be only a few steps, such as Steps 5 and 6, while some may be as large and detailed as the overview, such as Step 7.

4

Quality Systems

QUALITY SYSTEMS ARE MADE UP OF THE QUALITY organization and the written guidelines used to define the quality organization responsibilities as they relate to the rest of the organization. Quality systems are the result of the quality policy established by the executive management team. The two most important elements of quality systems are the quality manual and the organization's standard operating procedures. When developing the quality manual, it is recommended that attention be paid to following the guidelines established by the ASTM F2688[8] (Fastener specific), and ISO 9001[9] standards. If the organization has no intention of applying for ISO registration, ASTM F2688 is a good choice, but if ISO 9001 registration is desired, one must choose ISO 9001. Both of these standards are among the best available to set up a quality management system.

To proceed further at this point without defining who in the organization is responsible for quality would possibly lead some people down the wrong path when we discuss the contents of the quality manual and associated procedures that supplement implementation of manual policies. I do not want to start off with the notion that quality is the responsibility of the quality department. Nor do I want to simply state that quality is everybody's responsibility.

Let us look one more time at the definition of quality I provided in Chapter 2, which is: *Quality is achieved when we provide goods and services that meet or exceed customer requirements*.

To meet this definition, the part or service provided must conform to design or process requirements. The design or process must conform to its market requirements and to customer expectations. Therefore, three major groups with their necessary support groups are responsible for quality: marketing, engineering, and manufacturing/operations. For purposes of simplicity, I would like to call manufacturing/operations and respective support groups by a single term: manufacturing. This one word will mean either a facility that produces a part or a facility that provides value added. And I would like to use the term product to mean either a part or a service. The question of who is responsible for quality is now easier to define.

Responsibility for quality in an organization rests with marketing, engineering, and manufacturing along with the support groups that provide services to them. Each must be held accountable for their contribution to the overall effort. Marketing must make sure their concept of customer needs and requirements are fully understood and that they convey this information to the engineering group. Engineering must assure that they fully translate the marketing requirements to designs and processes that allow manufacturing to produce the product to fulfill purchase requirements. Manufacturing must assure that the end product they provide to the customer conforms to the facility's design engineering requirements.

You may be asking, "Where does the quality department fit into this picture?" First let me say that we must agree that the quality department or any of its people should not be held responsible for the quality of the product provided by the organization. How can they be if they did not market, design, or manufacture the product?

The quality department's function is to facilitate continuous improvement by providing services to marketing, engineering, manufacturing, and all their support groups. Their role is similar to that of another service group in the organization, the accounting department. I do not think I would find too many people who suggest that the accounting department is responsible for the organization's profit and loss statement. The results on this statement are only a report of what actually happened. So too with the quality department's role—they report on what took place. And, like the accounting department, the quality department provides assistance in identifying opportunities for improvement through measurement and communication. The quality department also has experts in the area of quality engineering and reliability, and technicians and inspection equipment to assist all other facility functions in their improvement projects.

The Quality Manual

With all these in mind, WHO is responsible for the quality manual and the standard operating procedures that augment it? The responsibility rests with the quality department. The quality department must work with all other departments within the organization to provide them with the guidelines they need to assure quality in their operations. Each individual department should have a hand in developing the quality manual, but the ultimate responsibility for writing and maintaining it rests with the quality function.

The guidelines for quality management and quality system elements are fully described in the ISO 9004-2008[10] Quality Systems standard. I recommend that readers acquire and review this document when establishing their own quality system and manual. I provide, for convenience, in Fig. 4-1 a partial listing of topics discussed in that standard.

The Quality Manual is a Level 1 document, and trans-

[8] Available from ASTM International, 100 Barr Harbor Dr., West Conshohocken, PA 19428.
[9] Available from ANSI Washington, D.C. Headquarters, 1819 L. Street, NW, 6th Floor, Washington, D.C. 20036.
[10] Available from ANSI Washington, D.C. Headquarters, 1819 L. Street, NW, 6th Floor, Washington, DC, 20036.

Partial listing of Topics Discussed in ISO 9004:2008

- Self-assessment
- Measurement Methods
- Quality Planning
- Risk: Assessment and Management
- Measuring and Analyzing
- Continual Improvement
- Outputs and outcomes
- Organizational Structure
- Improvement Cycle

Fig. 4-1—Partial Listing of Topics Discussed in ISO 9004:2008.

lates ISO 9001 (or ASTM F2688) requirements to the language of your organization (see Fig. 4-2). Management procedures are Level 2, and they document departmental requirements for compliance to the quality manual. Work instructions and forms are Level 3 and contain document-specific tasks necessary to complete an activity defined in the management procedures. Quality records are Level 4 documents and contain the necessary documentation or records of quality activities to meet the requirements of the quality manual. As you can deduce from the chart, the lower the level of documentation, the more detail is provided. The quality manual need not be as thick as the New York City telephone book, nor does it need as many details as the instruction manual for the space shuttle. A well-developed quality manual need only contain between 20 and 50 pages depending on the size and complexity of the organization.

Procedures

Let us take a closer look at how management procedures and work instructions tie together. For an organization's metrology department (the area in which technicians apply the science of measurement to calibrate test and measuring equipment), management will have a procedure on how to calibrate and maintain gauges and measuring equipment, but in order for the facility to implement that procedure, there has to be a work instruction on how to calibrate each

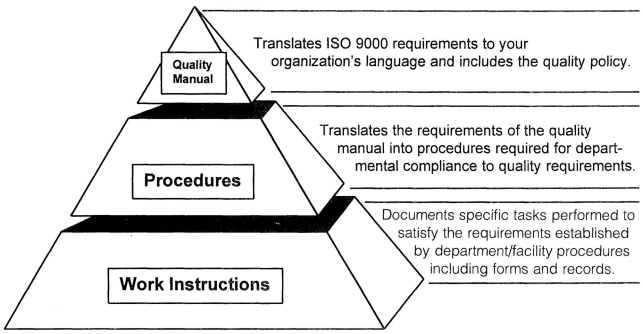

Fig. 4-2—ISO documentation pyramid.

category of gauge and measuring instrument in use at the facility. In this case, one could have up to 25 work instructions to satisfy a single management procedure. I will provide an example of each for clarification.

The first example is a management procedure on equipment calibration, and the second is a work instruction for calibrating a dial and vernier caliper.

STANDARD PROCEDURE
ABC COMPANY

SUBJECT:	Certification Instructions Equipment Calibration
PROCEDURE NO.:	ABC 11.01
REVISION:	1.0
PAGE:	1 OF 4
DATE:	mm/dd/yyyy
PREPARED BY:	author's name here

1.0 Purpose

1.1 The purpose of this procedure is to define the general conditions and requirements for implementing and maintaining a certified calibration program for our test equipment.

1.2 Compliance with this procedure will ensure the means for manufacturing accuracy through the consistent examination and control of measuring devices and accessories.

2.0 Application

2.1 This procedure shall apply to all equipment, whether privately or company owned, that is used or may be used for the appropriate measuring and/or judging of the manufactured products' conformance to specification.

3.0 Materials and Equipment

3.1 PC computer and calibration software.

3.2 Test equipment serialization procedure, ABC 11-XX.

3.3 Gauge Repeatability and Reproducibility Study work instruction ABC 11-01-XX.

4.0 Procedure

4.1 All test equipment that is used or may be used to determine the acceptability of manufactured product must be certified as accurate by the metrology department.

4.1.1 Employees must submit their test equipment to the metrology department for certification prior to use in manufacturing.

4.1.2 New company purchased test equipment must be certified by the metrology department prior to use in manufacturing.

4.1.3 All test equipment of new or unique design is subject to qualification through a Gage Repeatability and Reproducibility study in accordance with work instruction ABC 10-XX.

4.2 All test equipment submitted for initial certification will be permanently marked, if possible, with an identification/serial number, in accordance with ABC 11-XX.

4.3 Test equipment will be certified in accordance with appropriate quality assurance work instructions, and shall be tested against devices certified and traceable to the National Institute of Standards and Technology (NIST).
4.4 Test equipment determined to be accurate and reliable through examination by Metrology will be certified and the results of the examination recorded on the computer through application of the calibration software.
4.5 Certified test equipment then shall be released by Metrology for approved use within the limitations of the test equipment's intended application.
4.6 Test equipment determined to be inaccurate/unreliable through this process will be routed to an appropriate calibration or repair facility and the results of this action recorded.
4.7 All test equipment returned from calibration or repair facilities must be routed through Metrology for re-examination.
4.8 Following the initial examination and certification of each type of test equipment, subsequent test equipment examinations will be scheduled using the gauge calibration software system.
4.9 Test equipment due for examination and recertification will be printed out of the gauge calibration software on a weekly basis.
4.10 Metrology will exchange due test equipment with certified test equipment so as not to interrupt the manufacturing process.
4.11 Test equipment may be submitted to Metrology for additional examinations at any time, regardless of the scheduling program.
4.12 Test equipment found to be in use with expired certification tags or labels will be confiscated and/or prohibited from use until the appropriate recertification of the test equipment can be accomplished.
4.13 Test equipment examination intervals shall be scheduled on the basis of frequency of use, fragility, and the accuracy required of the test equipment.
4.14 Except for test equipment being returned for routine certification, rejection tags must be affixed to uncertified test equipment in inventory to prevent accidental reuse.

5.0 Auditing Procedure

5.1 Metrology shall be responsible for conducting sporadic, unannounced shopwide audits/inspections for the test equipment governed by this procedure.
5.2 Audits shall evaluate the present condition of the test equipment audited versus the same test equipment at the last recorded Metrology examination.
5.3 Audits will ensure control of measuring devices and accessories by requiring corrective action for any violations of this procedure.
5.4 Test equipment found to be in violation of this procedure, or designated tolerances and parameters, through Metrology auditing, may be confiscated and/or prohibited from use until appropriate recertification of the test equipment can be accomplished.
5.5 The auditor may grant an "operational deviation" for any equipment found to be in violation of this procedure or of the designated tolerances and parameters established for the test equipment.
5.6 Test equipment cited with an "operational deviation" must be submitted to Metrology within five working days of the citation for examination and appropriate adjustment. Example: A gauge block is out of specification, but used to complete an order. A correction factor is calculated to compensate for the error.

The preceding example is the system management procedure implemented to control test equipment calibration and certification. The method(s) by which the metrology department carries out this procedure is detailed in work instructions. For most organizations there are much more work instructions than management procedures simply because of the breadth of the area being managed. In our example for calibration, this procedure applies, as stated in 2.0, to application to all test equipment whether privately or company owned. There may be thousands of measuring devices covered by this definition. At least each category of measuring device should have a work instruction that details how it is to be certified.

Here is an example of a work instruction that ties in with the calibration procedure presented as ABC 11-01.

ABC COMPANY
STANDARD WORK INSTRUCTIONS

SUBJECT:	Calibration Procedure For Digital Calipers, Dial Calipers, and Vernier Calipers
Work Instruction No.	11-01-XX
Page 1 of 2	
Date Prepared	mm/dd/yyyy
Prepared By:	Insert Name
Approved By:	Insert Name

1.0 Purpose

1.1 The following work instruction is for use by Quality Control in establishing accuracy requirements of digital, dial, and vernier calipers.

2.0 Application

2.1 This work instruction is applicable to all calipers which are either in use or may be used to measure and/or determine the manufactured product's conformance to specifications.

3.0 Equipment

3.1 Gauge blocks certifiable to NIST.
3.2 Calibration test stand.
3.3 Cleaning solvent.
3.4 Lint free towels.

4.0 Documentation

4.1 Calibration control software.
4.2 Test equipment calibration data sheet (form 11-01-XX).

5.0 Procedure

5.1 Clean all surfaces of the caliper with cleaning solvent and line-free towels.

5.2 Readings are taken at 0.500-in. (1.27 cm) and 1.000-in. (2.54 cm) intervals throughout the measuring range of the measuring device for outside measurements using gauge blocks.

5.3 Readings are taken in three random locations along the measurement range for inside and depth measurements using the calibration test stand.

6.0 Acceptance Criteria

6.1 All readings are to be within one graduation mark of true value to the nearest 0.001 in. (0.002 54 cm).

6.2 The caliper must repeat within ±0.0005 in. (0.001 27 cm) on a second test at the same value.

6.3 Any caliper failing to pass all check points must be repaired before releasing for production

6.3.1 All repaired calipers must be examined by Metrology and meet the requirements of this work instruction for acceptance.

6.3.2 Calipers not meeting the requirements after repair shall be removed from service.

6.4 All calipers meeting all criteria shall be certified and released to manufacturing.

7.0 Records

7.1 Results of this examination shall be recorded on both the software system and on the calibration data sheet for hard copy backup.

7.2 The data entered into the software system shall be backed up daily on a disk and on the main computer's hard drive. This provides for three records, one of which is off site.

8.0 Calibration Schedule

8.1 Calipers shall be recalled for calibration and certification every 12 months.

The work instruction provides information the Metrology technician can follow so that the requirements of the management procedure can be satisfied. Work instructions should be prepared by someone in the department who is actually performing the task being defined. The reasons for this are many, but a very obvious one is that the only person who fully understands the actual procedure for doing the task is the one who performs it.

If we have the individual closest to the task prepare the work instruction, we must assure that he or she understands the content and intent of the management procedure that governs their responsibilities. Therefore, it is imperative to have involvement from the department task performers when management procedures are prepared. The best way to accomplish this is to ask for assistance from the task performers when the procedures are going through phase one of their development.

If you take another look at the two example procedures, you will notice something else if you are familiar with the ISO standards. In ISO 9001, the table of contents has *Inspection, Measuring*, and *Test Equipment* listed in Section 11. The procedure number and the work instruction numbers both start with the number 11. This format of numbering will be of assistance to your employees and to outside auditors when reviewing your compliance to ISO requirements or to any quality system if you tailor your procedure topic numbers to coincide with the numbers in the table of contents of your quality manual.

Fig. 4-3—PE/TQM interaction.

Another worthwhile addition to your procedures and work instructions is to include a process flow chart. This allows for two advantages; first, the flow chart provides a graphic diagram of the steps necessary to comply with the procedure/work instruction; second, it allows the procedure to be short on words because a picture truly is worth a thousand words.

Organizing For Quality

Setting up the quality organization is as important a task as anything we have discussed earlier. However, titles in the quality organization are not as important as the job descriptions of the individuals assigned to assure that quality systems are followed. Medium to large organizations will find it beneficial to have a separate group in the organization responsible for maintaining the systems. Smaller companies will have many key individuals who perform multifunctional tasks.

Even if the quality organization is a separate group or is an individual who has other duties, the checks and balances should be in place. There should not, for instance, be conflict between producing the product and assuring that the product meets customer requirements. With this in mind, there are a few guidelines that should be observed. An individual responsible for assuring that the product is shipped on time is not always a good choice for quality manager. When organizing, conflicts of interest must be identified and avoided. Obviously this is easier to accomplish in medium to large companies than in smaller ones.

Before assigning responsibility for quality, look at what the primary duties are for those in the quality function. There are two main responsibilities. The first and most important is preventing nonconforming products from reaching the customer. The second is finding ways to improve all functional activities.

Preventing nonconforming products from reaching the customer applies to both internal and external customers. Focusing on this responsibility not only satisfies those who purchase the product but, just as importantly, provides for

efficiency of operations, reducing internal costs. A great deal can be saved by doing the job correctly the first time. Some estimates have put the cost of nonconformance as high as 35 % of production costs. This cost is totally unacceptable and can be avoided through training and leadership.

The second function of a quality organization is to find methods of improvement. This function is carried out through measurement, analysis, evaluation, management reports, and participation on continuous improvement teams. These two functions do not necessarily fit in with other job functions whose task is to produce a product in a certain time period—they are even opposing. The quality department's role is not to expedite or "move" a product through the process chain—that responsibility rests solely with the group responsible for the process chain. If a job is held up by the quality department due to some nonconformance, it is not the responsibility of the quality department to find a solution to this problem. The quality department should assist, but the primary responsibility rests with the responsible group. To satisfy these two main functions, quality must be in a liaison with all other functions.

Figure 4-3 displays the interaction that must take place between quality and all other functions when seeking continuous improvement through the SPQP process. It also is a good example of an organization chart of interactions. All functions have a dotted line relationship with each other under the team management concept. All department managers in Fig. 4-3 ideally will report to the general manager or equivalent senior manager in the organization.

No matter what the organizational structure is, what is important is that the quality manager is on a par with other department managers. And the quality manager usually needs a persuasive personality that can influence his peers in day-to-day interaction to make quality the number one objective.

5

Quality Reporting

CONTRARY TO THOSE WHO BELIEVE THAT QUAL-ity is free, I submit that customer satisfaction has costs associated with it. These costs are a legitimate business expense, and like all business expenses we would like a return on that investment. I like to think of the cost of quality as an investment in both the hard and soft technologies of the business. The hard technologies are office equipment, machinery, buildings, gauges, test equipment, and similar items. The soft technologies are the people and their interactions with the hard technologies.

Cost of Quality

The cost of quality is generally 5–20 % of sales, and this accounts only for costs that can be quantified. Some costs cannot be determined, such as the price a company pays for dissatisfying a customer. Sure, we can count the cost of the returned item and the time we spend analyzing the complaint, but we cannot count the negative impression we made on our customer. Even when we look just at assignable costs, in a manufacturing facility this negative impression can amount to $1,500–$2,500 per year per employee. This certainly gives management reason to study the cost of quality and find ways to reduce it. This figure can be reduced effectively through a well-managed cost-of-quality program. Experience with effective cost-of-quality programs has shown the return on investment to be approximately 5:1 to 10:1.

Now that we have demonstrated how valuable these costs can be to management, let us see how a good cost-of-quality program can be structured. First and foremost, the top executive management of the organization must support the program. The quality department and the accounting department become business partners in this management tool. Together they collect the data necessary to assemble the report for staff management. The output(s) from the Cost of Quality Report are CPIs that can and should be displayed for employee awareness.

A few basic components are required to provide enough information to analyze accounting expenses and statistics. One needs certain pertinent data, such as cost of shipments (sales), cost of manufacturing (production), facility labor and overhead rates, rework hours, scrap costs, and cost of returns. These are broken down to: (1) *total prevention costs*, (2) *total appraisal costs*, (3) *total internal failures*, and (4) *total internal failures*. Then, through analysis, we can arrive at our CPIs. The CPIs as a minimum are: (1) total cost of quality (TCQ), (2) TCQ/product shipped, (3) TCQ as a percent of manufacturing cost, and (4) scrap as a percent of total pieces produced.

The collection of these data, as you can see, requires information from both the quality and the accounting departments. The quality department usually has the information on customer returns, the number of pieces scrapped and reworked, and the number of items recalled due to nonconformance. The accounting department has all cost data associated with the data supplied by Quality, as well as information on labor, shipments, and overhead. A simple cost-of-quality report may look like the sample shown in Fig. 5-1.

To provide more visibility to the CPIs at lower levels in the organization, one can develop run charts that display the TCQ over time, this allows everyone the opportunity to see just how well the facility is performing. If the TCQ CPIs are exhibiting continuous improvement, the employees gain a sense of achievement for their efforts. If the trend is in the opposite direction for any given CPI, the employees can see where they must seek better ways. A run chart could look like Fig. 5-2.

In this example, both the percent scrap and the cost of quality show a continuous improvement curve. This information is vital to reinforce employee self-esteem and to give everyone in the organization direction for future efforts. The input for future direction comes from an analysis of the various components that make up the cost of quality. Many of the largest gains in continuous improvement oftentimes come from departments outside of quality. This is what can be expected when the quality function and the other functions work as teams as I discussed in Chapter 4.

Quality System Audits and Layered Process Audits

Quality system audits are very effective in identifying opportunities for continuous improvement. Properly applied, it gives an honest and candid appraisal of how your organization is following the established quality systems and how effective they are.

There are different levels of system audits, and most segments of the organization can find one that can be used for their own self-assessment. Quality system audits can be conducted on top management all the way down the organization chart to the person doing the actual labor on any given task. All it takes is for someone to format the survey to fit the scope of the audited system. Everyone can benefit from this exercise because no one can ignore himself. Examples of systems that can be audited are numerous; I include a few here so one can appreciate the magnitude of scope: the quality manual, contract review, drawing control, calibration records, purchasing procedures, personnel training records, customer service procedures, manufacturing inspection procedures, invoicing procedures, and preventive maintenance schedules. System audits may be formal, or they may

ABC COMPANY
COST OF QUALITY REPORT
FY 2009

1.00	CPI METRIC	January	February	March	1st. Qtr
1.1	Total Direct Labor Hours	45,580	46,425	46,245	138,250
1.2	Total Shipments	125,877	127,630	125,721	379,228
1.3		25.02	28.73	23.76	25.84
1.4	Scrap Pieces	1,546	1,285	1,115	3,946
1.5	Rework Pieces	1,865	1,279	1,042	4,186
2.00	Rework Hours	578	599	475	1652
1.7	Plant Overhead & Labor Rate	57.00	57.00	57.00	57.00
2.00 PREVENTION COSTS					
2.1	Plant Prevention Costs	20,553	19,975	19,975	60,103
2.2	Total Prevention Costs	20,553	19,975	19,575	60,103
3.00 APPRAISAL COSTS					
3.1	Quality Assurance Labor	49,345	48,321	48,222	145,888
3.2	Quality Assurance Expenses	35,754	34,227	34,875	104,856
3.3	Total Appraisal Costs	85,099	82,548	83,097	250,744
4.00 INTERNAL FAILURE COSTS					
4.1	Scrap	38,681	36,918	26,492	102,091
4.2	Rework	32,946	34,143	34,143	101,232
4.3	Total internal Failure Costs	71,627	71,061	60,635	203,323
5.00 EXTERNAL FAILURE COSTS					
5.1	Justified Customer Returns	9,100	8,975	10,100	28,175
5.2	Stock Recalls	875	0	500	1375
5.3	Total External Costs	9,975	8,975	10,600	29,550
6.00 CRITICAL CPI					
6.1	Total Cost of Quality (TCQ}	187,254	182,559	173,907	543,720
6.2	Plant Scrap Rate (% pcs)	1.21 %	1.00%	0.88%	1.03%
6.3	TCQ / Product Shipped	1.49	1.43	1.38	1.43
6.4	TCQ / Manufacturing Costs	5.95%	4.98%	5.82%	5.55%

Fig. 5-1—Cost of quality report.

be informal; in general, formal audits follow an audit schedule, while informal audits are spur of the moment checks due to an issue or problem. Formal audits require documentation and follow-up corrective/preventive action on findings discovered during the audit. Informal audits are generally verbal, used as personnel development aids, and usually initiate a formal audit on the issue or problem that triggered the informal audit.

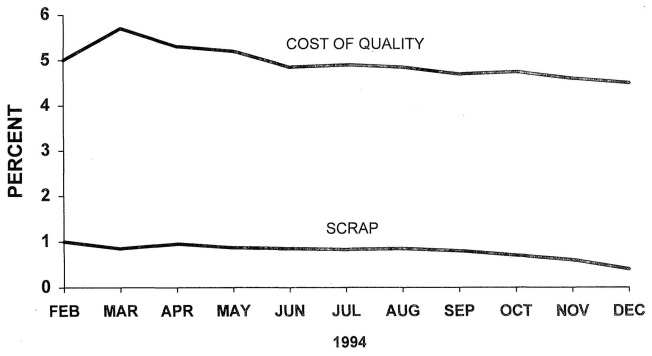

Fig. 5-2—Percent scrap and percent cost of quality.

System Audit Structure (Formal)

The structure used in formal system audits should follow in sequence steps in the procedure or work instruction. For instance, if we were developing a system audit of the management procedure explained in Chapter 4 (ABC 11-01), there would be questions designed to assure that the requirement in Paragraphs 1.0 through 5.6 of the management procedure were being adhered to. A sample question for Paragraph 4.1.1 may be: "Is all employee-owned test equipment certified? Submit a list of all production employees that shows test equipment owned and the date of last certification. Are there any exceptions to being current?"

The formal quality system audits should be conducted by a cross-functional team and contain no one from the system being audited. In other words, the audit must be conducted free of bias. As an example, if we were auditing purchasing procedures, we may have on our auditing team members from quality, engineering, and customer service. This auditing team would tour the purchasing department with the purchasing manager or supervisor.

Immediately after the survey, the team and the person representing the audited system should sit down and discuss the results, including any findings. This is very important because disagreements can be resolved much easier then, instead of a week or two later when the request for corrective/preventive action is received. This brings us to the next phase of the quality system audit, the request for corrective/preventive action. Each finding (deficiency) requires a corrective/preventive action request to be sent to the department manager for resolution. The department manager should be given sufficient time to respond, but a response should be expected in a reasonable time frame. Usually 15 working days is provided unless the deficiency is a threat to customer satisfaction, which would demand immediate action.

The quality department along with the human resources department is responsible for ensuring that auditors are properly trained and qualified to conduct audits. Only personnel who have received and successfully completed the training should be permitted to conduct audits. Special attention is given to working in teams, understanding differences, and problem solving to assure constructive and positive audits.

Documentation of all formal audits is best channeled through the quality department for retention and follow through. A system should be established to assure that corrective/preventive action identified on the Request for Corrective Action, and Request for Preventive Action reports is, in fact, in place. A member of the audit team from that area is given the responsibility to revisit the department and reaudit the deficient item after a sufficient amount of time has elapsed for the department to initiate corrective/preventive measures, and to verify that the issue has been resolved. What is important to understand is that quality system audits are a look at your own operations and are intended to be constructive. Many times procedures are revised because quality system audits find that deviation from original procedures result in an improvement. It is only natural for people to continually seek better methods to do their jobs.

Layered Process Audit

Layered Process Audit (LPA) is an important tool widely used in the auto industry (mandated by Daimler-Chrysler in 2003 and strongly recommended by General Motors) to monitor the production process, while at the same time driving continuous improvement. This audit process is always available to any organization that has a robust QMS modeled after the ISO 9001 system. The way I see it, the vigorous auditing of Work Instructions would go a long way to assure product and service processes if it were being applied as management intended.

The big difference to auditing process Work Instructions under LPA is the schedule of auditing, and the inclusion of workers, supervisors, and management directly responsible for the process. Under the ISO auditing scheme, those directly responsible for a process are excluded from the audit team. In addition, the schedule for audits is daily under LPA, rather than random under ISO 9001, thus giving more exposure to the process that yields a product or service.

Since the focus of a LPA plan is to check process steps related to known problems and causes of nonconformance, one will find the Flow Chart Analysis and the Process FMEA discussed in Chapter 2 a valuable resource. The Process Flow Chart Analysis identifies the major steps in a process that contribute to service/product failure. If we review Figs. 2-2 and 2-3 we can identify the major contributors to product failure in our Salt Bath Heat Treating process. The FMEA for this process, Fig. 2-4, identifies the control methods necessary to eliminate potential causes for nonconformance, and provides a control mechanism to avoid the nonconformance.

Using the information provided in the process FMEA for the Salt Bath Heat Treat process, one could establish a checklist to be used for the LPA. The example for the heat treat process is not the best example to use, because the controls are not performed on a frequent enough basis. A FMEA for a machine process that produces a large volume of parts per hour is better suited for the LPA system. For this reason, I would recommend that this auditing scheme only be applied when the volume of parts produced on a daily basis are realistically measured in a ppm analysis.

In general, using the checklist, the LPA is done daily (or per shift) by the process supervisor, weekly by the supervisor's manager, and monthly by the manager's boss. When a process step is found to be out of compliance with estab-

lished requirements, immediate corrective action is imposed by the auditor.

LPA checklists may have between 5 and 12 questions and the time to ask and verify a "yes" or "no" to these questions should be no more than 10 to 15 min. This is a very large commitment of time for a supervisor or manager, but time well spent. If after a month or two of 100% compliance with a given checklist, the timing of the LPA may be extended. More detailed information and guidelines to LPA may be found in the AIAG[11] publication LPA Guideline CQ1-8.

[11] Automotive Industry Action Group (AIAG), 26200 Lahser Rd., Ste. 2000, Southfield, MI 48,034-9738.

6

Supplier Partnerships and Control

Partners in Quality

ORGANIZATIONS THAT CONSIDER THEIR SUPPLI-ers to be part of their overall business strategy are going to be way ahead of their competition. Suppliers are an integral part of any organization's ability to operate in a cost-effective way. Companies who realize they are not always best at performing certain tasks and utilize the expertise and experience of suppliers will be rewarded with long-lasting business partnerships with selected suppliers. When developing a business partnership with a supplier, certain objectives need to be considered.

Improved Product Quality

One of the more important objectives is improved product quality. Business partners need to share information from the earliest stages of product development. I recommend that suppliers in a partnership relationship be permitted and encouraged to participate in your service/product quality planning (SPQP) process. Through this interaction, there may be processes or design changes identified that result in significant cost savings. Improved quality is also achieved through an analysis of your supplier's quality systems. Through quality system audits, opportunities for supplier improvement are identified, and by working with the supplier to meet these challenges, both benefit. Meeting this objective will be discussed later.

Cost Reduction

Another objective is to maintain or reduce costs associated with purchased material. In some organizations the material costs associated with purchased items can approach 100 % in the case of companies whose value-added contribution to the end product is mainly to assemble/build that product. A similar situation exists with distributors; they rely solely on their supplier for product cost, as the value added comes from the service they can provide. Even in organizations whose purchased material costs are only 20 %, there are considerable savings to be gained through a well-orchestrated supplier partnership.

Benefits to consider in a supplier partnership are blanket orders versus spot or single-purchase orders one lot at a time, value analysis through the SPQP process, and reduction in your supplier base.

Improve Delivery Performance

Creating or maintaining outstanding supplier delivery performance is another objective. This objective is achieved by opening up those communications necessary in partner relationships. Much can be gained when purchaser and supplier meet on a regular basis. Weekly meetings are recommended. Depending on the current order status, these meetings can be conducted as brief telephone conversations or as face-to-face meetings at either party's place of business. In addition, time should be devoted annually for an information seminar at your facility or off site in which you present your business plan to all key suppliers. This will be discussed later in this chapter when we discuss supplier involvement.

Trust

Depending on the nature of your business, another major objective is maintaining and controlling confidential and/or proprietary information. Your business is your business; to survive in today's global economy, only those who have a common interest in your organization's goals and objectives should know the details of your journey to satisfy these objectives. Some common sensitive areas are pricing, bid/quote information, process information, design specifications, company plans and goals, profit information, wage and salary scales, customer lists, supply sources, and supplier information.

Sourcing Considerations

There are three main considerations when selecting suppliers. One is the effectiveness of their quality systems, another is their process capability or capacity, and the last is their price. In a nutshell it comes down to quality, delivery, and value.

The key to assessing the expected quality performance of a future supplier is the Supplier Quality System Survey as part of the overall "partners in quality" (PIQ) concept. The survey should be designed to give an objective analysis of the supplier's quality systems, management goals, drawing and change control, procurement methods, production control, fixture and gauge control, process control, product control, documentation and records, packaging and shipping methods, and employee awareness of these systems.

Supplier Measures

The Partners In Quality Program should also provide for methods of measuring a supplier's performance to established criteria, including such things as on-time-performance, quality of supplied product, response to corrective action requests, cost containment, and meeting other value-added benefits. Many of these criteria are easily reported as CPIs and can be distributed to the supplier on a monthly or quarterly basis. Examples of purchasing reports will now be discussed and displayed for information and suggestions. The three examples given are very powerful CPIs when shared with your suppliers. All key suppliers

TABLE 6-1—Partner's in quality supplier rating summary.

Supplier[a]	Survey score[b]	Audit inspection[c]	Supplier status[d]
A	91.10	100.00	Certified
B	90.00	100.00	Certified
C	90.00	97.00	Preferred
D	81.40	98.10	Preferred
E	79.60	99.80	Preferred
F	78.20	99.20	Preferred
G	77.70	99.40	Preferred
H	76.40	98.60	Preferred
I	72.90	100.00	Approved
J	72.50	98.50	Approved
K	72.10	98.30	Approved
L	71.40	100.00	Approved
M	67.10	100.00	Approved
N	55.40	91.60	Conditional
O	55.00	99.50	Conditional
P	48.60	99.20	Conditional
Q	26.40	94.70	Conditional
R	26.10	100.00	Conditional

[a] Supplier code identifier.
[b] Score achieved on an on-site quality systems survey.
[c] Measure of incoming inspection results on a pieces received/accepted basis.
[d] Status of supplier based on composite of survey and audit scores.

would receive monthly the report shown in Table 6-1, allowing them to observe their current performance as compared with other suppliers who share your partnership agreement. By coding the suppliers as A, R (as needed), no confidentiality is compromised, as the supplier knows only that he is A or Q and does not know what code applies to others.

Figure 6-1, the PIQ Rating Summary, allows the supplier to see how the overall performance of the supplier base is meeting established goals. By knowing his individual score, the supplier has an understanding for how valuable his individual contribution is to that effort. If the supplier's score is below the average, we can assume we are not getting as much value added as we would from a supplier who is above average. This assists your purchasing department at negotiation time.

Figure 6-2 is an overall picture of your ability to receive orders from suppliers on time, which in turn provides confidence to your own production scheduling department in your ability to manage the purchasing function.

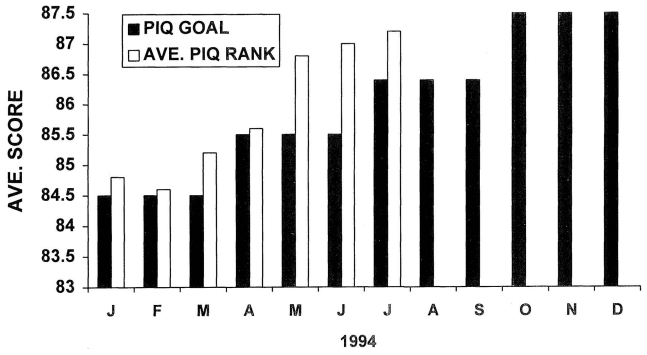

Fig. 6-1—PIQ rating summary.

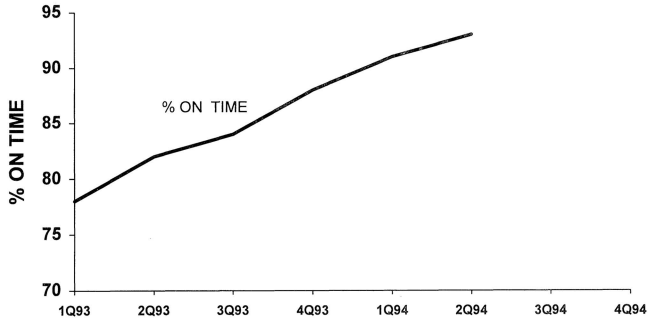

Fig. 6-2—Supplier on-time performance.

Supplier Involvement

One of the better ways to cement a partnership and to show your suppliers you are serious is to sponsor a "supplier day" at your facility. If you do not have adequate facilities, conduct the seminar off site at a local conference center. The objectives of the seminar are to review your company's business plan and goals, to discuss your continuous improvement progress, to establish supplier goals and improvement objectives, and to encourage involvement and participation. One method for structuring a program such as this is detailed in the following paragraphs.

If you do not have a list of your top 20 or so suppliers, prepare one using criteria that provide some measure to identify supplier worth such as dollar volume or critical components. After you know your top suppliers, send them a letter telling them about the seminar and invite them to attend by enclosing an RSVP form and a self-addressed envelope. If you do not get a response from some of your key suppliers, you may wish to consider asking suppliers whom you want to develop as future top suppliers to assure full attendance. After you receive responses and know which suppliers are interested, send a follow-up letter with a simple survey for them to complete. The survey should be designed to allow your suppliers to appraise your company as a business partner. A sample survey is shown as Fig. 6-3.

The rating scale goes from 5 to 1, with 5 representing excellent and 1 meaning very poor performance. The results of this survey should be analyzed carefully and shared with your suppliers. Where improvement is indicated, it should be pursued with a team approach including your suppliers whenever possible. Shortly before the seminar, provide the attendees with an agenda for the program. This gives the attendees time to develop the frame of mind you are hoping they would bring to the meeting. Included in the program should be a general business update by the top manager of the facility. This manager should also introduce the staff management and give a brief description of the continuous improvement programs underway. Each staff manager should give at least a 20-min talk on the continuous improvement projects in their respective departments. This demonstrates to the audience that continuous improvement can be applied to any discipline. It is not just a quality thing. This should consume most of the morning. In the afternoon, devote attention to your purchasing department's quality improvement objectives for suppliers. This part of the program should be shared by the purchasing and quality managers.

Supplier Evaluation of ABC Co.

Quality Attribute	Score: 5=Excellent/1=Unacceptable
1. Requests for quotation are clear and complete	
2. Blueprints and job specifications are accurate and legible.	
3. Satisfactory follow-up is given if a contract is not awarded on a quote.	
4. Purchase order format is clear.	
5. Purchase order information is accurate	
6. Invoices are paid according to stated terms and conditions.	
7. Purchase orders are issued within stated lead-times.	
8. ABC Co. provides the following information on a regular basis:	
a. Production plans for parts you provide a service.	
b. Your current delivery and quality rating	
9. ABC Co. communicates the level of quality expected.	
10. ABC Co. notifies you within a reasonable period after receipt if there is a problem with your service/product.	
11. Returned material is properly packaged and identified.	
12. ABC Co. employees are cooperative and respond to requests for information on a timely basis.	

In the following space, or on an additional submission, please list any questions/issues you want to discuss at our supplier seminar.

_____
_____
_____
_____
_____

Supplier Name: _____

Address: _____

City, State, Zip: _____

Fig. 6-3—Supplier survey form.

Leave an hour open for reviewing the supplier survey (Fig. 6-3) and for open discussion.

I have participated in several of these types of supplier involvement programs, and every one of them has been a success. When they are properly administered, both parties go away with a feeling of cooperation.

Supplier Quality Systems Survey

The Supplier Quality Systems Survey is a management tool that does many things for both the customer and the supplier. As the customer, you share with your supplier the quality philosophy your organization has chosen to apply to your business. You also have a consistent measure by which you can evaluate each supplier against their systems and each supplier with their competition. The survey requires communication between organizational counterparts in quality, purchasing, and others in each organization and develops understanding and relationships. The supplier gains because the survey provides a critical look at how well he is do-

ing business and to what extent he is satisfying the customer. All in all, the survey can serve both the customer and the supplier as they journey along the path of continuous improvement.

It is recommended that the quality systems survey be developed to follow closely your own quality manual since this survey will transfer your quality philosophy to your supplier. As an aid, I have prepared a model survey that follows the quality manual I present in Chapter 8. The Supplier Quality Systems Survey is in Appendix B.

When setting up the parameters of the supplier quality survey, special attention should be focused on assessing the supplier's management and their attitude toward teamwork and continuous improvement. Control systems to be assessed include document and change control, materials control, fixture and test equipment control, process control, product control, auditing methods, and quality reporting. Let us look at each of these elements in detail beginning with supplier management.

Supplier Management

A sense of the attitude carried by management in regard to PE/TQM principles has to be gained through the survey. We discussed these at length in Chapter 1. Is the management committed to team-oriented management and activities? Is there a customer focus that includes internal as well as external customers? Are there programs in place and planned for the future that assures the continued upgrading of employees through training? Does the management utilize the inherent job knowledge of their employees through empowerment and involvement of the workforce? And, is there a measurement system in place to track progress, such as CPIs?

Document and Change Control

There must be a system in place to assure that current documents and procedures are available to all users at the supplier's facility. It should also be established that obsolete documents and procedures are not available for general use, and are archived for retrieval by those with authorized need. Finally, the documents under control should be available at all locations where operations essential to the effective functioning of the quality system are performed.

Materials Control

There should be a system in place to assure that material, either purchased or produced, that is in inventory is identified as to inspection status and part identification. There should be a procedure for controlling suppliers, nonconforming material, corrective action, receiving inspection, packaging, and shipping. Work instructions for those who perform these functions should also be available.

Fixture and Test Equipment Control

Periodic calibration of test equipment and fixtures[12] are essential for control and verification of product quality. Controlled master standards shall be maintained and traceable to either national standards or manufacturers standards. The key elements of a successful fixture and test equipment program are:

- Calibration and certification of analytical equipment used to determine physical, chemical, or mechanical properties.
- Repeatability and reproducibility studies for equipment used to collect variable data.[13]
- Equipment history and inventory data.
- Records that include location, method of calibration, date of next certification, and current status.
- Marking system to identify equipment and its due date for certification.
- Procedures/work instructions for disposition of nonconforming equipment and fixtures.

Process Control

The supplier should have systems in place that provide a plan for production and identification of product. Better systems assign production to processes proven to be capable of achieving high levels of quality and output. This requires an analysis of the process through statistical methods discussed in Chapter 7. At a minimum, a suppliers system should provide for

- Documented work instructions.
- Compliance with the quality manual.
- Monitoring and controlling process parameters and product critical characteristics during production and assembly.
- Workmanship acceptance criteria via work standards or samples where possible.
- A safe, clean, and well-organized work environment.

Product Control

Product inspection and quality should be controlled to the fullest extent possible by the individual doing the job. I call this *point of control responsibility*; and where it can be applied, it is the most effective method of assuring product quality. The supplier's elements of product control should include

- Receiving inspection.
- First article inspection.
- Measurement system verification.
- In-process inspection to statistical sampling plans that specify zero defects.
- Final product audits.

Auditing Methods

Procedures must be in place to assure that all quality systems are functioning as written. This is carried out through quality system audits as discussed in Chapter 5. These audits should be scheduled according to the current status and importance of the activity. Results of the audits must be documented and deficiencies noted. All identified deficiencies require documented corrective action. Management responsible for the activity under evaluation should initiate and assure effective corrective action.

Quality Reporting

The supplier should have a cost-of-quality report in place that, at a minimum, tracks rework and scrap. The report should be distributed to appropriate management that can effect process and product improvements. When all eight criteria described above are in place and effectively implemented, one can be confident in the supplier's ability to satisfy your requirements and provide quality products.

[12] This applies only if fixtures are used as a final acceptance inspection device.

[13] ASTM F1469, Standard Guide for Conducting a Repeatability and Reproducibility Study on Test Equipment for Nondestructive Testing.

7

Statistical Quality Control Six-sigma, and Lean Manufacturing

ONE OF THE MORE EFFECTIVE TOOLS AVAILABLE to organizations that apply Performance Excellence and Total Quality Management (PE/TQM) is found in the applications of statistical quality control (SQC). The more common applications in use today include

- Pareto analysis
- Frequency distribution analysis
- Multivari analysis
- Measurement error analysis
- Control charts
- Cause and effect diagrams
- Process capability analysis
- Correlation analysis
- Design of experiments
- Acceptance sampling

Some of these applications can be used by nonstatisticians, and others require in-depth knowledge of statistical theory. The point is that everyone in the organization from top management to the hands-on employee can use at least some or all of these techniques to improve their effectiveness.

As discussed in earlier chapters, the commitment and understanding of upper management must be present for any program to succeed; this is especially true with a statistical quality control program. More often than not, when we apply statistical tools such as process capability and process control, we find out more about the process than we may have expected. We may find that our fixtures are not capable of positioning our part piece to assure precise contact with the tool or die. This may require significant expense to remedy. Unless there is commitment from upper management, the decision more often than not is: Do the best you can, we"ll sort out any defects if necessary.

It is not my intent to present a complete study on statistical methods. Primarily, this is a book on PE/TQM; however, it is important to provide a brief overview on the subject so those in upper management understand how SQC came to be and how some of the applications are applied to propel practitioners along the path of continuous improvement.

Quality Control

Quality control has been with us for thousands of years, but it was not until about 200 years ago, at the beginning of the Industrial Revolution, that we began to drift away from the craftsman method of assuring quality. The craftsman's method of controlling quality was a very personal one. He made sure that whatever he produced was, to his way of thinking, acceptable for commerce. It met his standards.

When the industrial revolution began, other influences arose that determined the quality of a product, the market, or the end user. In the beginning of this period, factories were small and located in the "industrial" cities. It was difficult to move commerce across the landscape, so industries served local communities. This provided for small lot sizes and screening (100 % inspection) as a method to control quality.

During the 1920's and into the 1940's the pace of manufacturing changed from small production lots to larger and larger production runs. Included with this increase in production were advances in engineering, which led to more complex design and assemblies. It was during this period that lot-by-lot inspection gained wide acceptance by management. During the 1940's and 1950's, lot-by-lot inspection was the only way quality control personnel (i.e., inspectors) could keep up with production because screening slowed the process too much.

However, it was not long before everyone realized that lot-by-lot inspection, although fast, had serious shortcomings, not the least of which was the possibility of accepting a lot containing nonconforming parts simply because the sample taken was free of these parts. Thus, the customer or end user would receive a percentage of parts that were useless, or worse yet, dangerous.

During the 1960's and 1970's, the shortcomings of both screening (time consuming and ineffective) and lot-by-lot inspection (not fully acceptable to the customer) encouraged management to develop what came to be known as in-process inspection. In-process inspection was usually accomplished by an inspector who patrolled the manufacturing floor checking on equipment, materials, methods, people, and output. In-process inspection was also sometimes carried out by the machine operator responsible for a particular phase of the manufacturing process. For example, a machine operator may measure a few pieces every hour during the production run to make sure the parts are within engineering specifications, or a plater may check the coating thickness on a fastener on one or two pieces every tenth barrel or rack to assure conformance.

In-process inspection coupled with lot-by-lot inspection was much more acceptable from the consumers' point of view because they were assured of a better chance of receiving a product to their requirements. But it still had its short comings:

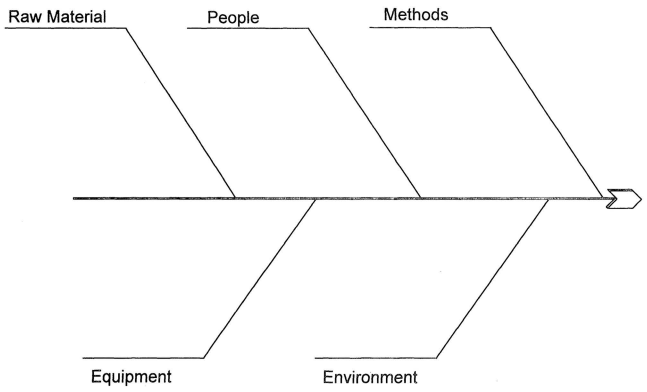

Fig. 7-1—Typical process stream.

- There was no way of knowing what went on between visits by the inspector.
- Lot-by-lot inspection still permitted nonconforming parts to be shipped, even with zero as the acceptance number for rejects.
- When nonconforming parts were discovered, it caused production delays that were unplanned.
- The costs of scrap and rework for the manufacturer were very high.
- The system bred mistrust between inspector and machine operator.

The ineffectiveness of screening, lot-by-lot inspection, and in-process inspection along with a business climate that demanded both increased profits and consumerism led management to an increased interest in modern SQC methods.

Statistical Applications

The need to better understand our manufacturing processes led to application of statistics and statistical process control (SPC). Management saw the use of SPC as a means of providing a better product for their customers while at the same time reducing the overall cost of quality. When implementing an effective SPC program, organizations needed to work under many of the philosophies found in W. Edwards Deming's 14 Points of Management (see Chapter 3). These 14 points, although meant for management, have wide application for all employees once upper management is applying PE/TQM principles throughout the organization.

Descriptive Statistics

Variation is present in all "like" things in the universe. There have never been any two things that are exactly alike. No two people are exactly alike, no two grains of sand, no two metal stampings, and so on. As long as we have the means, we can examine and analyze until we find a difference. This is an important concept to understand because variation is the cornerstone of our foundation for SPC.

In any industry, variation is caused by common and special causes that are present in any process stream. Figure 7-1 represents a typical process stream made up of raw materials, people, methods, equipment, and the environment surrounding the process. All or any one of the elements of a process stream may contain variation that could affect the output. By accepting variation as a fact of any process, we can deal with it in a scientific manner as statisticians.

The variation one can encounter in this process stream may be common or special:

- *Common cause variation*—a source of chance variation that is always present; part of the natural variation inherent in the process itself.
- *Special cause variation*—a source of variation that is intermittent, unpredictable, and unstable. It is signaled by an out-of-control condition on a control chart.
- *Control chart*—a graphic representation of the output of a process showing plotted values of some statistic gathered from that output, a central line, and one or more control limits. It is used to detect special causes of variation.

In the process stream, materials are expected to have certain properties, and the elements that contribute and define those properties are a source of variation. When the process making the material contains only common causes of variation, the process is said to be in control. If one of the properties should exhibit a new trait or characteristic, it may be a source of special variation. This must be evaluated carefully so as not to identify this variance as special when it may be common—we just did not see this side of the material before. Many sources of special variation can be influenced by the person running the process and to some extent can be overcome. The sources of common variation are not controllable by the process operator. They are present and will influence the process no matter what the person running it attempts to do to overcome that influence. Only a change in the process stream will change the variation inherent in the process.

We could look at each of the other elements of the process stream—people, environment, methods, and equipment—and see the same dilemma. They all contain variation—some we can control and some we cannot. A heat-treating process contains several elements that contribute to the successful end of meeting all the mechanical properties specified in the engineering specification.

Let us look at an example of the hardness of an ASTM A490[14] bolt heat treated to a specified core hardness of HRC (Hardness Rockwell C-Scale) 33/39. Data were collected on a 50-piece sample and the following values were observed as shown in Fig. 7-2. A statistician could describe these data in the form of a histogram as shown in Fig. 7-3.

When one looks at the two methods of describing the hardness data, it becomes obvious that the histogram provides a much clearer view than the table of values for the same data. When we look at the table, it is not readily apparent what the range of values is, what the most common value is, what data are in specification, or how the data are distributed. By having the same data in histogram format, we see at a glance that the range of values is from HRC 34 to 39; we see HRC 36 as the most common value; we see the values of all fall within the HRC 33-39 specification; and we know that the values are evenly distributed about the midpoint of the specified range.

It would be useful to further evaluate the data in Fig. 7-2 and learn a little more about the central tendency. There are three measures of central tendency that find application in

[14] ASTM A490-08b Standard Specification for Structural Bolts, Alloy Steel, Heat Treated 150 ksi Minimum Tensile Strength.

Hardness Data

36	35	35	34	36
34	37	36	36	37
35	35	36	36	37
36	37	35	37	38
36	35	35	34	36
34	37	36	36	37
35	35	36	36	37
36	37	35	37	38
38	37	35	37	38
36	36	37	37	38
36	38	37	35	36
36	35	34	38	39
37	36	38	35	37
36	37	36	35	36

Fig. 7-2—Hardness data.

statistical analysis; they are the mean, the median, and the mode. The mean is the numerical average calculated by adding all numbers in the set of data and dividing the sum by the number of Individual values in the data set. The median is the middle value in a set of data arranged from the smallest to the largest. The mode is the most frequently occurring value in a data set.

A small set of data (Fig. 7-4) will serve to illustrate these definitions. In this set of data, the mean is (33 + 36 + 35 + 37 + 37) ÷ 5 or 35.6. The median value is 36, and the mode is 37. To the industrial user of statistics, the mean, usually referred to as the average, is the most used statistic from a set of data. The average along with measures of dispersion is used to further define how the process is performing. There are two terms that relate to dispersion; they are range and standard deviation. The range is defined simply as the difference between the highest and lowest values in a set of data. The range of the data in Fig. 7-2 is 5, the difference between the high value of 39 and the low value of 34.

There are many ways to define standard deviation, but the one generally used in classic examples for SPC is: *standard deviation*—a measure of the dispersion of a series of data around their average (mean), expressed as the square root of the quantity obtained by summing the squares of the deviations from the average of the results and dividing by the number of data points minus one. This looks more compli-

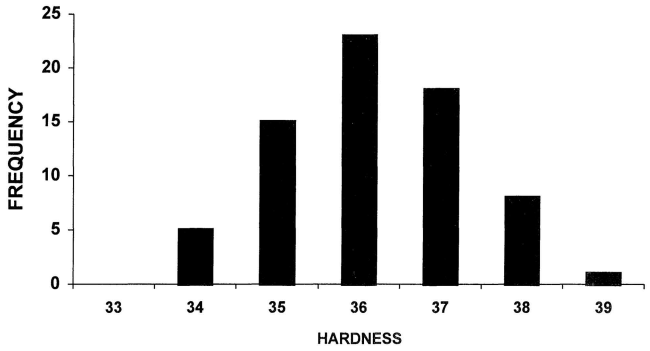

Fig. 7-3—Histogram of 70 hardness tests.

Test Data

33	36	35	37	37

Fig. 7-4—Test data.

cated than it is. Today, the calculation of the standard deviation (a) is accomplished with only an understanding of the basic mathematical skills of addition, subtraction, multiplication, and division. And if we are lucky, it can all be handled by a simple computer macro command once the raw data are entered. For the sake of completing the example, the standard deviation for the data in Fig. 7-2 is: a = 1.178723, or rounded off to two significant figures, 1.18, the mean is 36.28, the median is 36, and the mode is 36.

This technique is useful when studying raw data collected from a larger population of data and has application to both office and laboratory analysis. Better techniques are available to industrial applications that not only provide the descriptive statistics presented above, but that also give the analyst an idea of what the process is doing and capable of doing. This is called statistical process control or SPC.

SPC

SPC is a method of studying a process through the use of control charts. A control chart is a tool for the operator of a process, the manufacturing engineer when evaluating the process, or anyone else who has an interest in the process. Control charts are based upon data. The data must be collected in such a manner as to remove as much bias as possible. This requires the evaluation of devices used to measure the characteristics that become data. There are two definitions of data:

- *Variable data*—Characteristics that can be measured and expressed in values from a continuous scale. This type of data must be collected through a gauge or test device.
- *Attribute data*—Characteristics that can be defined as either pass/fail, yes/no, conforming/nonconforming, etc. A gauge or test device may be used as well as written or visual acceptance criteria.

For example, the hardness values in Fig. 7-2 are variable data because the values are from a continuous scale (i.e., 20 to 70 on a C-scale of a hardness tester). If we were determining what data in Fig. 7-4 are less than 36 because any value less than 36 was defective, we would be working with attribute data in the form of conforming/nonconforming. In this case, there are two values nonconforming and three values conforming. Typical gauges used in the collection of variable data would include micrometers, calipers, dial indicators, coordinate measuring machines (CMMs), electronic testers, hardness testers, etc. Gauges for attribute data include go/no-go fixtures, color charts, thread ring gauges, etc. Regardless of the type gauge used in evaluating the object under investigation, the gauge must have repeatability and reproducibility. There are several tests one may apply to determine an instrument's repeatability and reproducibility (R&R); the one discussed in Appendix A is ASTM F1469, Standard Guide for Conducting a Repeatability and Reproducibility Study on Test Equipment for Nondestructive Testing. This standard describes fully how to conduct the test and how to interpret the results. It also contains an example

for the user to follow. Briefly, when we evaluate for repeatability we are analyzing the instrument's precision, bias, and accuracy. In evaluating reproducibility, we are determining the instrument's ability to produce the same measurement on the same piece between two or more operators. There are several reasons one should conduct a gauge R&R. Among them are:

- To provide a criterion to accept new measuring devices.
- To compare one measuring device against another.
- To compare measuring devices before and after calibration or repair.
- To provide a basis for evaluating a measuring device suspected of being deficient.
- To provide a reliable measuring device for collecting data for SPC.

Variable Gauge Analysis

The variable gauge analysis is conducted with two or three operators and test parts of different values. Each of the two or three operators measures each test part in such a manner as to prevent operator bias in evaluation. It is advisable to have a third or fourth party participate in the study by collecting data from the operator's measurements. This way neither operator will know what the other got for a measurement until all data are collected.

All data are listed on a work sheet, and the necessary calculations are performed to complete the analysis. In most cases, a gauge error of 10 % of the specification tolerance, or less, is considered an acceptable variance for statistical control. If the error is greater than 10 %, the device must either be improved or replaced with one that is acceptable. More detail is provided in ASTM F1469.

There is also a study for attribute data one can apply to test devices that provide a go or no-go evaluation of the test part. The study is not as scientific as the one for variable type equipment, but it provides for some assurance of the measuring system.

Attribute Gauge Analysis

The attribute gauge analysis is conducted with two operators that each evaluate 20 test parts against two standards of known value, one conforming and the other nonconforming. In conducting this evaluation, it is desirable that some of the parts being tested be either slightly above or below the specification limits so as to truly test the measurement system. The test is run twice by each operator, and the results are recorded on the analysis work sheet. A sample attribute gauge analysis work sheet is provided in Appendix C. As with the variable gauge analysis, it is recommended that a third party be involved so as to lessen operator bias.

The measurement system is considered acceptable if all evaluation decisions are in agreement with each other. If any of the evaluations disagree, the system must be improved and then reevaluated for effectiveness. If the measuring system cannot be improved, it is considered unacceptable and an alternate measuring system must be developed.

Understanding variability, data, the process, and gauge R&R are requisites to evaluating the process through the use of control charts. There are several control charts available to study processes, but we will focus on variable and attribute control charts.

Variable Control Charts

We can apply variable control charts whenever we are able to collect variable type data. The more common variable control charts are:

- X & R *chart*—Control chart for averages and range
- X & s *chart*—Control chart for averages and sigma (?)
- *Median chart*—Control chart for median and range
- *Chart for individuals*—Control chart for a moving range

Attribute Control Charts

We apply attribute charts whenever we are collecting data that have only two options, right or wrong, yes or no, etc. The more common attribute control charts are:

- *p-chart*—Control chart for fraction defective
- *np-chart*—Control chart for number defective
- *c-chart*—Control chart for defects per unit (constant subgroup)
- *u-chart*—Control chart for defects per unit (variable subgroup)

All of the above control charts have unique characteristics that render them useful under given conditions. I will not attempt in this study to provide a step-by-step method for constructing the eight charts listed above, but I will provide some basic guidelines that should be followed regardless of the type chart selected to monitor a process. There are two books I recommend for the reader who is interested in learning more about the control charts and their construction. The first is Understanding Statistical Control.[15] and the second is Recommended Practices for Statistical Process Control.[16]

Guidelines for Control Charting

- *Management training*—Management must understand the value of SPC and the basics of application. They must drive fear from the corporate culture so that accurate reporting can occur. Employees must be permitted to concentrate on quality, not numbers. Management must understand that SPC will identify opportunities for improvement that may require capital investment in the process.
- *Employee training*—Employees need to be trained in basic SPC. They need to know how to determine when a subgroup is out of control. They need to be able to recognize trends and runs for sequential subgroups. They need to realize that all opportunities identified for improvement may not be addressed in the short term due to the need for capital expenditures. They need to understand what they can control and what must be changed by management in a process.
- *Understand the process*—Flow chart the process to understand how and where characteristics part are affected in the process stream. Determine all contributing elements from the process stream: material, methods, people, equipment, and environment. Ask what each contributes to the characteristics being evaluated during the charting process.
- *Choose the characteristics for charting*—Base your deci-

[15] Wheeler, D. J. and Chambers, D. S., *Understanding Statistical Control*, Statistical Process Controls, Inc., Knoxville, TN, 1986.

[16] Compilation from contributing authors, "Recommended Practices for Statistical Process Control," Industrial Fastener Institute, Cleveland, OH, 1991.

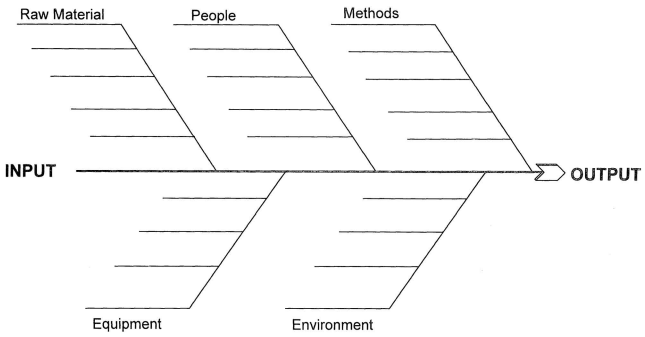

Fig. 7-5—Cause and effect diagram with inputs.

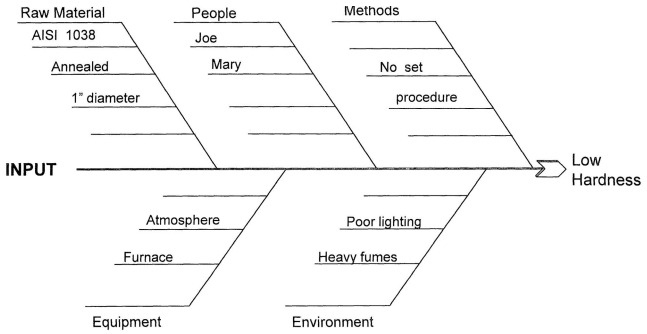

Fig. 7-6—Cause and effect diagram with influences on inputs.

sions on need for improvement. Do not attempt to chart every characteristic a process produces. Paretoize to determine which ones have the most effect on changing the output. Use the SPQP process to characterize characteristics as to their importance in satisfying the customer and chart high achievers from that list.

- *Choose your method of measurement*—Determine the test and measuring equipment by choosing ones that measure to at least 10 % of the characteristic's stated tolerance and one that has a gauge R&R $<$10 %.
- *Remove sources of variation*—When the process is studied, find ways to remove as many sources of variation as possible. The end result should leave only common causes of variation in the process stream to the greatest extent possible. As the process is charted, management should evaluate the results to find ways to reduce the common causes from the system by changing the process.
- *Process capability analysis*—Prior to allowing the operator to chart the process, one should first evaluate the process for process capability. The first thing a process capability study will tell us is if the process is in a state of statistical control. There is no point in going further with charting until this state has been achieved. This gives management a starting point in determining how well the process will answer the call to produce product within engineering specifications. A method to conduct process capability analysis is provided in ASTM F1503, Standard Practice for Machine/Process Capability Study Procedure.[17] For your convenience, a brief description of this standard is provided in Appendix A.

Cause and Effect Diagrams

A very simple yet powerful tool is the cause and effect diagram, or fishbone analysis. This tool utilizes the process stream model with a few modifications. A typical cause and effect diagram starts off as shown in Fig. 7-5.

You can see why it is sometimes referred to as a fishbone diagram. This tool has its greatest potential when a team is assembled to brainstorm a process. It would be good at this point to provide an example of how this tool is used. We will assume we have a team pulled together to evaluate the heat-treating process for ASTM A325 bolts. The hardness requirement is HRC 25-34, and we are having difficulty meeting this specification on a consistent basis. Some thoughts the team might come up with are shown in Fig. 7-6.

The next step would be to find ways to improve the system or to remove variables that contribute to the undesirable output, low hardness. Our team found many areas in the present system that needed mprovement. Not all would contribute to resolving the low hardness problem, but even those contribute to quality of work life, so it was decided to recommend all improvements to management for action. The team's recommendation is represented as Fig. 7-7.

Pareto Analysis

It is sometimes useful to group data in descending order to determine what inputs have the most impact on the data or situation. The tool used to accomplish this is called Pareto analysis, named after the Italian economist, Pareto. His theory was that to gain the most from our resources we should concentrate on the vital few, and not worry about the useful many. There are many applications for this theory when opportunities for improvement are so numerous that full-scale analysis cannot be done on them all. We can focus on the vital few that account for 80 % or more of the total opportunities.

A case study of an application of the Pareto principle would serve as a good example. At Kennametal, Inc. in Solon, Ohio, we knew we had an opportunity to improve our on-time performance to customer ship dates if we could reduce the lead time in our process engineering department.

We established a team from the process engineering department to flow chart the process. After the process was fully identified, we asked the team to find ways to reduce road blocks to doing their job in an efficient manner. Several items were identified as contributing to their failure to process an order. These were missing blueprints, unclear blueprints, service, off-loading, priorities, tooling/fixture availability, and system problems. An explanation is required here to make you aware of what each category represented. We process an order through Process Engineering by working on a job packet from Customer Service. The job packet contains: part blueprints, promised delivery date, special customer requirements, and the number of pieces required. It is the job of Process Engineering to develop a process routing to manufacture the order.

Off-loading means the job could not be run on the equipment originally scheduled for processing. Service is when a process engineer is called to clarify process instructions for an operator on a machine or when the engineer needs to call

[17] ASTM Committee F16 on Fasteners.

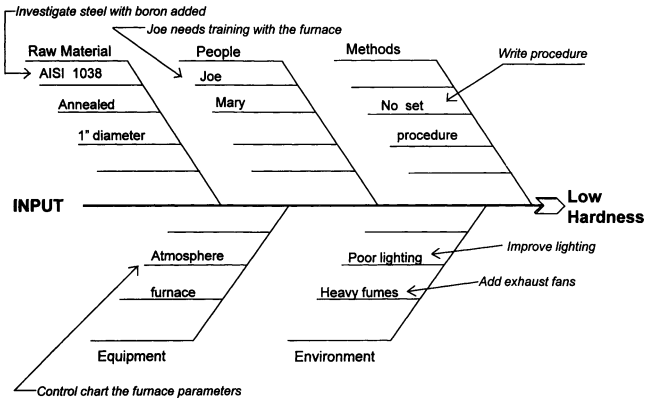

Fig. 7-7—Cause and effect diagram with improvement recommendations.

Customer Service or Design Engineering for clarification. Priorities are jobs that interrupt the job they are currently working on. System problems represented those times when the CAD/CAM program was down. The other categories are self-explanatory.

This list became our CPIs, and systems were put in place to track the number of occurrences for each of these indicators. We tracked results for 6 weeks and paretoized the data to identify opportunities for improvement. The accumulated data are shown in Table 7-1.

To make the data more meaningful and to present it in a fashion that would instantly define opportunities for improvement, we put the data in the form of a Pareto chart (Fig. 7-8).

From the analysis, service had the greatest number of occurrences, blueprint clarification had the second most, and missing blue prints were next in number of occurrences. These three categories represented 79 % of all reasons for delay. The next step was to develop an action plan to reduce the occurrences of these three factors. The strategies employed included cross training between design and process engineers and creating product-specific teams of design and process engineers, customer service representatives, and machine operators.

Several opportunities were identified as the result of this exercise. Through better tolerancing of our product (based on capability) we reduced tooling costs, programming costs, and manufacturing costs. By utilizing geometric dimensioning and tolerancing (GD&T), we improved our processing capabilities. Through a better understanding of our CAD geometric features and through silo tumbling we were able to utilize features of our standard parts on our custom-engineered parts.

The results of this project included reduced service and blueprint clarification occurrences, better communications between departments, better quality programming, and better efficiencies.

After 6 months, another Pareto analysis was performed and other opportunities were identified. The problems identified in the first analysis were all but eliminated as causes of delay (see Fig. 7-9).

The team now had a new set of challenges for continuous improvement, and they set about finding ways to reduce delays due to off-loading and the unavailability of tooling and fixtures and dealing more effectively with priorities.

The other statistical tools listed in the beginning of this chapter require a broader knowledge of statistics than covered in this book. Information on multivari analysis, correlation analysis, and design of experiments should be pursued in text books dedicated to those subjects. The effort would be well worthwhile as these tools are very effective in defining the root causes of variance, which, in turn, should lead to better efficiencies.

Lean/Six-sigma

Today, most quality and business executives believe that combining Lean Manufacturing practices with the methodologies of Six-sigma is the way to go in process management.

Lean manufacturing or lean production, which is often known simply as "Lean," is the practice of a theory of production that considers the expenditure of resources for any means other than the creation of value for the presumed customer to be wasteful, and thus a target for elimination.[18]

Six-sigma seeks to identify and remove the causes of defects and errors in manufacturing and business processes. It uses a set of quality management methods, including statistical methods, and creates a special infrastructure of people within the organization ("Black Belts," etc.) who are experts in these methods. Each Six-sigma project carried out within an organization follows a defined sequence of steps and has quantified financial targets (cost reduction or profit increase).[18]

Lean

In simple terms we use Lean practices to identify opportunities for improvement through elimination of waste (movement, processes, tooling, time, inventory, etc.), and act to remove those extraneous entities from the process stream. Common tools used in the elimination of waste are value stream mapping, Five S, Kanban (pull systems), and poka-yoke (error-proofing).

[18] From Wikipedia.com

TABLE 7-1—Pareto analysis.

	1st week	2nd week	3rd week	4th week	5th week	6th week
Missing B/P	35	37	25	30	27	23
B/P clarification	60	58	42	52	75	50
Service	65	78	60	88	79	72
Off-load	15	12	20	18	5	10
Priority	5	8	7	6	8	5
Tooling/fixtures	30	25	20	11	21	15
System down	3	5	0	0	3	4

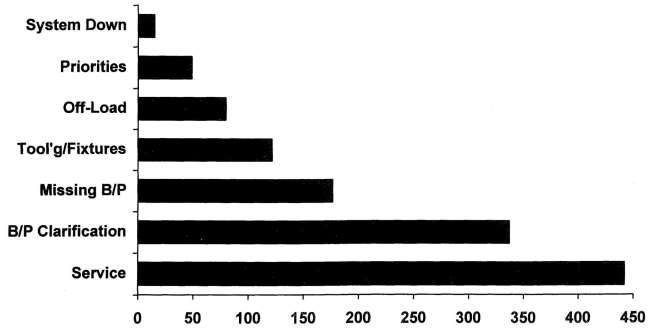

Fig. 7-8—Pareto Chart 1.

Value Stream Mapping

Value stream mapping is an expansion of Flow Chart Analysis discussed in Chapter 2. The expansion is that we flow chart the current steps, delays, and information flows currently required to bring a product or service to our customer. We begin with the original inquiry from the customer and end with shipment of our product/service to that customer. Each step in the value stream is thoroughly examined for opportunities to reduce time, cost, and effort. In most cases common sense will point the way for reduction in waste; in others, the deployment of Six-sigma will be needed to effect improvement.

The Five S (5s)

The 5s discipline requires clearing out things which are not needed in order to make it easier and faster to obtain the tools and parts that are needed to perform given tasks. It matters not whether the task is in manufacturing or in a service capacity. The idea is to have and keep the work place organized. The 5s's are:

- Sort—going through all tools and materials in the work space, and keeping only what is necessary to complete the given task, and removing and discarding all others.
- Straighten (or set in order)—to arrange the tools, equipment and parts in a manner that promotes work flow in order to maximize efficiency in the work place.
- Sweeping—the idea is to keep the work space clean in a systematic manner by assuring that the tools and materials necessary for work are always in place where they should be. A check for this is done at the end and beginning of each work shift.
- Standardization—the development of work procedures and methods as described in Chapter 4, Quality Systems. This assures that work is performed in a consistent and standardized fashion, and that job responsibilities are defined for all that perform a given task at a given work station.
- Sustaining—develop a culture that assures continuation of the previous 4S's through periodic review of work instructions and procedures that define the task at hand. This is best accomplished through internal audits described in Chapter 5, Quality Reporting.

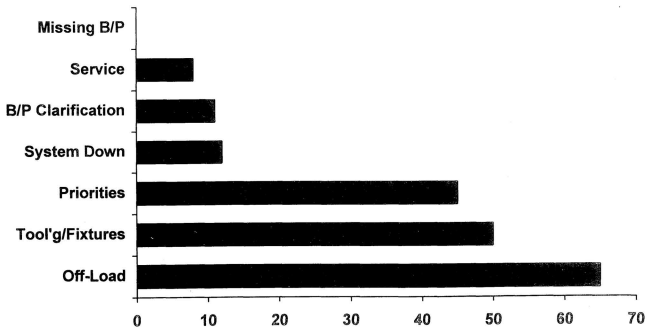

Fig. 7-9—Pareto Chart 2.

Kanban

Kanban (pronounced KamBan) is a system where processes are designed to permit just the right amount of material to be available as is necessary to complete the task at the time the task is performed. In the US, the term most closely associated with Kanban is Just in Time (JIT) production. This is a simple concept, but a very difficult one to deploy. It requires a close partnership with the supply chain (see Chapter 6, Supplier Partnerships) and internal operations. In the case of supply parts not manufactured in-house, we optimally will see three "bins" of parts: one bin on the factory floor, one bin in the factory's inventory, and one bin at the supplier. The idea is that as the factory bin is depleted, the bin from inventory is issued to the factory floor, and as soon as this happens, the supplier is requested to ship his bin to his customer (the factory). The shipping of the supplier's bin is his signal to produce another bin of parts to be available for the factory (the customer). The trigger for action on all three bins is the application of cards (or markers) that accompany the bins of parts. When a bin is empty, this card (which has all the specifications and quantities necessary to resupply the bin), is pulled and serves as the order for replenishment. The use of the term Kanban comes from the Japanese translation: Kan—meaning "visual," and Ban—meaning "card" or "billboard."

Poka-yoke

Poka-yoke—the idea behind poka-yoke is to establish methods of mistake proofing. A few examples should illustrate the principle. I picked two examples (Highway Rumble Strips and Automobile Fuel inlet/cap) off the web[19] that are common to most of us, and therefore we can truly appreciate the effectiveness of such poka-yoke applications. A viable method to identify situations in your business product/service is to perform a product FMEA described in Chapter 2, Strategic Planning. While working through the FMEA, one might encounter a situation under the "Current Control Method(s)" that poses a safety hazard. An example in the fastener industry may be the thread direction for a power miter saw arbor bolt. In this case, one would discover through a FMEA that a right-handed bolt may have a tendency to loosen while the saw blade is turning at high RPMs because the saw blade rotates in the same direction as the arbor bolt. Switching to a left-handed thread now puts the rotation of the saw blade and the arbor bolt in opposite directions thereby maintaining the tightness of the joint.

Rumble Strip Application of poka-yoke:

[19] From Wikipedia.com

Description:

Driving by Braille is not recommended; however, these carved depressions in the road are an effective warning that the vehicle's wheels are headed for danger. The little bumps provide the driver with tactile and audible warning that the car is not in its lane.

Automobile fuel inlet and cap application of poka-yoke:

1. Filling pipe insert keeps larger, leaded-fuel nozzle from being inserted.
2. Gas cap tether does not allow the motorist to drive off without the cap.
3. Gas cap is fitted with ratchet to signal proper tightness and prevent over-tightening.

Six-sigma

Six-sigma was derived out of the statistical application "process capability," and its goal is to provide no more that 3.4 defects per 1,000,000 opportunities. Or put another way, 99.9997 % good product/service. As one can imagine, this is not an easy goal to accomplish. It takes a great deal of effort on the part of management and practitioners to implement and provide desirable results from this quality tool. There are two methodologies used in Six-sigma applications: DMAIC and DMADV. The basics of each are to be found in the PIE continuous improvement process described in Chapter 3, Continuous Improvement. Specifically, in Six-sigma, the acronyms are described below.

DMAIC

- *Define* process improvement goals that are consistent with customer demands and the organizations' strategic goals.
- *Measure* key aspects of the current process that effect quality of output, and collect relevant data.
- *Analyze* the data to verify cause-and-effect relationships. Determine what the relationships are and attempt to ensure that all factors have been considered.
- *Improve* or optimize the process based upon data analysis using techniques such as Design of Experiments.
- *Control* to ensure that any deviations from target are corrected before they result in defects. Set up pilot runs to establish process capability, move on to production, set up control mechanisms, and continuously monitor the process via controls established in the Service/Product Quality Plan described in Chapter 2.

DMADV

- *Define* design goals that are consistent with customer demands and the organizational strategic goals.
- *Measure* and identify CTQs (characteristics that are Critical To Quality), product capabilities, production process capability, and risks.
- *Analyze* to develop and design alternatives, perform a DFEMA to create a high-level design.
- *Design* details, optimize the design, and plan for design verification. This phase may require computer designed simulations.
- *Verify* the design, set up pilot runs, implement the production process and hand it over to the process owners.

Implementation roles are similar in Lean and Six-sigma: in both cases management is key to developing the mind set and culture for improvement. Management must choose the best available individuals within the organization to lead the various employee teams to implement each strategy. Team leaders must be well trained and be able to motivate those who serve on the team.

There has been some criticism of Six-sigma, as in the following excerpt from Fortune magazine: "In fact, of 58 large companies that have announced Six-sigma programs, 91 percent have trailed the S&P 500 since, according to an analysis by Charles Holland of consulting firm Qualpro."[20] The main point of Holland's criticism was that Six-sigma is narrowly designed to improve upon existing processes.

With this in mind, I would suggest that organizations consider the use of Lean practices for existing processes, and the use of Six-sigma methodology DMADV for new product development.

[20] Betsy Morris, Fortune July 11, 2006.

8

Quality Manual Guidelines for ISO 9001

THE DEVELOPMENT OF THE QUALITY MANUAL IS A task that requires close coordination between all members of the management team. The quality manual describes how the quality systems are applied to each operating unit in the organization. As King Ramses[21] said, "So it is written, so it shall be." This is how auditors will interpret the contents of your quality manual. It is how your top management should convey the written document to the entire organization.

The quality manual should be formatted after guidelines that satisfy organizational goals, customer requirements, and international standards on quality. This is a huge task and not the sole responsibility of the quality department. It becomes necessary for all department and operating unit managers to supply input to the quality department as they formulate the document.

The guidelines provided in this chapter satisfy only national and international quality requirements. It is not possible to include organizational goals or customer requirements in these guidelines as they are dependent upon particular and unique demands. However, those requirements must be integrated where necessary.

The guidelines are fashioned after ASTM F2688[22] and ISO 9001.[23] ISO 9001:2008 is the most widely used international standard that specifies requirements for a quality management system, and requires third party certification (registration) in order for an organization to claim compliance to that standard. ASTM F2688-08 is a new international standard that was developed specifically for the Fastener industry. This standard does not require third party certification (registration). The ISO standard may apply to manufacturing or service applications, while the ASTM standard is manufacturing specific.

Each of these standards provides an excellent model for a process-based, customer-centered systems approach to business excellence.

The quality manual is considered a first tier document within the quality management system, and is supplemented with written procedures and work instructions, detailed in Chapter 4, Quality Systems. The first decision is to decide how your manual will be organized. There are no requirements specified by ISO as to how the quality manual should be formatted, but most organizations prefer to follow the organization structure in the standard. This makes it easier for auditors to verify an organization's conformance to the standard.

ISO 9001:2008 has eight main groupings and three Annexes in the table of contents. The first three listings in the table of contents are not required to be discussed within a quality manual. The next five requirements require detailed discussion in your quality manual. These are:

- Quality management system (see Fig. 8-1)
- Management responsibility
- Resource management
- Product realization
- Measurement, analysis, and improvement

Each of these topics contains requirements necessary to satisfy the standard, and you are required to address each of these requirements germane to your business practices. The relationships of these requirements are shown in Fig. 8-1.

In observing the relationships in Fig. 8-1, the interconnections are illustrated by the intersecting circles and the directional arrows. The quality management system is represented by the five intersecting circles. The flow of direction is counterclockwise and starts with management. The loop ends with data supplied to management and begins again with management's reaction to the supplied data. The customer involvement with the organization is illustrated by two-way communication between the customer and organizational management, and one-way communication providing customer requirements to the product realization functions. Customer satisfaction is a result of the organization's action/reaction to customer feedback and internal feedback on the quality management system's effectiveness.

Quality Manual

Suggested Table of Contents

1.0 Quality Management System
2.0 Management Responsibility
3.0 Resource Management
4.0 Product Realization
5.0 Measurement, Analysis, and Improvement

1.0 Quality Management System

1.1 The quality manual should identify how the interaction shown in Fig. 8-1 is implemented, managed, improved upon, and documented, including:

- The establishment of documentation such as the quality policy, quality manual, operating procedures, work instructions, and records.
- How this documentation is related to processes that affect quality, how they are sequenced, and their interaction to one another.
- How this documentation is monitored, measured, and analyzed; and how actions are determined to achieve continual improvement of these processes.

[21] One of the eleven kings of Egypt, B.C.

[22] Available from ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428-2959.

[23] Available from the American National Standards Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036.

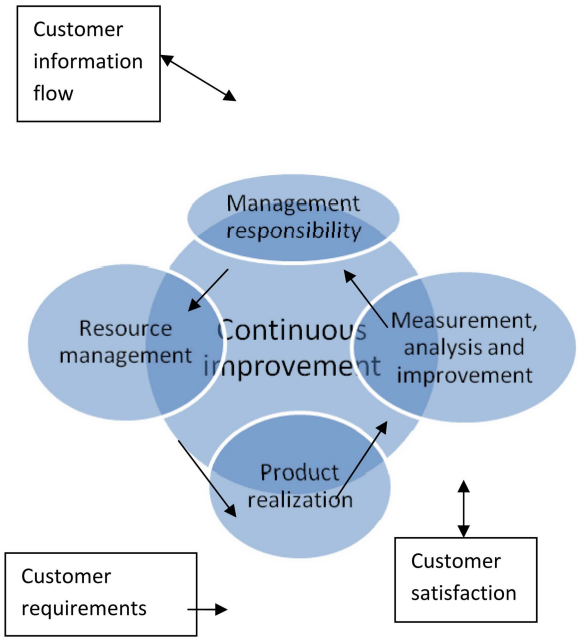

Fig. 8-1—Model of a process-based, customer-centered quality management system.

- How control is established and maintained for the documents contained within the QMS, and
- How records of conformance to these requirements are identified, stored, protected. Establish retention time and disposition of obsolete documentation.

2.0 Management Responsibility

2.1 In this section top management must provide evidence of its commitment to the development and implementation of the quality management system (QMS).

- Document how customer requirements are determined, are met, and how customer satisfaction is achieved.
- Document how the Quality Policy is germane to the organization's vision, how it addresses a commitment to continual improvement, how it provides for the establishment and review of quality objectives, how it is communicated within the organization, and the mechanism for its sustainability.
- Document how quality objectives and the QMS are planned to meet customer and organizational requirements.
- Document how responsibilities and authorities are defined and communicated within the organization to manage the QMS, including the role of the Management Representative.
- Document how management review of the QMS addresses data gathered through the measurement, analysis and improvement processes, and what actions are initiated as a result of that data to improve the effectiveness of the QMS.
- Records of these processes shall be maintained.

3.0 Resource Management

3.1 In this section, management must define how human resources, training, infrastructure, and the work environment are managed to meet the QMS requirements, including:

- Document how human resources are assigned to the QMS, how they are trained, evaluated for competency, how their effectiveness is determined.
- Document how the organization's infrastructure is determined and maintained to achieve conformance to product requirements. Infrastructure includes buildings, workspace, utilities, information services, processing equipment, and supporting services such as communications or transport.
- Document how the work environment is managed, including physical and environmental conditions, as well as things like noise, temperature, humidity, lighting, and weather to achieve conformity to product requirements.
- Maintain records of education, training, skills, and experience.

4.0 Product Realization

Throughout the Product Realization process the organization must assure that all customer requirements are understood and communicated, designed into the product, how product output processes are defined (including purchased items/services), and how monitoring and measuring equipment is controlled. Points to consider are as follows.

4.1 Planning and Customer Requirements

- Document product quality objectives and requirements.
- Document the processes, documentation, and resources specific to the product.
- Document how product validation, verification, process control, inspection, and testing are provided.
- Document how customer requirements, including specific delivery and post delivery requirements are identified.
- Document how the organization reviews the product requirements prior to submission of tenders, acceptance of contracts or orders, and acceptance of changes to contracts or orders.
- Document how arrangements for communicating with customers on such things as product information, order inquiries, and feedback (including complaints) are implemented.
- Maintain records that provide evidence that the realization processes and resulting product meet requirements.

4.2 Design and Development

- Document how review, verification, validation, responsibilities, and authorities for design and development are carried out.
- Document how inputs are reviewed for adequacy in meeting functional and performance requirements, statutory and regulatory requirements, and, where applicable, how information from previous designs may be incorporated.
- Document how the design and development outputs assure input requirements are satisfied, appropriate information is conveyed to purchasing, production, and service providers, and acceptance criteria is provided, and how product safety and preservation is to be achieved during its use.
- Document how periodic audits of the design and development processes are conducted to verify the ability of the design and development process to meet requirements and to identify opportunities for improvement. Records of this activity shall be maintained.

- Define how design and development outputs and inputs are verified and validated. Records of these activities shall be maintained.
- Document how design and development changes are reviewed, verified, and validated, as appropriate, and approved before implementation. Records of this activity shall be maintained.

4.3 Purchasing

- Document how Purchasing documents identify the product or service being purchased, including information regarding type, style, class, or grade, where such information is appropriate.
- Document how special requirements, such as specifications, drawings, reference standards, technical data, or quality system/certification requirements, are stated on the purchase order.
- Document how orders are reviewed for completeness and approved prior to release.
- Document how source inspection is performed when stipulated in the purchase order.
- Document how inspection or other activities are performed to assure conformance to dimensional, metallurgical, service, and other purchase order requirements.
- Document how suppliers are selected and evaluated to assure their ability to meet requirements. A listing of approved suppliers, and the criteria used to select them shall be maintained.

4.4 Production and Service

- Document how production and service operations are controlled, including:
  - Availability of information that describes the characteristics of the product,
  - Availability of work instructions,
  - Availability and use of monitoring and measuring equipment,
  - The use of monitoring and measuring equipment, and
  - Product release, delivery and post-delivery activities.
- Document how process capability is determined including machines, operators, software, and monitoring and measuring equipment.
- Document method(s) of product identification and traceability, where appropriate. When traceability is a customer requirement, records of identification and traceability shall be maintained.
- Document how the status of inspection (acceptance or rejection) is provided at the completion of each process during production.
- Document how customer supplied product for use in your operating processes is controlled and maintained.
  - Customer supplied product that is damaged or lost shall be reported to the customer, and if required, and possible returned. Records of this action shall be maintained.
- Document how preservation of product is maintained throughout production and delivery. Preservation shall include identification, handling, packaging, storage, and protection.

4.5 Control of Monitoring and Measuring Equipment

- Document how monitoring and measuring equipment is selected to provide evidence of product conformity to design and customer requirements.
- Establish procedures that define how monitoring and measuring equipment is used in accordance with intended requirements.
- Document how calibrations are performed at prescribed intervals, using certified measurement standards traceable to the National Institute of Standards and Technology (NIST) or equivalent. Where standards do not exist, the basis or method for verifying accuracy shall be documented.
- Document the methods of adjustment, readjustment, equipment identification, calibration status, and location of monitoring and measurement.
- Monitoring and measuring equipment shall be protected from damage during handling and storage.
- Document how the validity of product verified with monitoring and measuring equipment found to be nonconforming to requirements is acted upon. Records of this activity shall be maintained.
- When software is used to verify product, it shall be evaluated, to the extent possible, as is hardware.

5.0 Measurement, Analysis, and Improvement

In this portion of the quality manual document how you demonstrate conformance to product requirements and ensure conformity to your QMS, and how you continuously improve the effectiveness of your QMS.

It is in this section that you identify your methods of achieving continuous improvement, including statistical and advanced quality planning tools such as FMEA, PIE, Lean, and Six-sigma.

The areas to be addressed are:

- Customer satisfaction
- Internal audits
- Process monitoring and measurement
- Product monitoring and measurement
- Control of nonconforming product
- Analysis of data
- Improvement
  - Continual Improvement
  - Corrective Action
  - Preventive Action

5.1 Customer Satisfaction

Document how the organization monitors and measures customer satisfaction. Refer to the model of a process-based, customer-centered quality management system shown in Fig. 8-1. You should be able to demonstrate how customer satisfaction relates to correctly realizing customer requirement in your Product Realization phase, and then measuring and analyzing results, both internally and through customer feedback.

5.2 Internal Audits

- Document how internal audits are planned, scheduled, and conducted.
- Keep in mind that the audits must demonstrate how your organization conforms to the requirements of your QMS and to the ISO 9000:2008 international standard.
- Audit criteria, scope, frequency, and methods must be defined, and show how audits are conducted to assure objectivity and impartiality of the audit process.
- Records for responsibility and requirements for plan-

ning and conducting audits and records of audit results shall be maintained. Results shall include any opportunities for improvement identified during the audit process.
- Follow-up audits shall be conducted to verify actions taken to correct deficiencies and actions taken on the opportunities for improvement.

5.3 Process Monitoring and Measurement
- Document how processes are monitored and measured to assure they are capable of producing a product that meets established criteria within your QMS and to customer requirements.
- Applicable tools to meet this end are Process FMEAs, process and machine capability analysis (ASTM F1503 gives guidance), Repeatability and Reproducibility studies on test and inspection equipment (ASTM F1469 gives guidance), and internal audits.

5.4 Product Monitoring and Measurement
- Document how product characteristics are monitored and measured to assure that product requirements are met.
- Applicable tools to meet this requirement are Product FMEAs, PIE, Quality Plans, Control Plans, in-process inspection, statistical process control, product testing, and Six-sigma methodologies.
- Records must be maintained on evidence of conformity to acceptance criteria.
- Product release shall not occur until a relevant authority (it could be the customer) has affirmed that all requirements have been met. This action shall be recorded and maintained.

5.5 Control of Nonconforming Product
- Document how nonconforming product is identified and controlled to prevent its unintended use or delivery. Define controls and related authority for dealing with nonconforming product.
- Once nonconforming product is identified and isolated, it may be dispositioned in one or more of the following ways: eliminate the detected nonconformity (i.e., remove from conforming product), authorize its use, release, or acceptance under concession, or revise its intended use or application.

5.6 Analysis of Data
- You must determine, collect, and analyze appropriate data to assure and demonstrate the effectiveness and stability of your QMS.
- Demonstrate how the analysis of such data is applied to identify opportunities for improvement in your QMS.
- Specifically, the data shall provide information relating to:
  - Customer satisfaction (see 5.1)
  - Conformity to product requirements (see 4.1)
  - Process and product characteristics and trends including opportunities for preventive action, and
  - Supplier performance.

5.7 Improvement

5.7.1 Continual Improvement

Continual improvement shall be ongoing, for the QMS, and the operational effectiveness of the organization. Management shall use the following tools to achieve performance excellence:
- The Quality Policy
- Quality objectives
- Audit results
- Analysis of data
- Corrective and preventive actions, and
- Management review.

5.7.2 Corrective Action

There shall be a documented procedure established to define requirements for initiating corrective action. Corrective action shall be appropriate to the effects encountered. These shall include:
- Identifying nonconforming conditions,
- Reviewing nonconformities (including customer complaints),
- Determining their causes,
- Accessing the need for action to ensure that nonconformities do not recur,
- Identifying and implementing action needed,
- Evidence of results of actions taken, and
- Auditing corrective action taken.

5.7.3 Preventive Action

There shall be a documented procedure that determines action(s) necessary to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive action shall be appropriate to the effects encountered by these nonconformances. These shall include:
- Determining potential nonconformities and their causes,
- Evaluating the need for action to prevent occurrence of nonconformities,
- Identifying and implementing action needed,
- Evidence of results of the actions taken, and
- Auditing of preventive action taken.

Service and Distributer Industries

The first edition of this manual included two additional chapters which provided guides for the development of quality manuals for the Service and Distributer Industries. The third edition of ISO 9001 canceled the second edition (ISO 9001:1994) as well as ISO 9002:1994 and ISO 9003:1994. The latter two standards provided requirements for Distributer and Service industries, respectively. Organizations that in the past used these canceled standards may use ISO 9001:2008 with the exclusion of certain elements, i.e., design and development, and/or manufacturing, as appropriate.

Therefore, service and distributer organizations may use the guidelines for manufacturing organizations to develop their quality manuals that are provided in this manual. The only changes are to be found in 4.2 and 4.4.

9

Compliance with Public Law 101-592

ON 16 NOV. 1990, PRESIDENT GEORGE H. W. BUSH signed into law HR-3000, enacting Public Law 101-592 (hereafter referred to as the Fastener Quality Act, or FQA). The FQA was necessary in large part because there existed in the fastener industry those who were more interested in making money in fraudulent ways than in conducting business in an ethical manner. The business practices of those organizations included supplying fasteners with false certifications, unauthorized material substitutions, head marks inconsistent with performance levels, and other deviations from the standards they represented.

This phenomenon surfaced during the mid-1980's, and because of the seriousness of the consequences of applying substandard fasteners, the U.S. Government became involved. The results of misapplied fasteners included loss of life, human injury, equipment failure—including military tanks and millions of dollars in costs associated with these losses.

All of these could have been avoided if those who purchased the fraudulent fasteners had applied PE/TQM principles. The fastener industry could have escaped becoming a regulated industry with all the added costs to the industry and to the American taxpayer if good business practices had existed. Many in the industry are bitter, and who can blame them? From a quality professional's point of view, I am both elated and disappointed by the result. On balance, however, I am more disappointed because the absence of continuous improvement in operations resulted in unnecessary costs. The added costs will affect the American taxpayer more than the fastener industry. The following guidelines are supplied for application by fastener manufacturers, testing laboratories, distributors, and purchasers/users to assist in meeting the requirements of the FQA.

Fastener Manufacturers

- Apply TQM principles to your organization.
- Embrace performance excellence criteria.
- Establish total lot control and traceability.
- Apply this to all fasteners regardless of whether or not they are covered by the FQA.
- Know your suppliers and establish supplier qualification procedures.
- Register your logo or manufacturer identification mark with NIST.
- Maintain original test records for 10 years.
- Establish effective in-house testing criteria.
- Use IFI-139 as a guide. A description of IFI-139 is in Appendix B.
- Apply this standard to your outside testing laboratory as well.
- Purchase steel that is specially designed for the unique requirements of fastener manufacturing (ASTM F2282 provides specifications unique to fasteners).
- Apply the quality system requirements of ISO 9001, ISO/TS 16949, or ASTM F2688 to your operations.
- Name someone to be responsible and accountable for compliance.

Testing Laboratories

- Apply TQM principles to your organization. Become familiar with the following standards:
  - IFI-139
  - ISO/IEC Guide 25, General Requirements for Competence of Calibration and Testing Laboratories
- Study NVLAP certification requirements.
- Apply for NVLAP certification as soon as you are ready.
- Maintain original test records for 10 years.
- Test records must include:
  - A description of the fastener
  - Product specification and lot identification
  - The sampling standard utilized
  - The production lot size and sample size tested
  - A statement of conformance or nonconformance
  - It must be tamper resistant
  - It must be written in English
- Apply the quality system requirements of ISO 9001 to your operations.

Fastener Distributors

- Apply TQM principles to your organization.
- Establish lot control and lot traceability procedures.
- Set procedures to provide traceability to customers who request it.
- Know your suppliers and establish supplier qualification systems.
- Understand the product standards/specifications for the fasteners you distribute.
- Maintain original test records for 10 years.
- Apply the quality system requirements of ISO 9001 to your operations.
- Name someone to be responsible and accountable for compliance.

Fastener Users

- Apply TQM principles to your organization.
- Performance excellence criteria.
- Know your suppliers and establish supplier qualification systems.
- Purchase only from suppliers certified through ISO/TS 16949 or ISO 9000.

- Verify that your suppliers are registered in compliance with Section 8 of the FQA.
- Verify that the test report comes from an accredited NVLAP laboratory.
- Understand your rights under the FQA.
- Apply the appropriate fastener standard/specification for your application.
- Apply the quality system requirements of ISO 9001 to your organization.

A central theme that applies to the entire fastener industry and market is to apply TQM and Performance Excellence criteria/principles and establish quality systems that comply with ASTM 2688, ISO/TS 16949, or ISO 9001 standards. Application of these systems will provide for accountability, responsibility, and traceability for any fastener supplied through these systems and will assure ease of compliance with the FQA.

A free copy of the Fastener Quality Act, Public Law 101-592, is available from www.nist.gov.

Appendix A: Synopsis of ASTM Standards F1469, F1503, F2282, and F2688

Designation: F1469–99 (Reapproved 2004) Synopsis: Standard Guide for Conducting a Repeatability and Reproducibility Study on Test Equipment for Nondestructive Testing

This guide describes the steps required to conduct a complete repeatability and reproducibility (R&R) study on nondestructive test equipment. This guide is a manual (use of calculator) method. Other methods may utilize the application of computer driven software.

This guide can be used to evaluate all test equipment that provides variable measuring data.

A wide range of test equipment may be evaluated using this guide, and may include hardness testing machines, universal testing machines, torque wrenches, dial indicators, micrometers, dial indicators, optical comparators microscopes, magnetic and coulometric testers, x-ray spectrometers, and others that provide variable test results and do not render the test piece altered as a result of the test.

This guide is recommended for the purpose of evaluating test equipment that may be utilized in statistical process control, testing laboratories, and for in-process control of manufacturing operations.

The guide is easy to follow and provides reliable data and conclusions to assist in determining if test equipment is suitable for use in controlling output quality during manufacturing.

Designation: F1503–02 (Reapproved 2007) Synopsis: Standard Practice for Machine/Process Capability Study Procedure

A machine/process capability (MPC) study is conducted to provide a level of confidence in the ability of a machine/process to meet engineering specification requirements. This is accomplished through statistical process control techniques as defined in this practice.

This practice covers provision of a proper method for determining process capability for new or existing machines and/or processes. It is recommended that available statistical software be used for the calculation of the descriptive statistics required for decision making when using this practice. Where software is not available, Section 8 and Tables 1 and 2 are provided for manual calculations.

This practice is limited to bilateral specifications whose distributions can be expected to approximate a normal curve. This practice should not be applied to unilateral specifications (flatness, concentricity, minimum tensile, maximum hardness, etc.).

It is essential that all gaging systems used to evaluate product involved in the study have documentation for meeting requirements of a gage repeatability and reproducibility study in accordance with Guide F1469 or equivalent, before the machine/capability study is conducted.

Designation: F2282–03 Synopsis: Standard Specification for Quality Assurance Requirements for Carbon and Alloy Steel Wire, Rods, and Bars for Mechanical Fasteners

This specification establishes quality assurance requirements for the physical, mechanical, and metallurgical requirements for carbon and alloy steel wire, rods, and bars in coils intended for the manufacture of mechanical fasteners, which includes: bolts, nuts, rivets, screws, washers, and special parts manufactured through cold heading. (Note—The Steel Industry uses the term "quality" to designate characteristics of a material which make it particularly well suited to a specific fabrication and/or application and does not imply "quality" in the usual sense.)

Wire size range includes 0.062–1.375 in. Rod size range includes 7/32 in. (0.219) to 47/64 in. (0.734) and generally offered in 1/64 increments (0.0156). Bar size range includes 3/8 in. (0.375) to 11/2 in. (1.500). Sizes for wire, rod, and bar outside the ranges of this specification may be ordered by agreement between the purchaser and supplier.

Material is furnished in many application variations. The purchaser should advise the supplier regarding the manufacturing process and finished product application as appropriate. Five application variations are Cold Heading, Recessed Head, Socket Head, Scrap-less Nut, and Tubular Rivet.

Wire is furnished for all five application variations. Rod and bar are furnished only for cold heading applications.

Common terms used in the fastener cold forming industry are clearly defined and include carbon steel, alloy steel, annealing, spheroidizing, wire, rod, and bar, to name a few.

Metallurgical properties are defined, and limits are established for such properties as decarburization, hardenability, and mechanical requirements.

Designation: F2688–08 Synopsis: Standard Guide for System-Based, Customer-Centered Quality Plan for Manufacturers

This guide establishes recommended system-based procedures and customer-centered applications to assist manufacturers and alteration distributors in the development of process controls which are intended to produce quality products in a cost effective manner. These recommended system-based procedures/customer-centered applications allow an organization to continually improve operational effectiveness in a cost effective manner.

It is organized in such a fashion to enable the user to develop a quality manual along the sectional topics presented in the standard.

This guide uses principles from the Baldrige National Quality Award Criteria for Excellence as well as ISO 9001:2008 to provide guidance in establishing a quality control plan that may be used effectively by almost any industry.

Appendix B: Supplier Quality Systems Survey

SUPPLIER QUALITY SURVEY

SURVEY NO._____
SURVEY DATE_____

SUPPLIER NAME AND ADDRESS

_____
_____
_____
_____

PRODUCT / SERVICE SUPPLIED

_____
_____
_____
_____

RATING LAST SURVEY_____

DATE LAST SURVEY _____
CURRENT SURVEY _____

SUPPLIER STATUS

☐	CERTIFIED SUPPLIER	All elements are present and operational in the supplier's system they meet the requirements for certification status.
☐	PREFERRED SUPPLIER	The supplier has met our requirements for preferred status, and has planned commitments to obtaining certification status.
☐	APPROVED SUPPLIER	The supplier displays the organization and future direction to achieve the requirements of certified status, and meets the requirements of approved supplier.
☐	CONDITIONAL SUPPLIER	The supplier has not been surveyed, is in the process of being surveyed, or as a result of the survey has not obtained minimum criteria for a supplier rating

Supplier Representatives:

_____
_____
_____

Survey Team:

_____
_____
_____

SUPPLIER QUALITY SURVEY	RATING*	COMMENTS
A. MANAGEMENT		
1. Does the supplier management share the philosophy of partnership with its customers: to provide high quality products or service at competitive pricing with timely delivery in return for technical and quality support as well as a long term business relationship with (COMPANY NAME)?		
2. Are there active programs or plans to facilitate participation in Continuous Quality Improvement?		
3. Are programs for employee education and training present?		
B. ORGANIZATION		
1. Does the vendor have a clearly defined and documented Quality Control function? (Supply organization chart.)		
2. Does the Quality Control function have clear and documented authority to act on quality and non-quality issues through disposition of product?		
3. Is the Quality Control structure oriented for prevention instead of detection?		
C. FIXTURE AND TEST EQUIPMENT CONTROL (METROLOGY)		
1. Is there a separate unit dedicated to metrology?		
2. Is there a documented procedure for calibration of all equipment (including analytical equipment)		
3. Are capability studies performed and documented prior to use in production? (Repeatability and Reproducibility Studies?)		
4. Are calibration records maintained which include fixture and test equipment identification, location, method of calibration and certification, results, date of current and next calibration, and current status?		
5. Are fixtures and test equipment clearly marked with an identification, date of last calibration and date of next calibration?		
6. Is there a clear definition of dispositioning non-certifiable fixtures and test equipment?		
D. INSPECTION		
1. Is there a system to assure the quality of purchased materials, which may involve: a. incoming inspection b. vendor certification program c. source inspection		
2. Is there a system to assure product conformance to specifications at the initial setup phase of product manufacture?		
3. In the absence of SPC, is there a system with documentation to verify that product conforms to specification prior to shipment?		
4. Is there a system which provides lot traceability through each process and includes traceability of all raw materials used during manufacture?		

SUPPLIER QUALITY SURVEY	RATING *	COMMENTS
5. Is there a system that measures the effectiveness of the total quality systems through an evaluation of packaged, ready to ship product? (Final Product audit)		
6. Is there a system with supporting documentation that assures non-conforming product is removed from the normal process flow and clearly marked for disposition?		
7. Are inspection plans documented and do they include the following:		
a. sample size		
b. sample frequency		
c. acceptance criteria		
d. significant characteristics		
e. product disposition		
8. Are inspection plans designed for zero defects?		
E. PROCESS CONTROL		
1 Is statistical process control utilized to optimize processes and systems?		
2. Does SPC include the following programs: a. process capability studies? b. significant characteristic selection? c. reports to top management for action on noncapable processes?		
3. Are there documented process instructions for manufacturing and non-manufacturing jobs?		
4. Are critical process parameters monitored?		
5. Are critical and functional part characteristics monitored and documented during processing?		
F. QUALITY SYSTEMS AND ANALYSIS		
1. Are cost of quality reports generated and provided to management?		
2. Is there a system for problem identification and resolution that looks for root causes?		
3. Is there a documented system to provide and control changes to product and product specifications and processing?		
4. Is there a documented system to address customer returns ensuring prompt response to corrective action inquires?		
survey points scored:		
survey points possible:		
survey score:		

**See supplement entitled Quality Survey - EXPLANATION OF SCORING SYSTEM.*

COMMENTS

printed in U.S.A.

Explanation of Quality Survey Scoring System

Each survey question will be rated on the basis of the following point system:

Rating	Explanation
10	This element is present, documented, and successfully operational in the Supplier's/Subcontractor's quality system and displays a history of consistent application and continuous improvement.
9	This element is present, documented, and successfully operational in the Supplier's/Subcontractor's quality system.
6	This element is included in the Supplier's/Subcontractor's quality system; however, documentation is incomplete and/or additional development is required.
4	This element is included in the Supplier's/Subcontractor's quality system; however, documentation is inadequate and additional development is required.
2	This element is included in the Supplier's/Subcontractor's quality plan, but has no present application and requires substantial development.
0	This element is not included in the Supplier's/Subcontractor's quality plan.

Appendix C: Attribute Gauge Analysis Form

	OPERATOR A			OPERATOR B	
N	1st Evaluation	2nd Evaluation		1st Evaluation	2nd Evaluation
1					
2					
3					
4					
5					
6					
7					
8					
8					
9					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					

FOR THE SYSTEM TO BE ACCEPTABLE, ALL EVALUATIONS PER LINE ITEMS MUST AGREE.

GAUGE TYPE	GAUGE NO.	DATE
OPERATOR A	OPERATOR B	

ATTRIBUTE GAUGE ANALYSIS

Subject Index

A

acronyms, ix
ASTM Standard F1469-99, 51
ASTM Standard F1503--02, 51
ASTM Standard F2282-03, 51
ASTM Standard F2688-08, 51
attributes
  control charts, 40
  gauge analysis, 40–41
  gauge analysis form, 57

C

cause and effect diagrams, 41
communication, viii, 5
continuous improvement, 17–23
control plans, 11–16
  method of evaluation, 16
  responsibility, 16
  reaction to out-of-control, 16
  control method/sample plan, 11
  controlled characteristic, 11
  process point control, 11
cost
  quality, 29
  reduction, 33
critical performance indicators (CPIs), vii
customer and market focus, vii, 2–3

D

descriptive statistics, 38–39
DMADV, 44
DMAIC, 44

E

effects of failure, 9–11
employee survey, 2–3
empowerment and involvement, 4
evaluate, 20
external customers, 2

F

failure mode and effects analysis, 9–13
fasteners
  distributors, 49
  manufacturers, 49
  users, 49–50
five 5s, 43
flow charts, 7
  analysis, 7
FMEA, 9–13
futuristic quality planning, 6–16

I

improve delivery performance, 33
improved product quality, 33
improvement methodology
  evaluate, 20
  expectation, 20
  initiate, 20
  plan, 18–20
initiate, 20
internal customers, 2
ISO procedures, 25–27

K

Kanban, 43
knowledge management, 4–5

L

layered process audit, 29–32
leadership commitment, vii
lean, 42

M

management's role, 1–5
measurement, analysis, knowledge management, vii, 4–5
method of evaluation, 16

O

organizing for quality, 27–28

P

Pareto analysis, 41–42
partners in quality, 33–36
PIE expectations, 20–23
poka-yoke, 43–44
process,
  flow analysis, 10
  management, viii, 5, 21–22
  point control, 11
Public Law 101–592, 49–50

Q

quality
  control, 37–38
  cost, 29
  policy, 6
  reporting, 29–32
quality manuals, 45–48
  guidelines, 45–48
quality systems, 24–28
  audits, 29–32

R

reaction plan, 16
recognition and awards, viii, 4
responsibility, 16
results, viii

S

six-sigma, 42, 44
sourcing considerations, 33
SPC, 39–40
statistical applications, 38
statistical quality control, 37–44
strategic planning, vii, 5, 6–16
suppliers
  involvement, 34–36
  trust, 33
  management, 36
  measures, 33–34
  partnerships and control, 33–36
  quality systems survey, 52–56
system audit structure, 31

T

testing laboratories, 49
trust, 33

V

value stream mapping, 43
variable control charts, 40
variable gauge analysis, 40
vision and policy statement, 19

W

workforce focus, vii, 3–4

About the Author

Jack P. Pekar is a graduate of the Ohio University with a Bachelor of Science in Education, majoring in mathematics. He is the lead principal for PT&G Consulting, specializing in the Baldrige National Quality Program's Criteria for Performance Excellence.

Jack has been active in the fastener and quality profession since 1964. His experience includes that of line inspector, supervisor, manager, and owner as he gained knowledge in his chosen profession. He worked for such fastener manufacturers as Lamson & Sessions, E.W. Ferry Screw Products, and SPS Technologies. At these organizations, he gained valuable experience in all phases of fastener processing. At Cleveland Twist Drill, Allied Machine & Engineering, and Kennametal Inc., he gained knowledge as a fastener purchaser and user. At these organizations, he set up programs to assure strong and viable supplier bases. He led all of these companies to many successful certification awards from major corporations as well as ISO 9000 registration.

Jack has been a member of ASTM International (ASTM) since 1976 and served as subcommittee chairman for F16.93, Quality Assurance Provisions for Fasteners, Vice Chairman of F16.01, Test Methods, and Main Committee Chairman of F16 on Fasteners. He is a Fellow of ASTM, and a senior member of SME and ASQ. He served on the Board of Directors of the American Association for Laboratory Accreditation (A2LA), and ASTM. Jack also served on the Board of Examiners for the Baldrige National Quality Program during 2002, 2003, and 2004.

In addition to his business activities, he was active civically and served on the Board of Directors and as Vice President of the Solon Chamber of Commerce. In 1991, Mr. Pekar received the President's Award from that organization for outstanding community service.

www.astm.org

ISBN 978-0-8031-7005-6
Stock #: MNL22-2ND