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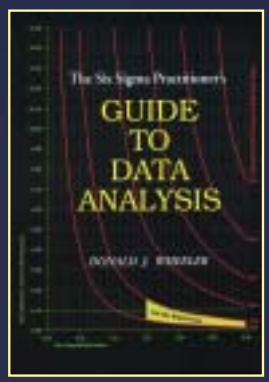

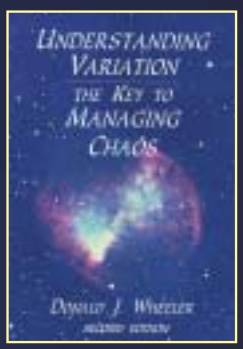

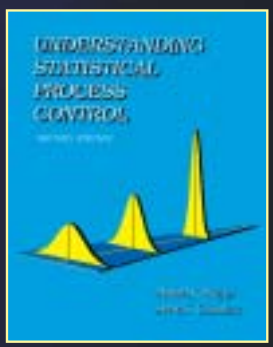

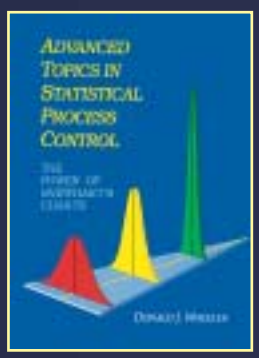

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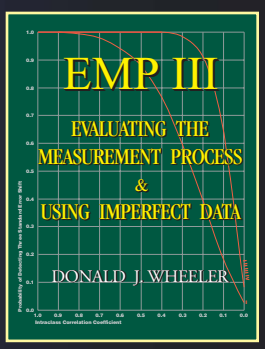

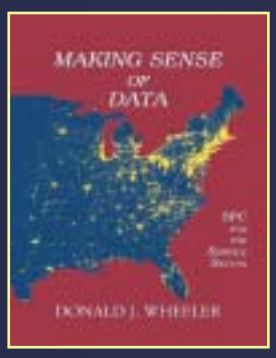

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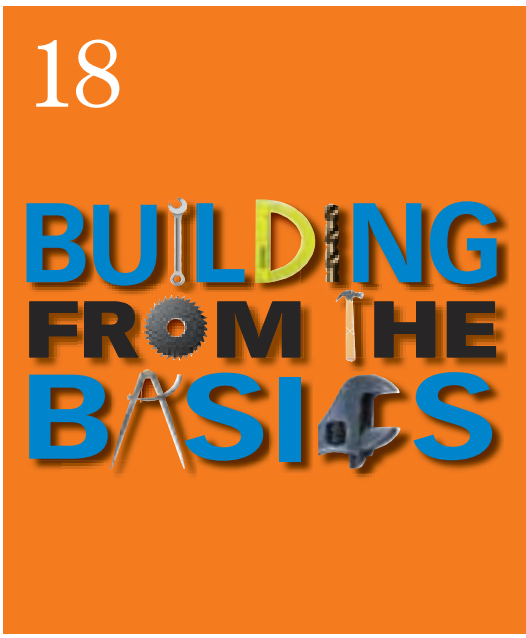

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Build relationships with your suppliers.

- **FINDING FAULT**
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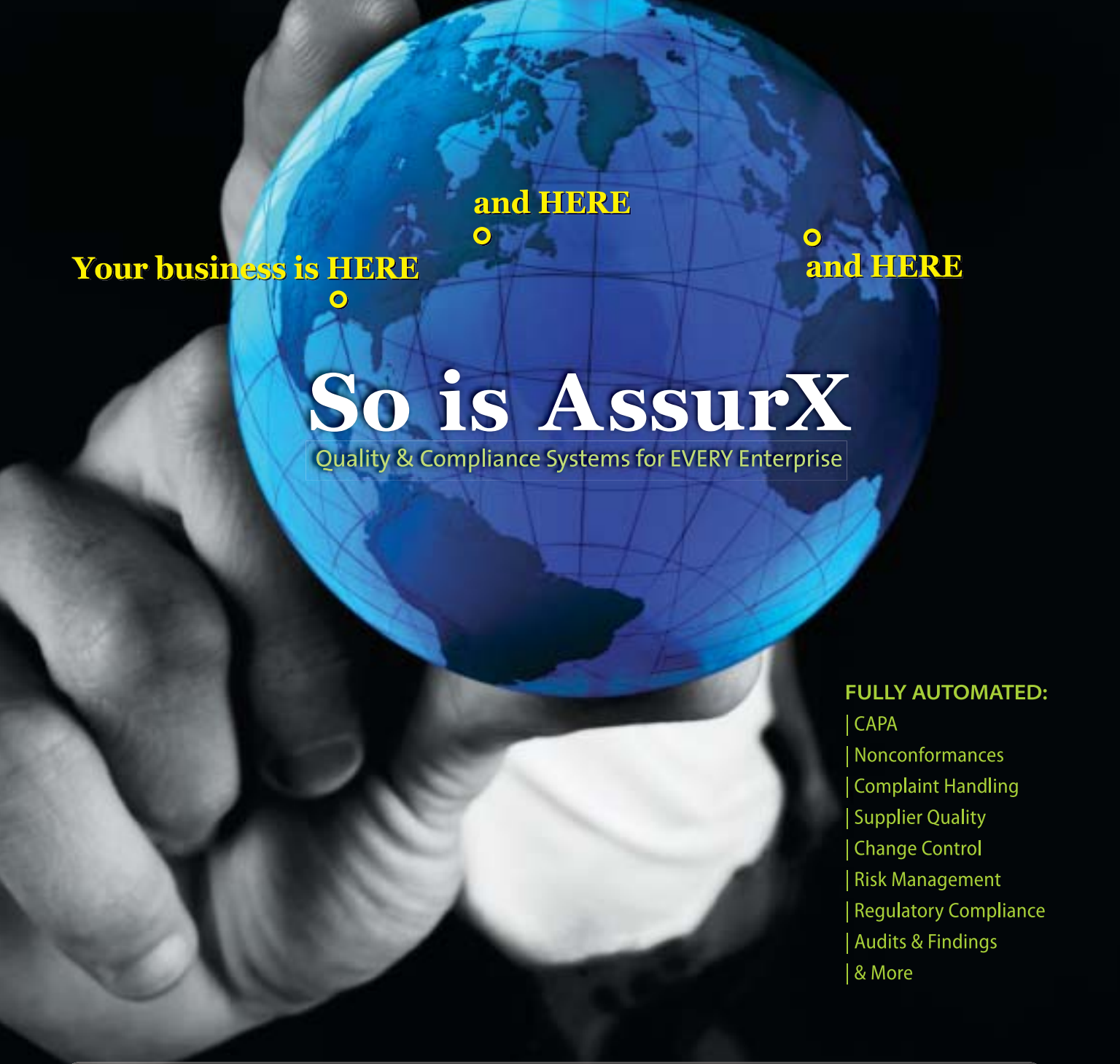

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Pay It Forward

Mentorship helps bridge knowledge gaps

A POPULAR WAY of keeping in touch with friends these days is through the social networking site Facebook. And, as a result of this "electronic voyeurism," you often wind up knowing more about people than you normally would.

An old high school friend's "status" (a brief description of what that person is thinking or doing) recently referred to an exhausting day spent in *kaizen* training at the manufacturing company he works for.

Excited by the reference to my own field, I started up a lively—and humorous—electronic exchange that included plenty of quality "shop talk."

Finally, one of his colleagues who had been following our conversation chimed in: "What the heck are you two talking about?"

If you are receiving and reading QP, you are—at the very least—already familiar with the fundamentals of quality. But, like my friend's colleague, many of your peers and coworkers may not be, or they still have a lot to learn. This issue of QP is devoted to the basic tools of quality. Beginning on p. 18, "Building From the Basics" is a perfect reference for those new to the profession, but it also serves another purpose: a means for the more experienced to help others nail down the basics. Consider passing this issue on.

The nation's workforce faces a "brain drain" of drastic proportions as baby boomers filter out of the workforce and millennials stream in. This changing of the guard requires knowledge transfer, and one highly effective way of doing that is mentorship.

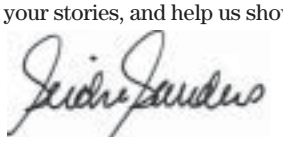
Via ASQ's mentor network, less-experienced members benefit from the experience of ASQ fellows, who can provide education and career advice. To join or to learn more, visit www.asq.org/members/communities/mentoring.

ASQ's Each One Reach One program rewards members for recruiting new members. To find out more, visit www.asq.org/members/eoro.

Finally, all QP articles are archived at www.qualityprogress.com, including the bimonthly Back to Basics columns—a great place to begin a quality education.

We want to hear from you: Last month, QP launched a new, occasional column, Perspectives, in which current events are discussed in terms of quality. (The second installment on maintaining quality in troubled times begins on p. 8.) If you have a quality perspective to offer on a current event or situation, e-mail me at editor@asq.org.

Every profession is feeling the economy's cruel pinch, and quality is not immune. QP is looking for personal accounts of how quality and your job or department have suffered in recent months. Do you have advice for others on surviving economic hardship? E-mail me your stories, and help us show others who may be struggling that they're not alone. QP



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INBOX

Credit where it's due

The response to the question from Sam Bass in Expert Answers (Nov. 2008, p. 12) may be academically and politically correct, but it misses the point. What Bass describes is a violation of the ASQ code of ethics, Article 7: Assure that credit for the work of others is given to those to whom it is due.

I have experienced this situation myself. If it is not appropriate for Bass to seek employment with an organization that promotes ethical practices, he can take other actions. I would suggest he continue to provide solutions but make it more formal, such as documenting his periodic or on-demand reports. That way, his value is recorded and organization members can still use the information to advance the organization.

Also, because I have been described as a type A person, I feel the pings from the statement made by Bass. Does he believe type A people are bad and type B people are good? I don't think personality type should be an issue.

What Bass is experiencing is rampant across most businesses. If not contained, idea people will disappear into their own world at the cost of humanity's well-being and advancement.

J.P. Russell
Gulf Breeze, FL

Commander-in-chief concerns

We at the Joseph M. Juran Center are very supportive of ASQ President Roberto Saco's vision for the new president of the United States ("To the New U.S. President," Oct. 2008, p. 8). We certainly see major segments of our society ripe for a quality transformation: From education to energy and power to healthcare to infrastructure to government agencies, we see what Juran described as "islands of excellence in a sea of mediocrity." Saco's vision is synchronous with Juran's vision for a "Century of Quality."

While all of our our executive advisory board members care about all of these things, we believe it useful to cite some specifics about their various passions:

- Bob Galvin, chairman emeritus of Motorola, recently authored a book titled *Perfect Power*, in which he calls for a quality revolution in the power industry fueled by a demanding standard of nine sigma.
- The honorable Paul O'Neill, former secretary of the treasury, believes the pursuit of perfect patient safety and the theoretical limit in all of healthcare can save approximately 50% of the $1.5 trillion healthcare bill of the United States—enough savings to balance the federal budget and provide healthcare for every uninsured American.
- Bill Watkins, CEO of Seagate Technologies, along with other leaders in Silicon Valley, believe the new technology start-ups can and should be led toward perfect quality in the very early stages.

The table is set for the next U.S. president, as Saco suggests. What is needed now is an inspired vision, massive re-education and leaders by the thousands.

James F. Buckman
On behalf of the Joseph M. Juran Center
Carlson School of Management
University of Minnesota
Minneapolis

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BY MICHAEL D. NICHOLS AND KARIM HOURY

Adapting to Troubled Times

Versatility is key if quality is to come to the forefront

IF, AS SOPHOCLES said, "There is no success without hardship," then the current economic environment is a perfect opportunity for those in the quality field to lead the drive to success. As we react to the disheartening daily news from Wall Street and other financial capitals around the world, we need to ask ourselves: How can quality help? How can it position companies for success? What should the role of quality be in these times?

Quality personnel should recognize the economic climate as an opportunity to demonstrate the impact quality can have. But it's up to quality and Six Sigma leaders to adapt their skill sets, techniques, tools and leadership styles to help their companies navigate the troubled waters.

This will demonstrate to the organization's senior management that their quality teams are nimble and quick to react to a rapidly changing economic environment. It will show that these members of the workforce can support the bottom line by delivering hard savings.

There are several practical tips to help you do just that. While you may be doing many of these tasks already, we hope these 12 points serve as a reminder of other actions that may be helpful to you.

We have grouped our recommendations into three categories: immediate, near term and long term, or strategic. Immediate activities are tasks that can add value within the next 30 days; near-term activities are those tasks that can help you in the 30-day to six-month window; and long-term activities are those that require a window of six to 18 months.

In every case, leveraging internal company relationship networks and a deep understanding of where all current improvement projects stand will not only help you better prioritize, but will also allow you to enhance the quality team's credibility exponentially.

Immediate actions

1. **Identify the gaps.** Connect with the finance department to understand the size of the company's profit-and-loss gap. Get the numbers for the entire organization and for each functional area.
2. **Focus on the numbers.** Shift your team's focus from projects centered on metrics improvement to cost of poor quality (COPQ) reduction. Accelerate projects that deliver hard dollars vs. those that drive productivity improvement or cost avoidance. Communicate to leadership any potential projects that would have an immediate revenue or COPQ impact. Prepare a list of your top 10 project opportunities for senior leadership approval and highlight those with "quick hit" opportunities.
3. **Use lean and *kaizen*.** Reach out to the functional areas tasked with the largest dollar reduction targets and offer to help via brainstorming sessions. This can be accomplished through *kaizen* events or by offering quick failure mode effects analysis (FMEA) sessions for any process modification opportunities that have already surfaced. Approach transaction-heavy departments tasked with headcount reduction with a proposal to run lean capacity analyses to help them identify areas of opportunity. Then deploy other lean tools, such as value stream mapping, to determine the size of the opportunity for each target process, while removing waste. This is a perfect time to organize lean or *kaizen* events that could help implement rapid change. This may also require you to lead a few refresher sessions on lean tools.
4. **Be proactive.** Pitch bold ideas—for example, outsourcing or off-shoring—that will yield savings in the next six to 12 months and offer to get the analysis under way immediately. This will allow you to leverage your financial analysis skills, as well as tools such as FMEA, in support of initiatives that may be new to your company. Table 1 provides a sample of proposed sigma tools in support of reengineering efforts that may apply to certain functional areas.

Near-term thinking

5. **Stay customer focused.** This is not the time to impact the quality of your firm's products and services negatively just because the attention is on cutting costs. Reach out to your customers and see how you can help them. They are also feeling the pain of the economy.
6. **Communicate.** Continue to share and elevate any dashboard or scorecard data related to process performance or voice of the customer feedback that may be monitored and managed by a quality project management office. Often, hard times and budget cuts become excuses for reducing quality performance targets. Make sure everyone knows the quality of your products and services is more important than ever.
7. **Stay on course.** Keep pushing your ongoing quality deployment program. Be flexible and adjust your plan, but do not put the program on hold. Document all the actions you are taking in the short term to ensure sustainability.

Proposed sigma tools in support of reengineering / TABLE 1

Traditional reengineering levers *Suggested sigma tools*	Operations	Customer service	Technology	HR and training	Building services	Communications	Finance	Risk	Audit	Legal	Relationship management and sales	Product management
Location/task driven wage arbitrage (offshore, outsource) *FMEA*, process maps, hypothetical testing, value stream maps*	◕	◕	◕	◕	◕	◑	◑	◔	○	◑	○	○
Center of excellence (like-functions grouping) *Hypothetical testing, process maps, capacity analysis, voice of the customer*	◑	◑	◕	◔	○	◑	◕	◔	○	◑	◑	◔
Span-of-control optimization *Capacity analysis, benchmarking*	●	●	●	●	●	●	●	●	●	●	●	●
Process improvement *Process maps, value stream maps,* kaizen*, voice of the customer*	●	●	●	●	●	●	●	●	●	●	●	●
Quick cost containment (travel, consulting costs, etc.) *FMEA, financial analysis*	●	◕	●	●	●	●	●	●	◔	●	○	◑

* Failure mode effects analysis

Proposed degree of applicability by functional area ◯ ➡ ● Low High

8. **Keep training on the radar.** This is a double-edged sword. If leadership is committed to maintaining staff during the downturn, use this time to complete any required training. If times require you to minimize training and travel, use your quality staff to assist in coaching more projects that will deliver results.

Long-term strategy

9. **Get close to senior management.** Help senior management connect the dots by linking any cost savings your Six Sigma projects may yield to an opportunity for reinvestment in the business (R&D, marketing and technology).
10. **Hold people accountable.** Partner with the finance team to flesh out timing of savings availability and hold project teams accountable for delivering the benefits. For example, at one *Fortune* 100 company, a senior executive in each functional area was accountable for the results of Six Sigma and other business transformation projects.
11. **Establish targets.** Take advantage of the economic environment to pitch the concept of setting dollar targets at the company, department and project levels, or propose dollar and metric targets for 2009 to support your process excellence initiative. Make sure to get your CFO's buy-in first.
12. **Be strategic.** Use this time to evaluate your strategic market position and competition. Establish partnerships with the corporate strategy function. Align process metrics with strategy maps.

Stay in the foreground

We face challenging economic times. But this also presents an excellent opportunity for quality practitioners to shine and demonstrate that their technical, leadership and change management skills are up to the challenge and can quickly adapt to any situation to support stakeholder expectations.

Companies will also benefit from taking advantage of the expertise that resides in their quality groups. By quickly redeploying these skills, they can create opportunities to free up funds for reinvestment when their competitors may be retreating. This will ensure that quality remains at the forefront of the effort to help maintain or increase customer loyalty.

The quality function must not migrate to the background as a result of the economic downturn. And it won't, as long as you can demonstrate the value you can deliver to the bottom line and top line growth of the company. QP

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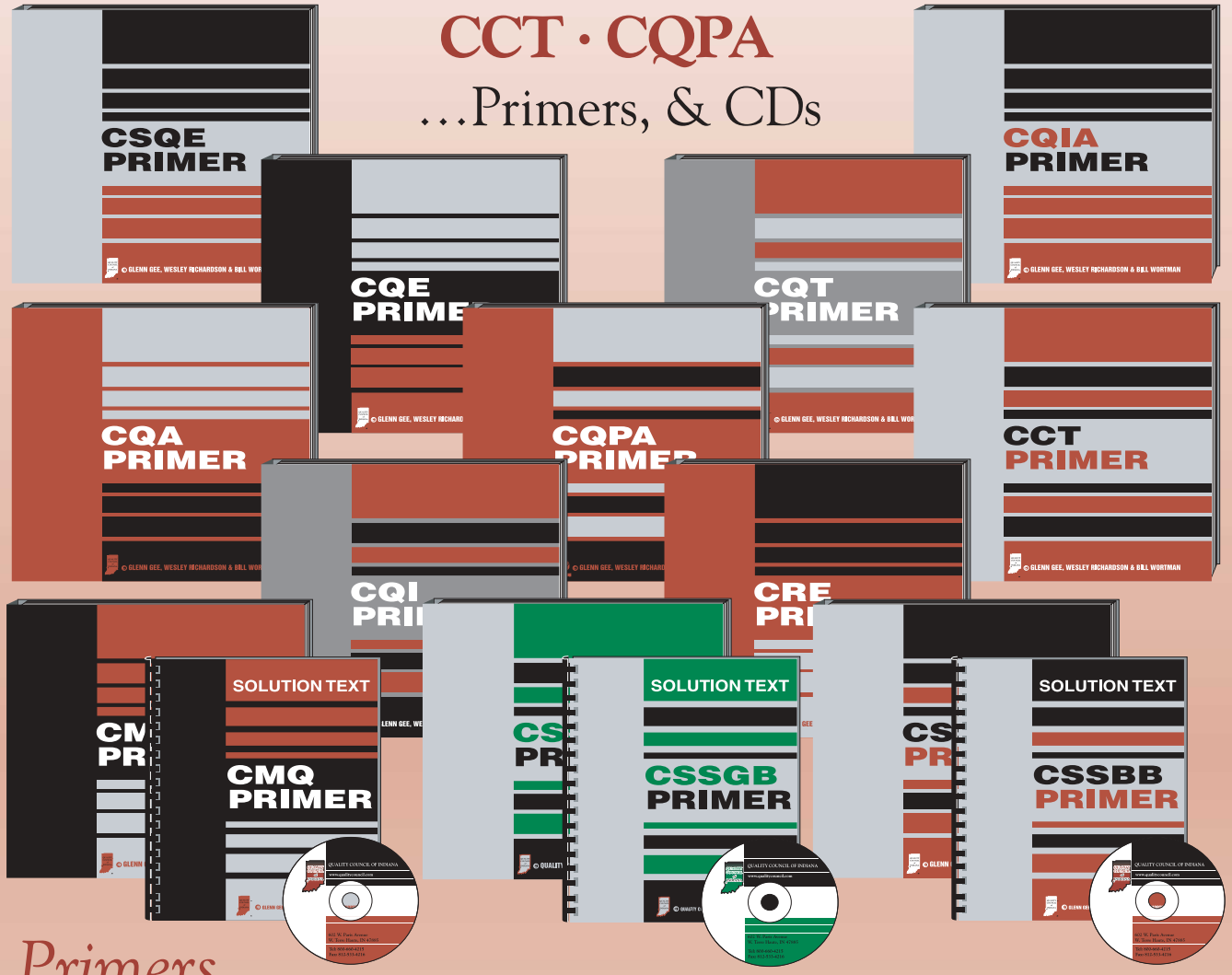

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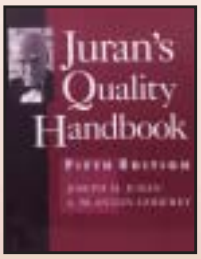

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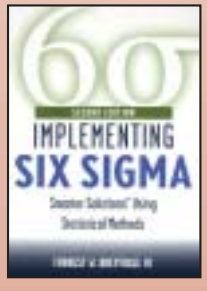

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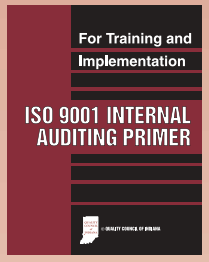

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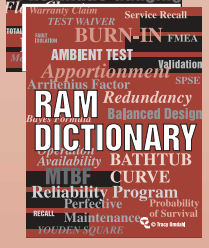

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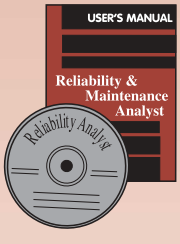

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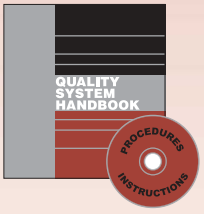

EXPERTANSWE

Satisfactory solution

Q: My company is looking for ways to measure customer satisfaction. We would like to use a system that includes a bar chart in some way. How should we approach this?

Mary Abraham
Tools Inc.
Sussex, WI

A: Customer satisfaction can be measured in many ways, most of which can incorporate a bar chart, or Pareto chart. I'll outline the benefits here, but you also can find resources to help you on the ASQ website or in "Building From the Basics," which begins on p. 18 of this issue.[1]

Designing a measurement and data collection system for customer satisfaction can be difficult. Your customers will likely have many touch points with your company where they may experience satisfaction or dissatisfaction (sometimes called moments of truth).

Product use, delivery of service, calls to a customer service center, billing or using your company's website are just a few of the ways a customer can interact with your company. Multiple products or multiple service offerings also complicate the design of your data collection efforts. Because customers' opinions about your products and services can change over time, satisfaction measures should be conducted on a regular or even continuing basis.

Direct measures of customer satisfaction include interviews, focus groups and surveys. Indirect measures of customer satisfaction and dissatisfaction can include the number of referrals and recommendations made by customers, market share, sales, repeat sales and customer retention. The number of complaints and compliments received, warrantee claims and product returns will also reflect customer satisfaction. Data from these measures can be segmented, summarized and plotted on a bar chart.

Some companies can make use of customer satisfaction data provided by external organizations, such as the American Customer Satisfaction Index (www.theacsi.org) or JD Power (www.jdpower.com). This data can easily be trended and summarized in a bar chart. Companies that take measurement seriously use multiple methods for tracking customer satisfaction trends. Some companies have even created their own customer satisfaction indexes using multiple measures.

Before you get started, make sure your executive management team is committed to reviewing the data on a regular basis and implementing any needed changes based on the results of your measures. It would be a waste of your customers' time and your company's resources to collect this information and just summarize it in a report or PowerPoint presentation.

Ken Cogan
Sr. manager, performance management
Columbia, MD

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Confidentially speaking

Q: I would like to know the difference between a 95% confidence interval and 2-sigma value for any parameter. I often come across these terms in situations where both are expressed as percentages. But, at the same time, they have their own meanings.

Subrata Chakrabarti
Indian Space Research Organization
Trivandrum, India

A: Most of us are familiar with the bell-shaped normal distribution curve. If we know the mean and the standard deviation of the process, then we can calculate various probabilities associated with the distribution.

For example, we can compare the process distribution to the specifications and estimate the percentage of the output that is defective. By estimating the annual cost of the defects generated by this process, we can go one step further and compare it to a more expensive process that produces fewer defects.

For example, suppose a wholesaler has a contract with a beverage maker. The wholesaler wants a 12-ounce energy drink. The contract requires that 99% of the cans contain at least 11.9 ounces. The contract also requires the average fill to be greater than or equal to 12 ounces, with 95% confidence.

The beverage maker does not have a statistician, so it is not sure if it is in compliance. The company asks for help, and we tell them to collect a random sample of 20 cans and measure the fill level. The company gets the following results, which are illustrated in Figure 1:

$$\bar{X} = 12.117;\ \sigma_{\bar{X}} = 0.0607$$

First, we check to see if 99% of the population is greater than 11.9 ounces. We use a normal probability table to look up the value of the "Z score" associated with having 1% of the distribution in the tail, and apply the Z score to this equation:

$$\bar{X} - Z_{\alpha}(\sigma_{\bar{X}}) = 12.117 - 2.33(0.0607) = 11.97 \text{ oz.}$$

The calculated statistic is greater than 11.9 ounces, so the first requirement has been met. Then, we look at the second requirement. We know the mean of the sample (because we calculated it), and it is greater than the 12-ounce requirement. But are we confident in the result? We don't know the mean of the population. Perhaps we got lucky with the sample. How much sampling error is present?

We can create a confidence interval to account for the sampling error by using the equation:

$$\bar{X} \pm \frac{Z_{\alpha/2}\sigma_{\bar{x}}}{\sqrt{n}}$$

Where $\bar{X}$ is the sample average, $Z\alpha/2$ is the Z score from a normal probability table, with $\alpha/2$ probability, $\sigma_{\bar{x}}$ is the sample standard deviation and *n* is the sample size

We will use $\alpha = 0.10$, because $\alpha/2$ will give us 5% error in each tail, and we are really only concerned about the lower tail. Plugging in the values, we get:

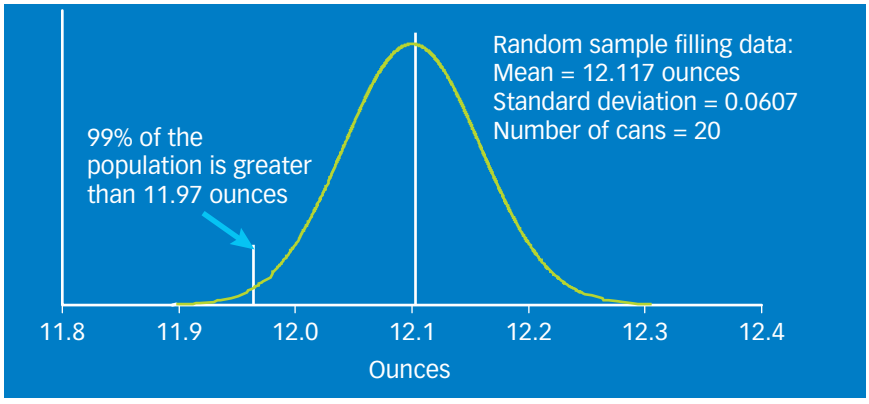
$$12.117 \pm \frac{1.645(0.0607)}{\sqrt{20}} = (12.095, 12.139)$$

Because the lower boundary of the confidence interval is greater than 12, we can be at least 95% confident the average fill level meets the second contract requirement.

What does the confidence interval really mean? The lower and upper bounds of the confidence interval give us a range that is likely to contain the true population mean. We will never know the true population mean unless we measure the entire population.

But we can take a relatively small random sample, calculate the confidence interval and infer from the associated level of confidence that the population mean is somewhere between the lower and upper bounds of the interval. We could be wrong, and we will never know the truth unless we measure the entire population.

Energy drink data / FIGURE 1



The equation for the confidence interval allows us to change the confidence level by inserting a different value for α. The confidence is simply $(1 - \alpha) \times 100$, so if $\alpha = 0.05$, then the confidence level is $(1 - 0.05) \times 100 = 95\%$. Use $\alpha/2$ for two-sided confidence intervals and α for one-sided confidence intervals.

One more important point: The width of the confidence interval is a function of two things—the alpha (which is dictated by the desired confidence level) and the sample size. Therefore, the higher the confidence level, the wider the confidence interval. Since *n* is in the denominator, the bigger the sample size, the tighter the confidence interval.

Andy Barnett
Principal consultant, Master Black Belt
Quintiles Consulting
Houston

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Standard question

Q: My organization is planning to be certified to ISO 9001:2000 in February 2009. Are we going to need to implement ISO 9001:2008 instead? If we don't need to, should we anyway?

Bapuraj A.N.
Electronia Ltd.
Al Khobar, Saudi Arabia

A: Two basic points: First, the changes to ISO 9001 with the 2008 standard will be relatively minor and are not intended to add new requirements. Second, if a system meets the 2000 version, it should have no problem meeting 2008.

Certainly my advice is to get the 2008 version as soon as possible and confirm the system meets it. If the question relates to a certification audit in February, I would think it should be to the 2008 version. The best thing to do is contact the registrar and have a conversation about this.

Jack West
Management consultant
The Woodlands, TX

FOR MORE INFORMATION

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AUTOMOTIVE QUALITY

The Big Three: Will a Bailout Be Enough?

Perceptions and high costs, not poor quality, led to U.S. automakers' woes

It's not that General Motors, Ford and Chrysler are building subpar cars. The quality is there, but so are the higher costs to produce vehicles that some foreign manufacturers don't face, as well as ongoing perceptions among consumers that the quality of U.S.-built vehicles lags behind foreign competitors' products.

Those reasons led the Big Three to near bankruptcy, prompting them to spend the last few months trying to convince Congress they need a multibillion dollar bailout to survive.

"There are soft spots in the U.S. auto industry, but quality isn't one of them," said John Casey, the head of ASQ's Automotive Division and the director of supply chain improvement at the Whitehall Group in Troy, MI. "Perception of quality, too, is so real."

In the early to mid-1980s, consumers perceived—and rightly so—that Japanese manufacturers were building superior cars, Casey said. For instance, Japanese automakers were producing vehicles with 1.5 defects per car, while U.S. automakers had three defects per car.

Toyota was making its initial splash of success with high-quality, affordable cars, while domestic manufacturers' sales and production took a beating. Since the early 1990s, the gap between foreign and domestic products has been closed "on the backs of quality people and the quality movement," Casey said.

"Today, while the standards are higher and tolerance for defects is more strict, the gap between the Japanese and domestic automakers is real, but insignificant," Casey said, noting that Japanese manufacturers are at 0.9 defects per car and U.S. automakers are at 0.95. "The gap is nowhere near where it once was."

"It's the perception of quality (that) is massive," said Casey, who spent 20-plus years as the director of supplier quality at GM's North American headquarters in Detroit. "The Japanese have taught us that quality is an absolute."

> "Quality has got to be **the engine of continuous improvement.** Toyota is the best I've seen in terms of '**I'm here for quality.** We have to give it to our customers every day.'"

In addition to this ongoing perception problem, there are significant disparities in the costs of doing business between domestic and foreign manufacturers, including:

- Federal income taxes: General Motors paid $37.16 billion in 2007, and Toyota paid $7.61 billion.
- CEO compensation: Ford's Allan Mulally received $21.7 million in 2007, and Toyota's Katsuaki Watanabe was paid $900,000 in 2005.[1]
- Employee wages and benefits: The average hourly wage and benefits for Big Three workers is $72.21. Toyota and Honda's employees average $48 in hourly wage and benefits.[2]
- Labor groups: Union contracts and pensions boost the cost of each American-made vehicle by an estimated $2,300 per vehicle.[3]

As auto sales have plummeted from an average of 17 million a year in the past nine years to 10.5 million this year, foreign manufacturers have benefited from less overhead to weather the storm. For instance, U.S. automakers are stuck with more factories and workers than they need at this time of sagging sales.

"They're caught in a situation where they have not yet learned how to make money on small cars," said Kim Korth, president of IRN Inc., an automotive consulting firm.[4]

Part of early government bailout packages included restructuring plans for the Big Three to shift toward more fuel-efficient vehicles. This would include plant closings, vehicle brands being eliminated and smaller dealerships closing.

Still, quality must remain a central focus for automakers during this period of transition, Casey said.

"Toyota has created an unstoppable, unbelieveable culture of

quality—that everybody is responsible for quality every single day. Quality has got to be the engine of continuous improvement," Casey said. "Toyota is the best I've ever seen in terms of 'I'm here for quality. We have to give it to our customers every day.' The domestic [automakers] don't have that," he said.

But it's not just the Big Three that must bring quality to the forefront.

"It's a message to us all," Casey said. "You must, must, must focus on quality. This applies to all of us—even the people making popcorn machines. Act with a passion and a sense of urgency. If you need help—get it. Don't wait."

—Mark Edmund, associate editor

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1. Procon.org, http://bigthreeauto.procon.org.
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3. Jerry Zremski, "Big 3 Can Point to Better Vehicles as They Take Their Plea to Congress," *Buffalo News*, Dec. 5, 2008, www.buffalonews.com/nationalworld/national/story/512918.html.
4. Ibid.

Quality News Today articles were also used to compile to this report.

ASQ

ASQ SIGNS PACT WITH BUSINESS GROUP IN INDIA

Making another inroad to promote quality and business excellence outside the United States, ASQ has formed a pact with a large association of businesses in India.

The agreement with the Federation of Indian Chambers of Commerce and Industry (FICCI), signed in late November, allows ASQ to participate in India's local quality movement and disseminate ASQ's body of knowledge.

FICCI's membership includes more than 1,500 corporations and more than 500 chambers of commerce and business associations.

In 2007, ASQ established an office in New Delhi to offer training and certification to quality professionals. ASQ also operates an office in China, and the organization is taking further steps to expand offerings in Brazil, Mexico and South Korea in the coming years.

"This agreement opens many doors for both ASQ and senior-level executives in India," said Roberto Saco, ASQ's president. "Bringing ASQ's body of knowledge to India will assist Indian corporations, executives and quality professionals in producing quality goods and services, which is good for both India and the many multinational corporations that do business there."

For more information about ASQ's activities in India, visit www.asq.org/global/countries/india.html.

Who's Who in Q

NAME: Amar Raja Thiraviam.

RESIDENCE: Daytona Beach, FL.

EDUCATION: Master's degree in industrial engineering from University of Central Florida (UCF) in Orlando. He is pursuing a doctorate in reliability engineering at UCF.

INTRODUCTION TO QUALITY: Statistics and reliability engineering courses taught by Linda Malone at UCF.

CURRENT JOB: Reliability engineer at Teledyne-Ocean Design Inc., a manufacturer of subsea electrical and fiber optic interconnect systems.

ASQ ACTIVITIES: He has worked on several Community Good Works Six Sigma projects through Section 1509 and participated in several certified reliability engineer and certified Six Sigma Black Belt exam review workshops. He has also presented at many ASQ conferences.

OTHER ACTIVITIES/ACHIEVEMENTS: Research awards at UCF in 2003-2004; Future Leaders of Manufacturing Award from the Society of Manufacturing Engineers; and Presidential Doctoral Fellow at UCF.

PUBLISHED WORKS: At different conferences, he has presented papers on topics such as aesthetic engineering and quality improvement of complex systems.

RECENT HONORS: ASQ Freund Scholar in 2008.

FAVORITE WAYS TO RELAX: Traveling, watching and playing cricket, and listening to music.

QUALITY QUOTE: Even the greatest minds, such as Einstein, have struggled in explaining the mystery of time. Reliability engineers continue to unravel this mystery of time by ensuring quality over time.

ASQ

ASQ PRESIDENT-ELECT, BOARD CANDIDATES NAMED

E. David Spong has been identified as the candidate for ASQ president-elect for the 2009-2010 membership year by the board of directors.

Spong will become the 61st president of ASQ following next year's elections, assuming another candidate doesn't enter the election through petition.

Spong, now a consultant, is the retired president of aerospace support for Boeing Integrated Defense Systems in Missouri.

Other candidates announced for the board of directors are:

- **Director:** Lloyd Barker, director of corporate quality, Alcoa Inc., New York.
- **Director:** Kay Kendall, principal, BaldrigeCoach, Massachusetts.

Other candidates announced are:

- **Chairman:** Roberto M. Saco, owner and principal, Aporia Advisors, Florida.
- **President:** Peter L. Andres, quality engineer of integration, simulation and testing for Boeing Integrated Defense Systems, California.
- **Treasurer:** Jim Rooney, director, quality and lean Six Sigma Services, ABS Consulting, Tennessee.

The results of the election will be announced in May during ASQ's annual business meeting, which will be held in conjunction with the World Conference on Quality and Improvement in Minneapolis.

ASQNEWS

LEARNING ABOUT LOYALTY A survey is being conducted to learn how ASQ sections can improve the ASQ experience for members. Input from the survey will help leaders make decisions on future products and services. Those who complete the survey can enter a drawing to win one of four registrations to this year's ASQ World Conference on Quality and Improvement. Take the survey at www.asq.org/mr/09-sect-sat.html until Jan. 30.

NEW SCHOLARSHIP The Healthcare Division will award one annual $2,000 scholarship in honor of Florence Nightingale, who is widely recognized as the initiator of nursing as a profession. The scholarship recipient will be announced at the Quality Institute for Healthcare, May 18-20, in Minneapolis. For more information, visit www.asq.org/health/scholarship/index.html.

CAPITOL Q

Det Norske Veritas Healthcare Inc. (DNV) has been granted Medicare-deeming authority by the Department of Health and Human Services. DNV becomes the first approved national Medicare accrediting body whose accreditation process incorporates an ISO 9001 platform. ASQ had endorsed the concept that independent bodies that incorporate recognized quality management systems should be permitted to have a role in the Medicare accrediting process … ASQ may petition to be involved in providing input to the Centers for Disease Control and Prevention's CDC Working Group on Processes to Prevent Hospital Infections. ASQ would be able to provide council members with information on where quality may be beneficial.

Capitol Q is a regular Keeping Current feature that highlights ASQ's advocacy efforts with government leaders.More information about ASQ's legislative activity and other issues and activities can be found at ASQ's Advocacy Room at www.asq.org/advocacy/index.html.

Mr. Pareto Head BY MIKE CROSSEN

AWARD

3 ACHIEVE BALDRIGE AWARD

Three organizations have been named recipients of the 2008 Malcolm Baldrige National Quality Award. They are:

Poudre Valley Health System, Fort Collins, CO, in the healthcare category. The private not-for-profit healthcare organization serves residents of northern Colorado, western Nebraska and southern Wyoming.

Iredell-Statesville Schools, Statesville, NC, in the education category. This K-12 public school system, located in southwestern North Carolina, includes 19 elementary schools, seven middle schools, five high schools, two alternative/at-risk schools and two early colleges.

Cargill Corn Milling (CCM), Wayzata, MN, in the manufacturing category. CCM employs 2,321 people and operates nine manufacturing facilities in eight states.

Baldrige examiners selected these three recipients after receiving and judging 85 applications this year and conducting site visits for 13 applicants.

The Baldrige program is managed by the National Institute of Standards and Technology, an agency of the U.S. Commerce Department, with sponsorship and administrative support from ASQ. The awards will be presented during a Washington, D.C., ceremony early this year.

For more information about the award and this year's recipients, visit www.nist.gov/public_affairs/releases/2008baldrigerecipients.htm. Watch for profiles of each award recipient in future issues of QP.

ONLINE ONPAPER

QUICK POLL RESULTS

Each month at www.qualityprogress.com, visitors can take a short, informal survey, and we post the results. Here are the numbers from a recent Quick Poll:

Could quality methods and principles have prevented the current financial crisis?

- Yes 71.2%
- No 28.7%

Visit www.qualityprogress.com to answer the most recent Quick Poll question posted:

"Which of the seven basic tools of quality do you consider the most important?"

- Cause-and-effect diagrams
- Control charts
- Check sheets
- Histograms
- Pareto analysis
- Scatter plots
- Stratification

SHORTRUNS

THE AMERICAN NATIONAL STANDARDS INSTITUTE (ANSI) focused on food safety during a meeting last month. Participants in breakout sessions widely agreed that to make progress, a permanent infrastructure that looks at the issue of food safety is needed. Many suggested that ANSI could coordinate such an infrastructure. Attendees also came to the consensus that greater cooperation between the Food and Drug Administration, the U.S. Department of Agriculture and industry is needed. For more information, visit http://web.ansi.org/news_publications/latest_headlines.aspx?menuid=7.

THE INTERNATIONAL SOCIETY OF AUTOMATION has announced that it transferred its Certified Industrial Maintenance Mechanic (CIMM) certification program to the Society for Maintenance and Reliability Professionals. CIMM certification provides a third-party assessment of the skills of industrial maintenance mechanics who are responsible for preventive, predictive and corrective maintenance, and who perform troubleshooting and analysis.

ENGINEERS WEEK is slated for Feb. 15-21. The goal of the National Engineers Week Foundation, a formal coalition of more than 100 professional societies, major corporations and government agencies, is to ensure a well-educated and diverse future engineering workforce by increasing understanding of and interest in engineering and technology careers among young students and by promoting precollege literacy in math and science. Engineers Week also raises public understanding and appreciation of engineers' contributions to society. For details, visit www.eweek.org.

CANADA'S NATIONAL QUALITY INSTITUTE has announced that its Quest for Quality training is now available as a webinar. For details, visit www.nqi.ca/NewsEvents/details.aspx?ID=672.

BUILDING FROM THE BASICS

Master these quality tools
and **do your job better**

QUALITY CONTROL is about models, methods, measuring and managing. It's about uncovering a problem and finding the solution. It's about using the right techniques at the right time to make things better.

One of the forefathers of quality, Kaoru Ishikawa, knew how to make things better. He taught quality and promoted it in Japan for decades. He believed that 95% of a company's problems could be solved by a select number of quality tools.

The powerful collection of tools that Ishikawa had in mind is referred to by different names: "the old seven," "the first seven" or "the basic seven." Whatever you call them, it's imperative to know them all—inside and out—if you are to succeed as a quality professional.

We asked seven of QP's frequent contributors to each cover one of the tools in about 500 words. Their respective explanations (presented here in no particular order) get to the heart of these tools. True, they could have written much, much more, but these illuminating snapshots give you the basics you need to understand—or explain to others—how these tools are used.

Chances are, as a quality practitioner, you're familiar with most of the seven. If you feel the need to brush up more on one or two, however, there are additional resources listed at the end of each article. QP's website (www.qualityprogress.com) offers articles on the basic tools, and ASQ's website is stocked with publications (www.asq.org/books-and-publications.html) and other resources to help you learn about quality.

Each of these seven tools is indispensable and can make a difference in the way you work. As the American psychologist Abraham Maslow noted, "If the only tool you have is a hammer, everything starts to look like a nail."

The Tools

Histograms

Statistics and data analysis procedures can be divided into two general categories: quantitative techniques and graphical techniques.

Quantitative techniques are statistical procedures that yield numeric or tabular output. Examples of quantitative techniques include hypothesis testing, analysis of variance, point estimation, confidence intervals and least-squares regression. Graphical techniques include histograms, scatter plots, probability plots, residual plots, box plots, block plots and ballots.

Exploratory data analysis (EDA) relies heavily on these and other similar graphical techniques. Graphical procedures are not just tools used within an EDA context; they are the shortest path to gaining insight into a data set in terms of testing assumptions, model selection and statistical model validation, estimator selection, relationship identification, factor effect determination and outlier detection. In addition, good statistical graphics can effectively communicate the underlying message that is present within the data.

A histogram is a graphical display of tabulated frequencies, which are shown as bars. It illustrates what proportion of cases fall into each of several categories. A histogram differs from a bar chart in that it is the area, not the height, of the bar that denotes the value—a crucial distinction when the categories are not of uniform width. The categories are usually specified as nonoverlapping intervals of a variable. The categories (bars) must be adjacent. Figure 1 is an example of a histogram.

Although A. M. Guerry published a histogram in 1833, Karl Pearson (1857-1936) first used the word "histogram" in 1891. Pearson was a scientist in Victorian London. As a student at Cambridge University, Pearson learned to use applied mathematics as a pedagogical tool for determining the truth (in other words, one that provided the standards and the means of producing reliable knowledge).

Pearson's passionate interest in mathematical statistics was a means to the truth. He established the foundations of contemporary mathematical statistics and helped create the modern

Histogram example / FIGURE 1

Worksheet example

The Bulldogs bowling team wants to improve its standing in the league. Team members decided to study their scores for the past month. The 55 bowling scores are:

103	107	111	115	115	118	119	121	122	124	124
125	126	127	127	129	134	135	137	138	139	141
142	144	145	146	147	148	148	149	150	151	152
153	153	154	155	155	155	156	157	159	160	161
163	163	165	165	167	170	172	176	177	183	198

Using the table on the histogram worksheet, they estimate B (the number of bars) to be seven. The highest score was 198, and the lowest was 103, so the range of values is:

R = largest – smallest

R = 198 – 103 = 95

The width of each bar is:

W = R ÷ B

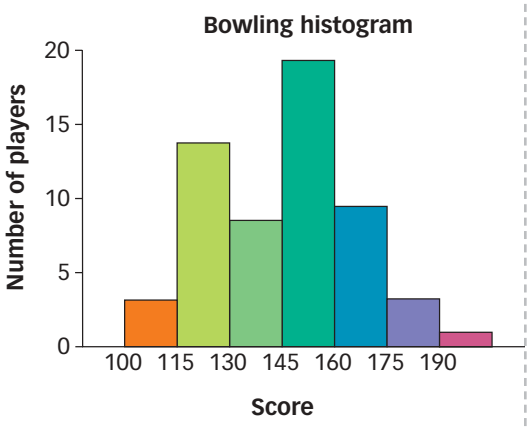
W = 95 ÷ 7 = 13.6

The bowling scores have no decimal places, so the bar width must not have decimal places. They round 13.6 up to 14. Because 14 is an awkward number to work with, they decide to adjust W to 15. Choosing 100 to be the lower edge of the first bar, the lower edges of the other bars are

100 + 15 = 115

115 + 15 = 130, and so on

The histogram they drew seems to indicate a double-peaked, or bimodal, distribution: a group of players who score in the low 100s and another more talented group that scores in the mid-100s. To improve the team's standing, members can try to improve everyone's score, which would shift the entire histogram to the right. Or, they could focus their efforts on improving the poorer players, which would narrow the distribution, making the team as a whole more consistent.



Source: Nancy R. Tague, *The Quality Toolbox*, second edition, ASQ Quality Press, 2005.

world view. His statistical method not only transformed our vision of nature, but also gave scientists a set of quantitative tools with which to conduct research.

Pearson introduced the histogram Nov. 18, 1891. While presenting a lecture on maps and chartograms, he coined the term to describe a time diagram. He explained that the histogram could be used for historical purposes to illustrate blocks of time for "charts about reigns or sovereigns or periods of different prime ministers."

Figure 1 is an example of a histogram with bimodal distribution. Other histogram distributions are comb, truncated or heart-cut, and dog food.[1]

—James J. Rooney

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1. Nancy R. Tague, *The Quality Toolbox*, ASQ Quality Press, 2005, pp. 298-299.

Control Charts

Control charts are statistically based graphical tools used to monitor the behavior of a process. Walter A. Shewhart developed them in the mid-1920s while working at Bell Laboratories. More than 80 years later, control charts continue to serve as the foundation for statistical quality control.

The graphical and statistical nature of control charts helps us:

- Quantify the variation of a process.
- Center a process.
- Monitor a process in real time.
- Determine whether to take action on a process.

The structure of control charts

Constructing control charts is straightforward and, more often than not, aided by computer software designed specifically for this purpose. Minitab and JMP, among others, are commonly used.

Figure 2 illustrates the general form for a control chart. Its critical components listed here correspond with the numbers in the figure:

1. X-axis: This axis represents the time order of subgroups. Subgroups represent samples of data taken from a process. It is critical that the integrity of the time dimension be maintained when plotting control charts.

2. Y-axis: This axis represents the measured value of the quality characteristic under consideration when using variables charts. When attributes charts are used, this axis is used to quantify defectives or defects.

3. Center line: The center line represents the process average.

4. Control limits: Control limits typically appear at ±3σ from the process average. More details about control limits can be found in the online version of this article at www.qualityprogress.com.

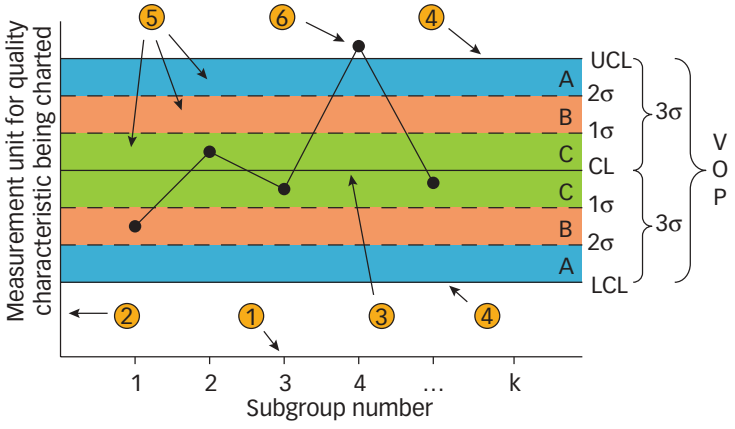
5. Zones: The zones represent the distance between each standard deviation and are useful when discussing specific out-of-control rules.

6. Rational subgroups: The variation within subgroups should be as small as possible to make it easier to detect subgroup-to-subgroup variation.

Notice there are no specification limits present on the control chart in Figure 2. This is by design, not by accident.

The presence of specification limits on control

Control chart structure / FIGURE 2



VOP = voice of process
UCL = upper control limit
LCL = lower control limit
CL = center line

charts could easily lead to inaction, particularly when a process is out of control but within specification.

Types of control charts

Control charts can be categorized into two types: variables and attributes. Charts fall into the variables category when the data to be plotted result from measurement of a variable or continuous scale. Attributes charts are used for count data in which each data element is classified in one of two categories, such as good or bad.

Generally, variables charts are preferred over attributes charts because the data contain more information and are typically more sensitive to detecting process shifts than attributes charts. A more detailed discussion on variables and attributes charts can be found in the online version of this article.

Using control charts

A control chart that has not triggered any out-of-control condition is considered stable, predictable and operating in a state of statistical control. The variation depicted on the chart is due to common-cause variation.

Points falling outside the limits are attributed to special-cause variation. Such points, regardless of whether they constitute "good" or "bad" occurrences, should be investigated immediately while the cause-and-effect relationships and individual memories are fresh and access to documentation for process changes is readily available.

As the time between the out-of-control event and the beginning of the investigation increases, the likelihood of determining root causes diminishes greatly. Hence, the motto "time is of the essence" is most appropriate.

Highly effective tool

A control chart is relatively easy to develop and use, and it can be a highly effective statistical tool when selected properly and used correctly. Its selection and use alone, however, is not sufficient. When so indicated, control charts must be acted on in a timely manner so the root causes may be identified and removed from the process.

One last thing: When in doubt, avoid tampering with the process.

—T.M. Kubiak

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Pareto Analysis

In 1950, Joseph M. Juran rephrased the theories of Italian economist Vilfredo Pareto (1848-1923) as the Pareto principle, often referred to as the 80-20 rule. The rule postulates that in any series of variables (problems or errors), a small number will account for most of the effect (for example, 80% of customer complaints come from 20% of customers, or 80% of a company's profit comes from 20% of products made). Juran referred to the "vital few" versus the "useful many."

A Pareto chart graphically displays the relative importance of differences among groups of data within a set—a prioritized bar chart. Depicting values from the highest to the lowest in the form of bars (left to right), the Pareto chart has many potential uses for decision making, for example:

- Relative frequency of categories of occurrences.

- Which 20% of sources caused 80% of the errors.
- Relative costs incurred in producing different types of defectives.
- Determining which category or categories should be the focus of improvement efforts.

For example

Crackers Are Us (CAU) is a fictitious bakery that produces crackers for the consumer market. Crackers are sold to distributors, which sell to retail stores. The product package and the company's website provide contact information for submitting consumer complaints. CAU's complaint unit logs every complaint. Overall, complaints (the numbers reflect units) for the past month were the highest on record. The month's summary is shown in Table 1.

A Pareto chart graphically displays the data (see Figure 3). It appears that 78% of the complaints came from 20% of the complaint categories. Further analysis may indicate a need for nested Pareto charts, which are more discrete breakdowns of the top 80% or weighting of the categories by dollar cost.

Ensure the categories chosen are clearly differentiated to avoid overlap. The intention of the graphic is to clarify the data represented. Remember the data source: Garbage in is garbage out.

The Pareto chart is a valuable means for visualizing the relative importance of data.

—Russ Westcott

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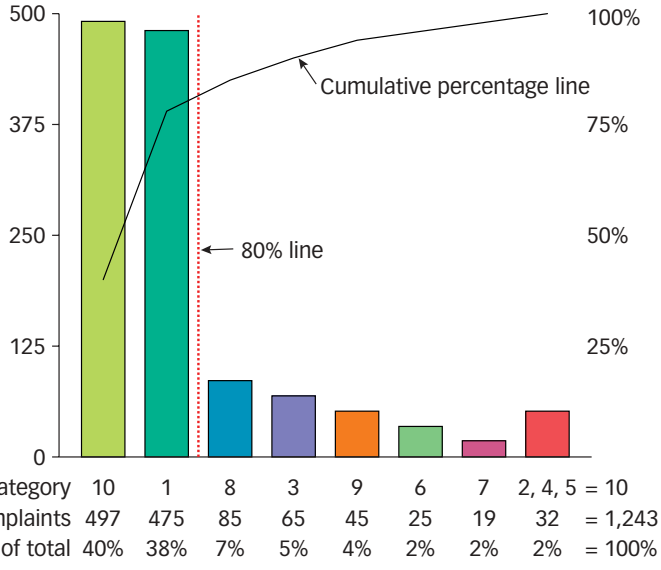
Monthly complaint summary / TABLE 1

Complaint type	Category	Number of complaints	Percentage of total
Too soft (break easily)	1	475	38
Too hard (difficult to chew)	2	5	0
Too crumbly (disintegrate easily)	3	65	5
Too bland (not enough flavor or seasoning)	4	15	1
Too irregular in shape (not standardized shape)	5	12	1
Too unappealing (color, smell, appearance)	6	25	2
Too much salt (or other seasoning)	7	19	2
Too much fat (trans fat or other fat)	8	85	7
Too few beneficial nutrients (too much filler)	9	45	4
Too damaged (soaked, burned, dented)	10	497	40
Total complaints		1,243	100

Pareto chart / FIGURE 3



Cause and Effect Diagrams

This now-familiar tool was reportedly developed by Kaoru Ishikawa of Tokyo University. The Japanese name is *Tokusei Yoin Zu*, or "characteristics diagram."[1]

The cause and effect diagram has been defined as a "tool for analyzing process dispersion. It is also referred to as the Ishikawa diagram and the fishbone diagram because the complete diagram resembles a fish skeleton. The diagram illustrates the main causes and sub-causes leading to an effect (symptom)."[2]

Ishikawa defined the effect to control or improve as the quality characteristic (Y in Figure 4) and the potential causes as the factors (X variables in Figure 4).[3] He first used the diagram to show the relationship between cause and effect in 1943.

When developing the tool, Ishikawa reported that in almost half of the cases, the reason for variation, or dispersion, was due to:

1. Raw materials.
2. Machinery or equipment.
3. Work method.

Joseph M. Juran described the diagram in the context of quality improvement, indicating that it is an example of a graphical method used to arrange a number of theories in a manner that allows the user to better understand interrelations.[4]

Figure 5 illustrates a traditional manufacturing example in which the tool "identifies many possible causes for an effect or problem. It can be used to structure a brainstorming session. It immediately sorts ideas into useful categories."[5] In a service industry example, the main characteristic groupings can include people, processes, policies or technology. Characteristic groupings will vary.

Wikipedia adds that "a common use of the Ishikawa diagram is in product design to identify desirable factors leading to an overall effect."[6]

Chrysler, Ford and General Motors included a high-level example of the diagram while discussing control charts for variables in their *Statistical Process Control (SPC) Reference Manual*.[7]

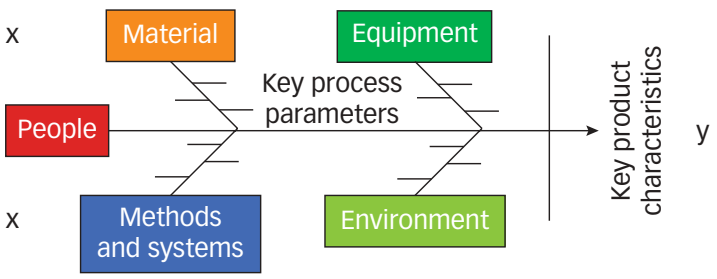
Then, they applied the diagram in their *Measurement Systems Analysis Reference Manual* third edition, (see Online Figure 4) to identify some potential sources for measurement system variability,[8] using the following characteristic groupings: standard, workpiece, instrument, person and procedure, and environment.

I have used an adaptation or variation of the diagram over the years. Figure 6 uses the typical fishbone diagram groupings to define inputs that need verification in the process model graphic. The figure illustrates that "fundamental quality management science recognizes the need for appropriate controls on the quality of the inputs as well as controls for the process itself and the output."[9]

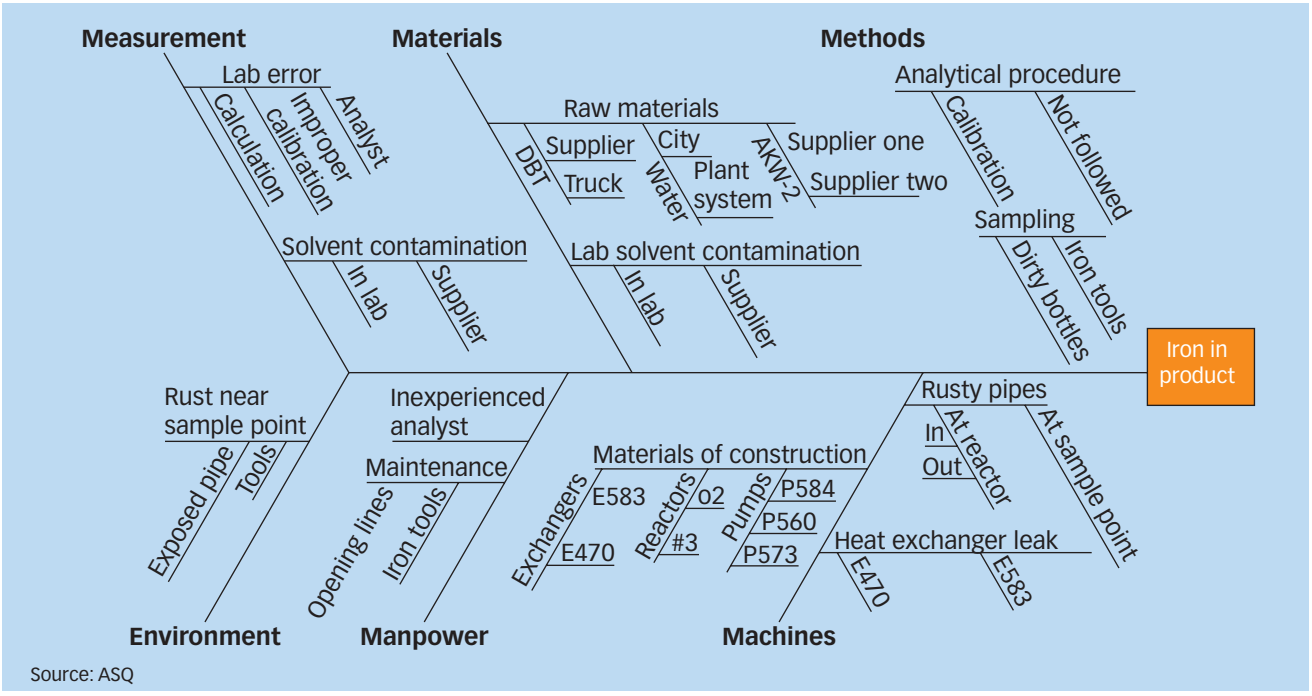
I have also used a more traditional application of the diagram (Figure 4) to depict the relationship between key product (Y) and key process characteristics (X variables) in a Six Sigma context.

The Society of Automotive Engineers published sev-

High-level fishbone for key characteristics / FIGURE 4



Fishbone diagram / FIGURE 5



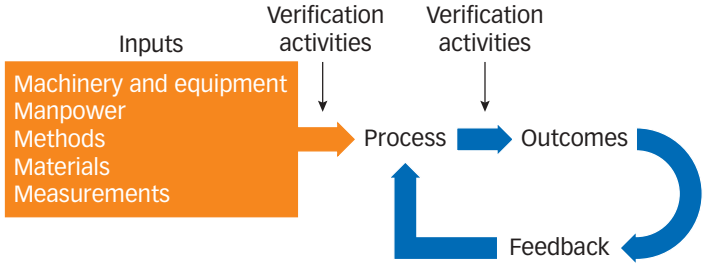
Source: ASQ

eral papers on Six Sigma in 2007 that applied the diagram as a diagnostic tool for problem solving that can improve service quality (noise)[10] and identify potential causes of manufacturing process variation.[11]

As with many quality tools, such as failure mode effects analysis and control plans, this diagram should be constructed using brainstorming methods by a cross-functional team to capture broad organizational input.

–R. Dan Reid

Process model / FIGURE 6



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Check Sheets

Stop arm, horn, brakes and vacuum!

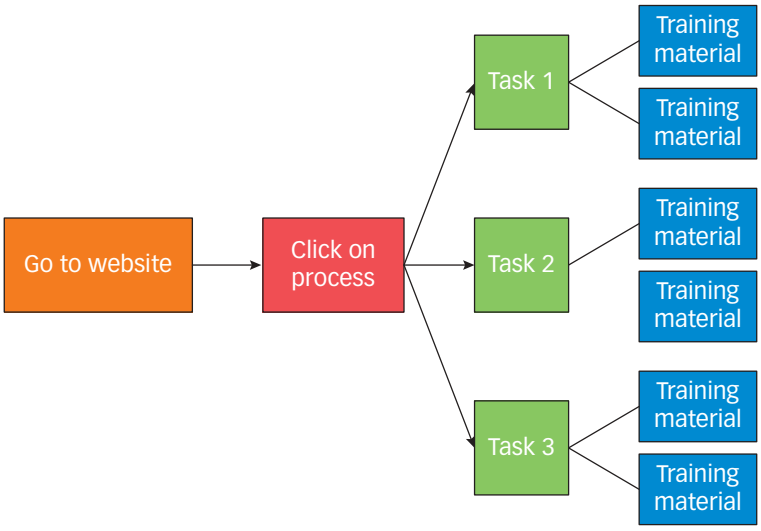
As a 16-year-old going through school bus driver training, this was a very important checklist. As simple as this seems, the instructor boiled down starting the bus route to these four import checks (see Figure 7). Yes, there were other inspections to be made. But when you sat down in that driver's seat, these were the last things that were to be done prior to moving the bus and starting the route. If any of these four items weren't working, the bus did not move, and the mechanic was to be called.

So what about the checklist, otherwise known as a check sheet? What role does this tool play in executing processes? Is there still relevance for such a simple tool in today's high-tech world? Here is a simple review of a quality tool with a very high return on investment.

School bus route start check sheet / FIGURE 7

Parameter check	Yes	No
1. Stop arm: Does the stop arm deploy and do the stop lights work?		
2. Horn: Does the horn sound when pressed?		
3. Brakes: Does the pedal stay off the floor when the brakes are pumped?		
4. Vacuum: With the stop arm out and the brake pedal depressed, does the vacuum gauge read the appropriate level?		

Automated check sheet / FIGURE 8



Memory jogger

Joseph M. Juran considered the check sheet a type of lesson learned. He likened the check sheet to a memory jogger, as a reminder of what to do and what not to do.[1] In environments in which repetitive activity is commonplace, the check sheet is a perfect tool to do just that: jog the memory to make sure processes are followed completely.

Making the connection between a memory jogger and a process is a logical role the check sheet can play.

Perhaps the strongest message ISO 9000:2008 delivers is that the reliance on memory is not the way business is conducted.

Historical uses

In case the phrase "check sheet" is a new term for you, here are a couple of points to consider. If you've ever made a grocery list, completed a form of some type or executed an inspection plan, you've used a check sheet.

From manufacturing to medicine, from the public domain to the private sector, check sheets have been used to ensure that what is to be accomplished is completed in a reproducible and repeatable fashion, opportunity after opportunity. Check sheets help drive consistency in execution on every occasion.

Uses and forms

Check sheets can be created by watching an individual do a series of tasks and jotting them down as they're performed. Check sheets can be created by breaking down a process into its critical tasks and capturing

them in a work instruction.

Today's technology enables the user to go to a website, call up the process that is to be executed and easily access the process (check sheet) for the task that must be completed.

Figure 8 shows how automation can assist in developing and implementing a check sheet. As long as the individuals doing the tasks have access, they can get all the information they need to execute the process flawlessly. If needed, a simple click can give them access to training material for the elements of the check sheet.

Get started

Whether the opportunity is in manufacturing, quality inspections, medical or IT, check sheets are a helpful tool. Whether they are simple memory joggers or sophisticated applications, check sheets accomplish the same purpose: They help remind the person doing the tasks what must be done.

—Keith Wagoner

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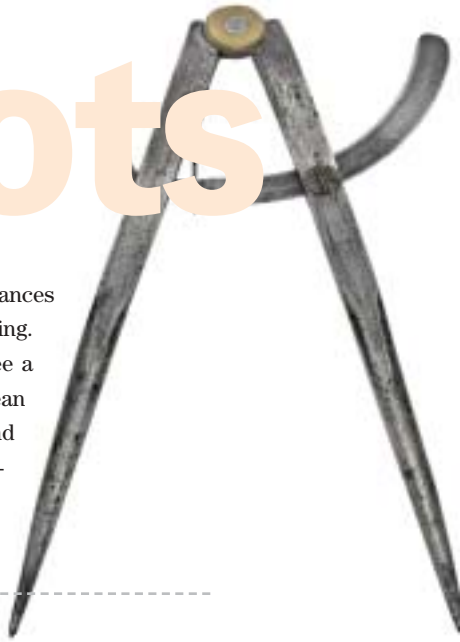
Scatter Plots

Scatter Plots



Plot the data. Is there a statistics professor anywhere on the planet who doesn't stress that? If you are investigating a potential relationship between two variables, then a scatter plot is the tool to use.

A scatter plot is a simple visual form of graphical analysis. Let's use a general example to flesh out its usefulness.

You are wondering if temperature at a point in your process is related to the number of defects you observe. Data from 20 lots have been collected and recorded in Table 2.

Using that data, you can set up a plot with the independent variable (temperature) on the x-axis and the dependent variable (number of defects in the lot) on the y-axis. You can plot the 20 observations in this example (or in any situation) on a piece of grid paper or by using a tool such as Excel.

Seeing is believing

In Excel, put the data in columns, highlight the temperature and defects columns, click the Chart Wizard icon, select XY Scatter and follow the menu prompts until you're finished. When the plot is complete, take a look at the result (Figure 9, p. 28).

Because this is meant to be a visual tool, believe your eyes. If there appears to be a pattern, such as a line or a curve, then you have a relationship. What do you see in the example? There seems to be pretty clear evidence there is a direct relationship between the two factors. If you need to look very hard for a pattern or find yourself wondering if one is there, chances are there isn't a relationship worth pursuing.

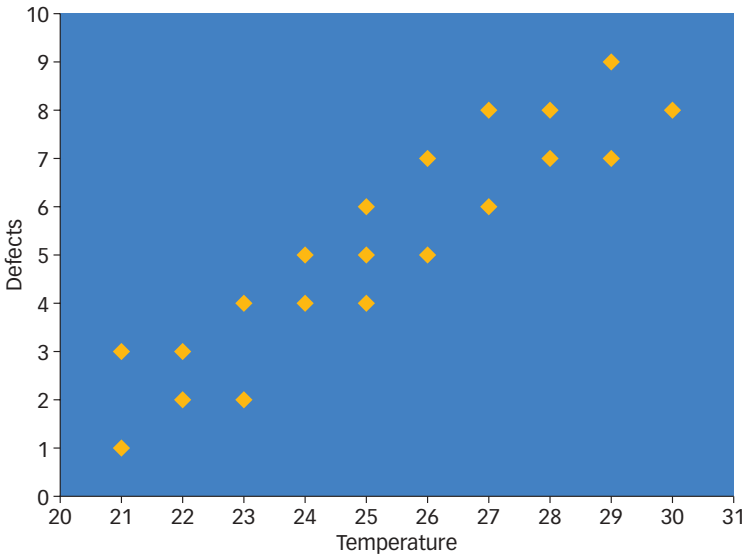
A few words of warning: You may see a relationship, but that does not always mean one variable drives the other (cause and effect). Both may be driven by a third factor. Just because your grass grows and your neighbor's grass grows at about the

Lot data / TABLE 2

Lot	Temperature	Defects
1	22	2
2	29	9
3	21	3
4	30	8
5	25	4
6	23	4
7	22	3
8	29	7
9	26	7
10	25	5
11	28	7
12	27	8
13	24	4
14	26	5
15	25	6
16	27	6
17	23	2
18	28	8
19	21	1
20	24	5

same rate doesn't mean one causes the other. They are both driven by other factors, such as the weather or fertilization practices. The indication of a relationship merely means additional investigation is worthwhile.

Defects vs. temperature / FIGURE 9



Next step

What do you do next? Talk with the process experts, search the literature and gather and plot more data. You may want to better define the relationship by using additional quality tools more advanced than the ones dealt with in this collection.

You can quantify a relationship by establishing a correlation coefficient. You also can create a predictive model of the relationship: It may be linear (for straight lines), quadratic (for curved lines) or some combination.

If you want to learn more, look up correlation coefficient, predictive model, linear relationship or quadratic relationship in Excel using the help function, in your favorite textbook or on the internet.

—Peter E. Pylipow

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Stratification

Stratification is a fancy word for a simple concept: breaking down data into categories so you can make sense of it. The concept is as old as rational thinking itself. For decades, giants of quality improvement, such as Walter Shewhart, W. Edwards Deming, Joseph M. Juran and Kaoru Ishikawa, have recommended its use.

To illustrate how handy it can be to have this tool in your arsenal, consider the following scenario:

Get a handle on the problem

An airline company was trying to understand its relatively high rate of baggage-handling errors. Someone asked whether there were certain time periods when the problem was worse or better. That way, the airline could pinpoint a time and investigate what may have been going on then.

The team stratified the data by week and produced a control chart of the weekly data, only to find random variation. Further stratification by day of the week and time of day also failed to pinpoint the problem.

The team asked whether it was possible that only certain airports accounted for the high error rate. To answer the question, it stratified the data by airport and whether it was the departure or arrival city. But, again, the team found nothing unusual.

Finally, someone came up with the theory that, be-

cause passengers were checking in earlier and earlier these days, the bags were being misplaced in storage areas while awaiting the arrival of the incoming aircraft. When the team stratified the data by time of check-in, they found that the majority of the errors had occurred on bags checked in more than three hours prior to departure.

Take your pick

The airline team stratified—broke down, categorized and separated—the data several ways during their exploration to get closer to the root cause of the problem. They could have stratified the numbers in many other ways: by weight or size of bag, by whether check-in was at curbside or the inside counter, by agent or by baggage handling crew at the departure site or destination airport.

In practice, there are always many ways to stratify data. Knowledge of the system and intuition are the best guides. A cause-effect diagram can also be used to guide this thinking.

Stratification is an underlying tool that is often used with the other six basic quality tools. In the early stages of this scenario, the airline team produced a control chart after stratifying the data by week to see if there were any abnormal weeks.

Check sheets often contain columns or rows to tally stratification information, such as time of day or operator. A Pareto diagram stratifies data by categories, such as cause or location. Histograms and scatter diagrams can also be used to display and compare the data after stratification.

Think ahead

The most important time to think about stratification is before you collect data. If the airline team had not collected the basic data involving time of check-in, they would not have been able to look at whether that was a factor in the baggage-handling problem without taking several months to collect the necessary data.

As a result, the team discovered what many quality professionals already know: A little bit of thinking and planning in the present will save you—and your customers—lots of headaches in the future. QP

—Paul Plsek

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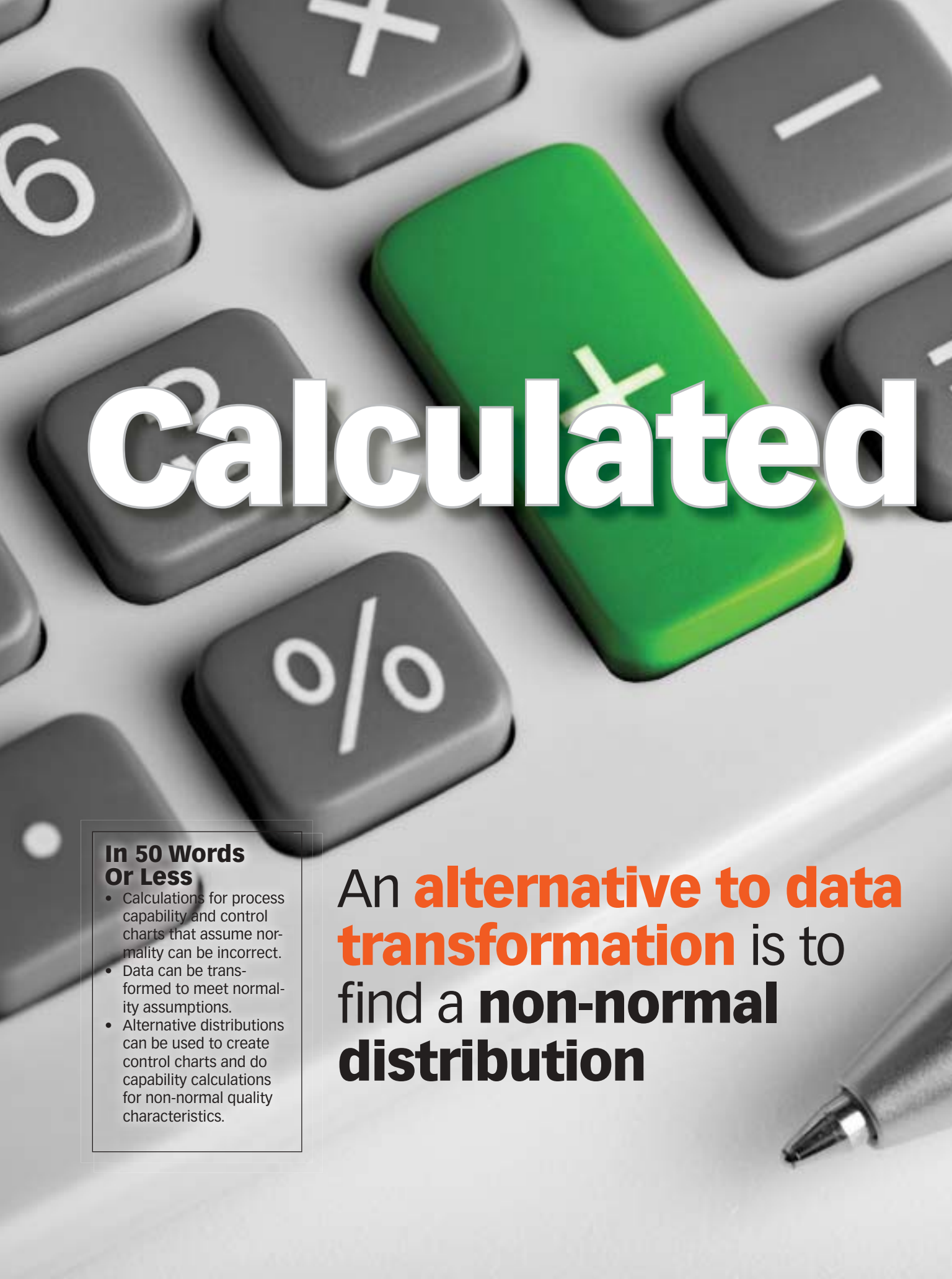


Calculated

In 50 Words Or Less

- Calculations for process capability and control charts that assume normality can be incorrect.
- Data can be transformed to meet normality assumptions.
- Alternative distributions can be used to create control charts and do capability calculations for non-normal quality characteristics.

An **alternative to data transformation** is to find a **non-normal distribution**

Decisions

by Robert W. Sherrill and Louis A. Johnson

CONSIDER THE FOLLOWING examples of key quality characteristics for different products:

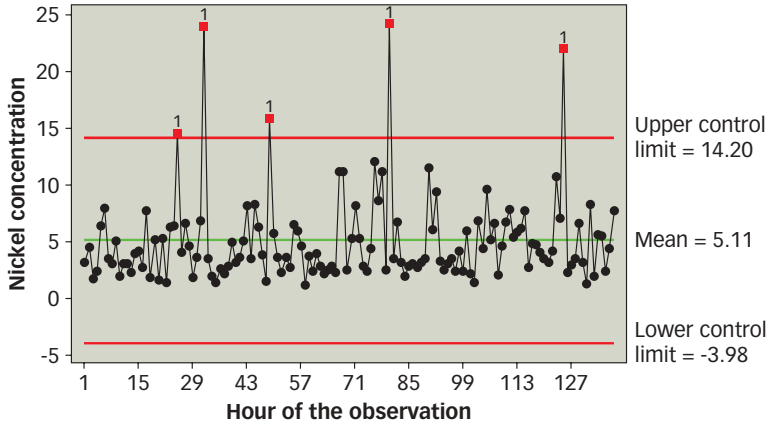
- Trace contaminant concentration in a semiconductor raw material.
- Noise level from a portable generator.
- Concentricity of an engine drive shaft.
- Distance to target for several points of an airplane wing profile.
- Breaking strength of an LCD screen.

Customers expect the suppliers of these products to provide proof of process control and process capability. When suppliers create control charts and run capability analyses, they assume their data follow a normal distribution. However, the natural distribution of these quality characteristics—and hundreds more like them—is not the normal distribution. Therefore, standard textbook calculations for process capability and control charts that assume normality can be incorrect.

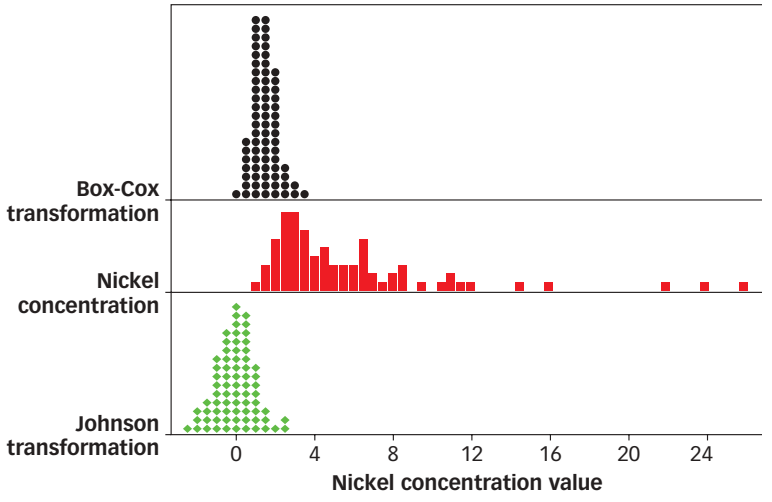
This situation was a major problem in the past, but today it can be easily solved using the calculation capabilities of statistical software and an understanding of distributions that provide good models for most non-normal quality characteristics, such as the exponential, lognormal and Weibull distributions.

Knowing how to use transformations or other distributions to create control charts and carry out capability calculations for quality characteristics that do not follow the normal distribution is essential for today's quality professional.

Individuals control chart of nickel concentration / FIGURE 1



Distribution of nickel concentration and two transforms / FIGURE 2



Purity essential

DuPont EKC Technology Inc. manufactures patent specialty chemicals used in the manufacture of wafers for the semiconductor industry. The purity of these chemicals is critical to their performance, so the company commonly measures the concentration of trace contaminants, such as the element nickel, to demonstrate process control and capability to high-end customers. These measurements rarely follow a normal distribution, so they provide a good numeric example to illustrate our calculations.

Sampling the process over time, 138 nickel concentration measurements were collected. The one-sided upper specification limit for this process is 20 units (actual values are proprietary).

Process control

Before calculating process capability, the process first must be stable or in control, meaning that all the data came from a single distribution, usually assumed to be the normal distribution. Figure 1 shows an individuals control chart of the nickel data with limits calculated based on the assumption that the data are normally distributed. The points above the upper control limit indicate that the process is out of control, but is this the correct conclusion?

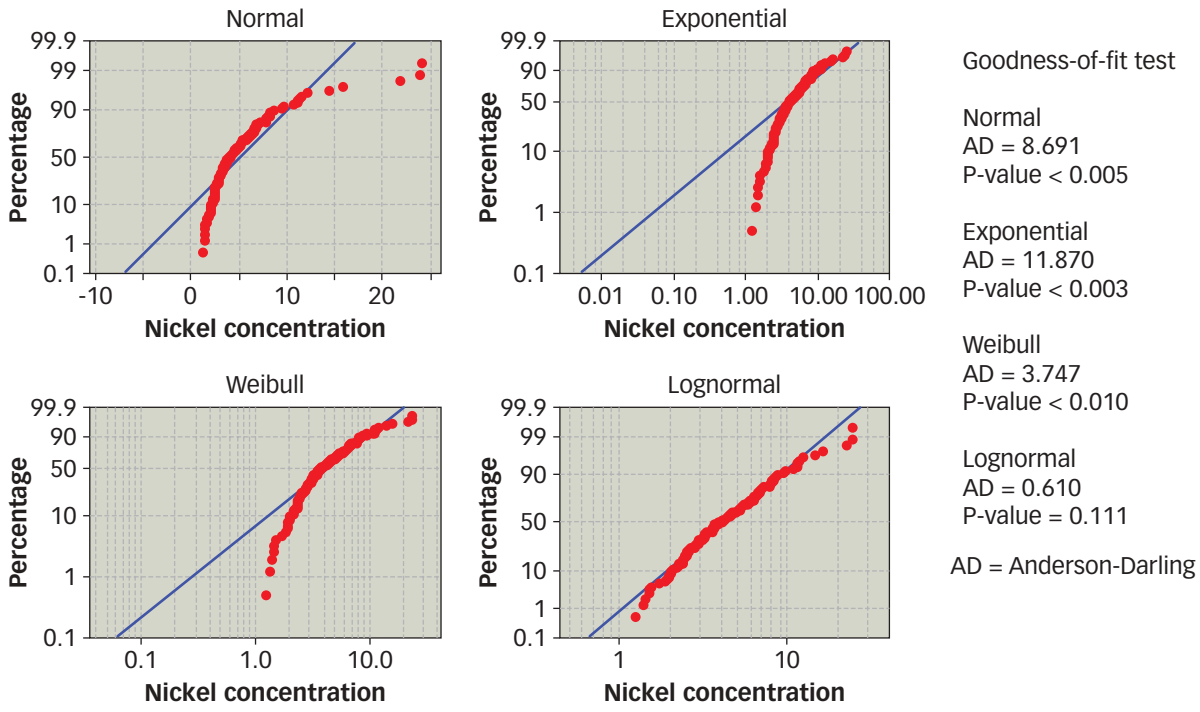
Two clues indicate it may not be correct. First, the follow-up investigation of the out-of-control points found no special source of variation that could have caused them. Second, a histogram of the data did not show that the data were normally distributed, but that they were skewed toward higher values. This led us to suspect the incorrect assumption of normality may have caused the process to look as though it was out of control when it was not.

When the natural distribution of a measurement is non-normal, there are several ways to accurately determine whether the process is in control.

First, the data can be transformed to follow the normal distribution, and then standard control chart calculations could be used on the transformed data. Two transformations, the Box-Cox and the Johnson,[1] are common. The Box-Cox is often called the power transformation because the data are transformed by raising the original measurements to a power λ (y transformed = y^{λ}).

Typical values for lambda (λ) include 0.5, 2, 0 and -1, corresponding to the square root, square, log and

Probability plots for nickel concentration / FIGURE 3



inverse transformations, respectively. The Box-Cox transformation is limited to non-negative data values, but this issue can sometimes be resolved by adding a constant to the original data value as a part of the transformation.

The Johnson transformation computes an optimal transformation function from three flexible distribution families. This makes it powerful enough that the Johnson transformation can sometimes find an acceptable solution when the Box-Cox cannot.

Transformation of the original non-normal data using these two methods can be performed with several statistical software packages. Figure 2 shows the original nickel concentration data distribution, as well as the data after using the Box-Cox and the Johnson transformations using Minitab 15 software. The original data are skewed to the right, but both transformations produce a new data set with a distribution following the familiar bell curve.

Transformations clearly can provide a solution to the non-normality issue. They are mathematically correct to use whenever an appropriate transformation can be found. However, one drawback might be a loss of physical connection with the measurement. In our example, the log of the nickel concentration measurements or an even more complicated transformation would be analyzed, rather than the original measurements. Interpreting the log of the nickel concentrations could be challenging.

An alternative to transforming the data is to find a non-normal distribution that does fit the data. Many distributions other than the normal distribution can be used to model a response. The exponential, lognormal and Weibull distributions usually work well. Our next step will be to use probability plots to find a distribution that fits our data.

Figure 3 shows probability plots for the nickel concentrations using the normal, lognormal, exponential and Weibull distributions. Our statistical software has calculated the x and y axis of each probability plot so the data points will follow the blue, perfect-model line if that distribution is a good fit for the data.

For example, because the data points fall well off the blue line in the exponential probability plot, we can conclude that the exponential distribution is a poor model for the nickel concentration data.

On the other hand, data points in the lognormal probability plot follow the model line very well, indicating that the lognormal distribution provides a good model for the data. Additional support for the lognormal model can be seen in the high p-value (p-value = 0.111 > .05) for the Anderson-Darling goodness-of-fit test.

This p-value indicates there is not enough evidence in the data to reject the null hypothesis that the lognormal distribution is a good model for the nickel data. So, a high p-value is the second indicator of a good fit of the data to a distribution.

Based on the results of this distribution identification analysis, we can conclude that the lognormal distribution is a good model for the nickel data. Andrew Sleeper has written an excellent guide providing more information on the application of distribution analysis.[2]

Constructing the right chart

Now that we know that the lognormal distribution provides a good model for the data, we can use that distribution to construct the proper individuals control chart.

A standard individuals chart for normally distributed data with +/-3 sigma control limits has control limits at the 0.135th and 99.865th percentiles of the data distribution and a center line at the 50th percentile.

A percentile is the value below which a certain percentage of the measurements fall. For example, the 99.865th percentile of our nickel concentrations is 25.302; therefore, 99.865% of nickel concentrations would be smaller than 25.302.

To construct an equivalent control chart for our data, we determine the same percentiles for the lognormal distribution that describes the nickel data.[3] These percentiles are shown on the lognormal probability plot in Figure 4. Our control chart will have an upper control limit at the 99.865th percentile, a lower control limit at the 0.135th percentile and a center line at the 50th percentile.

Figure 5 indicates the process is in control, where only common cause variation is seen in the nickel concentration values. This was not the conclusion reached by Figure 1, with the incorrect control chart based on the assumption of normality. By evaluating the distribution of the data, we have constructed the correct control chart and revealed that the process is in control. We can now carry out the process capability calculation.

Process capability

Determining process capability quantitatively answers the question. "Is my process capable of meeting my customer's specifications?" The answer can take many forms. For example, estimating a defect level of 3% implies meeting your customer's specifications about 97% of the time.

The most common capability index is C_{pk}, which for normally distributed data takes the familiar form of the distance from the data average to the closest specification, divided by three standard deviations. Surajit Pal defines a more general calculation of C_{pk}, which is derived as follows:[4]

$$C_p = \frac{\text{allowable spread}}{\text{Process spread}} = \frac{\text{upper spec} - \text{lower spec}}{X_{0.99865} - X_{0.00135}}$$

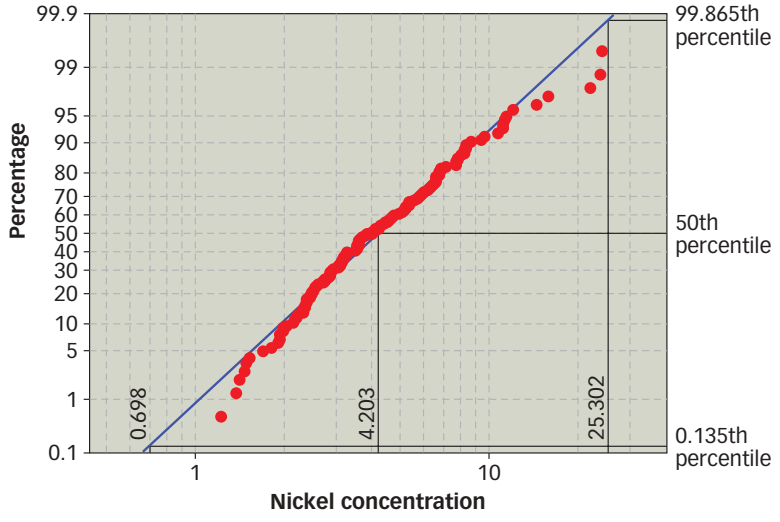
in which $X_{0.99865}$ and $X_{0.00135}$ are the 0.135th and 99.865th percentiles of the distribution that describes the quality characteristic of interest. If C_{pl} and C_{pu} are the acceptable spread with respect to the upper and lower specifications defined as:

$$C_{pl} = \frac{\text{median} - \text{lower spec}}{\text{median} - X_{0.00135}} \qquad C_{pu} = \frac{\text{upper spec} - \text{median}}{X_{0.99865} - \text{median}}$$

then C_{pk} equals the minimum of C_{pl} and C_{pu}.

C_{pk} is an indicator of the percentage of the parts

Lognormal probability plot of nickel concentration / FIGURE 4



beyond the upper or lower specification, whichever percentage is greater. When the data are not normally distributed, we can use the probability plot to estimate the distribution percentiles and compute the capability estimate.

For the nickel concentration, which has only an upper specification = 20, C_{pl} cannot be calculated and $C_{pk} = C_{pu}$. The appropriate percentiles are taken from the lognormal probability plot in Figure 4, and C_{pk} is calculated as follows:

$$C_{pk} = C_{pu} = \left[\frac{20-4.203}{25.302-4.203}\right] = 0.75.$$

Figure 6 shows Minitab's output when determining the process capability using the lognormal distribution and an upper specification of 20. Similar to the probability plot, the histogram shows the data are modeled well using a lognormal distribution. The process capability is $C_{pk} = 0.75$ with an observed performance of approximately 21,740 parts per million falling outside the specification limit.

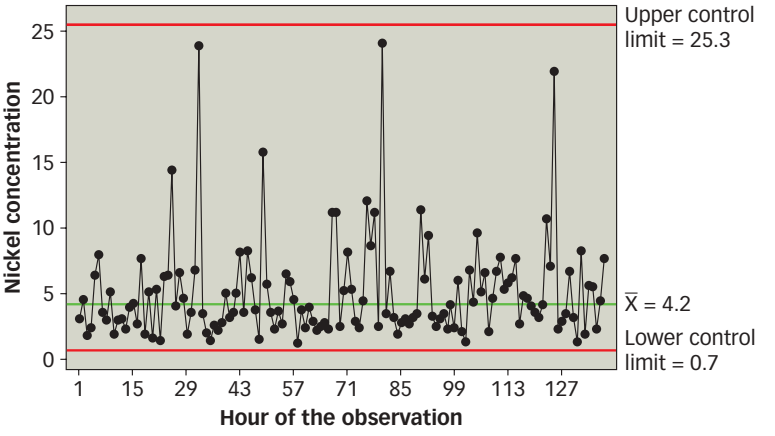
Note that the capability output matches the calculation from the most recent equation above. So the calculation of C_{pk} for non-normal data is straightforward if you are able to calculate the percentiles of the appropriate distribution. These percentiles can easily be determined from the appropriate probability plot of the data generated by standard statistical software.

Bottom line

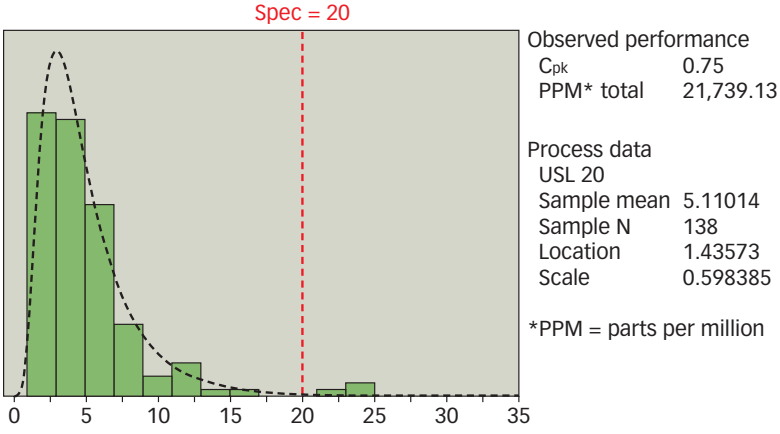
Many key quality characteristics follow distributions that are non-normal. In the past, demonstrating stability and capability required the assumption of normally distributed data. However, if data do not follow the normal distribution, the results generated under this assumption could be grossly incorrect.

Whether you decide to transform your data to follow the normal distribution or identify an appropriate non-normal distribution model, calculations illustrated in this article can be used to verify process control and calculate process capability for non-normal quality characteristics. QP

Individuals control chart of nickel concentration / FIGURE 5



Process capability of nickel concentration / FIGURE 6



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ISO-lating

WHEN PHYSICIANS' CLINIC of Iowa (PCI) and the U.S. Department of State Medical Services (MED) were searching for a way to better manage their organizations, both turned to ISO 9001:2000 in the hope that the standard could organize their practices and help them improve service to patients.

PCI is a multispecialty group practice with five locations, all of which are in Cedar Rapids, IA, while MED provides family practice care in almost every country in the world. These healthcare organizations are extremely different when it comes to size and scope, but colleagues from the two groups have found common ground through the ASQ Healthcare Division, and they did again when discussing their experiences implementing ISO 9001.

When MED was in the midst of its effort, a representative from PCI visited Washington, D.C., to offer advice in the hopes the government group would be able to avoid some of the pitfalls inherent in the process. Later, individuals from each organization discussed the similar successes and challenges they met on their respective journeys. Their collective experience shows how healthcare organizations of any size can benefit from this approach.

In 50 Words Or Less

- Looking for better ways to structure their organizations and improve service, two healthcare groups turned to ISO 9001:2000.
- The standard provided requirements that helped them meet their goals by establishing a quality management system.
- By following the standard, the organizations improved efficiency and their bottom lines.

the PROBLEM

In need of **management systems,** healthcare organizations **turn to ISO 9001:2000**

by Robert Burney, James Levett and Paula Dolan

Join the establishment

For PCI, the primary motivation for establishing a management system was to combine its diverse specialty practices into a single organization. For MED, it was the realization that simply "hiring good people" would not ensure good care in a geographically diverse environment.

Both organizations needed to establish common goals, consistent practices, control of documents and metrics for continuous improvement—all of which are required under ISO 9001.

For PCI, the standard provided the discipline to create a cohesive entity with common goals and a shared vision. For MED, ISO 9001 was flexible enough to adapt to its unique practice environment and provided a global, external evaluation system.

Healthcare is a highly regulated industry, and the standard calls for an organization to meet "statutory and regulatory requirements."[1] This includes mandatory requirements, such as those put forth by the Occupational Safety and Health Administration, as well as elective requirements from accreditation bodies, such as the Joint Commission on Accreditation of Healthcare Organizations.

It was determined that a quality management system (QMS) established under ISO 9001 would help both organizations meet all types of regulatory requirements. For example, the MED laboratory was better able to respond to a surprise audit by the College of American Pathologists (CAP) because MED had established good document control procedures and, as the CAP auditor noted, "calibration of monitoring and measuring devices."

For both organizations, the "certificate on the wall" wasn't the ultimate goal. The creation of an effective QMS that would result in improved organizational performance was the No. 1 benefit from the perspective of senior management.

Implementing a solution

For MED, the initial scope of the ISO 9001 project was limited to the office in Washington, D.C., where the group provides clearance exams, medical evacuations, logistics, quality control and oversight of overseas health units.

The $160,000 budgeted for the project was spent on more than 1,000 hours of training and consulting. Multiyear funding for the project's budget was part of the initial management commitment and was requested to help avoid the vagaries of annual budgets in a government bureaucracy. Customer service was a new concept to a government agency, and several training sessions were held on that subject. PCI's budget of $108,000 was spent in a similar fashion—that is, largely on training and consulting.

Compared to MED, the PCI group consisted of more physicians (50 vs. 25) but about the same number of staff (200). Both groups used an outside consultant, and both relied on internal quality improvement staff to handle the writing and logistics of implementing the standard (two staff personnel at MED and one at PCI). Both had a commitment from senior management—a key factor for success. Both organizations held meetings with employees individually, in small groups and in large groups to promote understanding of the standard and how it applied in the employees' work areas.

In addition to the direct monetary costs, there were time costs for instituting a new management system. PCI estimated that time at 2,345 hours over 2.5 years. MED did not record time, but it had two individuals who spent most of their time for two years on the project. In both cases, there was a serious commitment of time and money.

Both organizations visited local businesses that were registered to ISO 9001. Although useful, implementation strategies differed, and not all techniques were transferable. Still, it was helpful to see actual documents and the overall organization of the QMSs at outside businesses.

In the end, however, implementation depends on leadership style and the nature of the organization. For example, PCI created a physician quality council and a data collection committee. MED used an existing senior management group, and the quality improvement section received all data. PCI held management review sessions every three to six months. MED held one every month during the last five months of the project.

For both organizations, activities intensified in the final six months prior to the registration audit, with numerous practice audits conducted by internal and external auditors.

Fighting pushback

Initially, the prevailing attitudes at MED fell into two camps: "If I wait long enough, this will pass" and "This doesn't affect me." There was also a general attitude of "This is extra work I don't have time for." A series of

Success was **not a lightning bolt.** Improvements in process were **gradual and progressive.**

town-hall meetings by the medical director helped dispel the feeling that the project would go away in time, but a few one-on-one discussions were also needed.

Another helpful tactic was frequent internal audits and monthly management review meetings. A consultant helped with the audits, which also provided additional training for internal auditors. At the initial management review meetings, inadequate preparation was immediately obvious to senior management, but progressive improvement was evident at the meetings that followed.

MED discovered that persistence pays. When someone finally gets serious about the program, it's necessary to be there to provide help and encouragement. There is, however, a balance between doing the task for someone and helping them do it for themselves.

Top-down edicts generally didn't work or resulted in pro-forma compliance. Some reluctant participants eventually got on board as charts and graphs revealed interesting and useful information.

For example, MED encouraged staff to track time as a data element. Results were plotted as a run chart using the scatter plot function in Excel. With this technique, every case is a dot on the chart, and each dot is linked to a corresponding case. Outliers can thus be identified and investigated. For one outlier in the laboratory specimen processing chart, for example, the cause turned out to be a data-entry error.

Success was not a lightning bolt. Improvements in processes were gradual and progressive, rather than sudden and dramatic. Success with the ISO 9001 registration process was easy to measure thanks to compliance-related data, such as time to respond to internal audit findings. Success could also be seen in the greater awareness of organizationwide objectives.

At PCI, the ISO 9001 QMS was presented to physicians as a system that would support their practices, improve efficiency and prepare them for future quality initiatives, such as pay for performance.

Stand to benefit

PCI realized significant financial savings in accounts receivable, workers' compensation and contracted reimbursements. The gains were the result of a careful examination of the processes and a focus on improvement.

In a survey at the end of the registration audit, MED employees cited document control as a major gain, particularly the ability to find documents easily. Many of the organization's metrics focus on time, and processes happen faster now because MED is able to identify the steps in a process that are the most time-consuming and direct improvement efforts there.

For example, upon initial measurement, the time it took to pay vouchers for healthcare expenses of employees varied from a few days to many weeks. A goal was set to respond to the client within two days when initial information was needed and to pay the completed voucher within two days. Within 30 days of revising the process in this way, all vouchers were processed within the specified times.

The MED exam clinic initially measured the time to complete a physical exam for each provider but soon realized it was only one step in a larger process of obtaining a clearance for overseas travel. Now, the clock starts when the employee calls to schedule an exam and ends when the clearance has been issued. This has enabled MED to focus on delays in the overall process that were previously invisible. The number of exams pending for other studies decreased from 88 to 22 over the ensuing eight months.

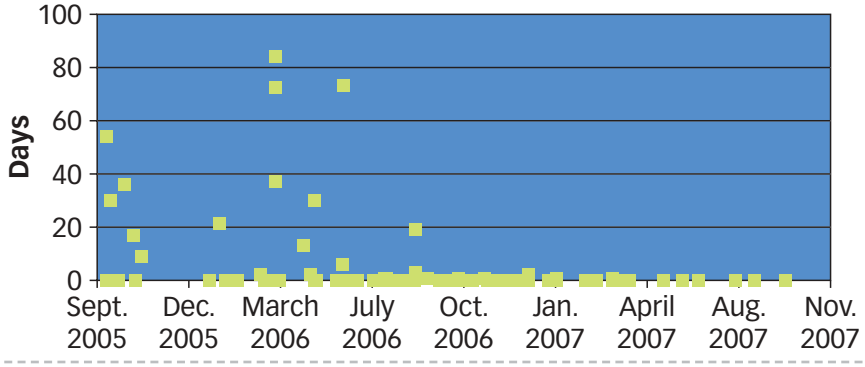
Another area that required attention was the process of receiving medical clearance to serve overseas or to transfer to a new position overseas. An individual must meet rigorous standards to qualify for medical clearance, which is based on MED's review of each candidate's medical history and a physical examination.

The section of MED that handles the more complicated clearances has always experienced a heavy workload in the spring and summer, corresponding to the summer employee transfer season. Now, the department sends out reminders in the employee's

STANDARD RESPONSE

Share your experiences with ISO 9001 implementation—the challenges, the success stories—by logging on to www.qualityprogress.com and using the comment feature on this article's page.

Drug Enforcement Agency registration before and after ISO 9001:2000 / FIGURE 1



birthday month to suggest obtaining the needed clearance in advance of the busy season to avoid delays.

Previously, the clearance process took 145 days to complete. Now, all clearance requests are completed within 10 days, and complaints from patients about the process have disappeared.

Improvement was also seen in the MED quality improvement section that obtains and renews Drug Enforcement Administration registration for providers. The group had never looked at the time required to accomplish the task but did so in May 2006 as part of the preparation for ISO registration. When initial measurements indicated the process could take months to complete, it was streamlined to occur reliably within 48 hours (see Figure 1). This was a dramatic example of iterative process improvement: The more MED looked at the process, the more opportunities for improvement it found.

When pressed by senior management about financial gains, most in MED pointed to improved efficiency in processes. This benefits customers, as well as employees, who don't spend as much time doing the work. As a result, there is greater surge capacity for the busy season. This is difficult to quantify, and the gains are shared among many people.

It has been argued that many of the efficiency gains could have occurred without a formal ISO 9001 process. This is true, but the fact remains they weren't done before. Many of the processes had been performed by the same people for years. ISO 9001 provided the stimulus to improve and the discipline to measure these processes.

Tough act to follow

It is worth emphasizing that ISO 9001 registration is not a trophy to be put on a shelf. Any certification or accreditation effort should be viewed as an improvement tool and not as an end in and of itself.

No organization exists to achieve ISO 9001 registration. That is not the goal. The process provides the discipline and structure to help achieve the organization's goals. The registration certificate is documentation that there is a management system in place.

PCI successfully maintained its momentum through a second registration audit. MED continued with internal audits the month after registration and a management review three months later. It also plans to extend its scope to include 180 overseas health units.

Both organizations believe ISO 9001 is a management system that is applicable to any healthcare setting, regardless of any other requirements that may apply. Whether an organization is in the private healthcare sector, such as PCI, or in the government sector, such as MED, everyone faces increasing financial pressures in the short term. ISO 9001 provides the tools to provide better care at lower cost. QP

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NOTE

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Contacts

Project improves member call rate, nets **$3.3 million** in savings

by Susan E. Daniels, editor at large

In 50 Words Or Less

- A process improvement team used lean Six Sigma tools to improve member contact rates at a healthcare support company.
- The contact rate went up 65%, improving member outcomes and return on investment.
- The effort earned the team a silver award in ASQ's International Team Excellence competition.

that Count

A TEAM DEDICATED to improving member contact rates at Healthways pulled just about everything from its lean Six Sigma toolbox for the project. For its efforts, the team earned a silver award in ASQ's International Team Excellence Award competition at the World Conference on Quality and Improvement held last May in Houston.

The list of tools included house of quality, project charter, supplier, inputs, process, outputs and customers (SIPOC) analysis, measurement system analysis, stability analysis, normality tests, muda walk, process capability test, fishbone diagram, benchmarking, brainstorming, the five whys, process mapping, process assessments, capability analysis and t-tests.

Based in Nashville, TN, Healthways provides programs to health plans, employers and healthcare providers to improve patients' health, enhance the care experience and reduce the cost of care.

TELEPHONE WORKERS at Healthways typically are healthcare professionals.

Healthways' contractual requirements typically focus on its ability to decrease healthcare spending for members, while improving quality of life. Its programs cover areas such as smoking cessation, nutrition, fitness, lifestyle management, health risk assessments and disease management.

With a vast amount of data available to measure overall performance, Healthways already knew member satisfaction in the area of member contacts was an opportunity for improvement.

To assist in project selection, the team used a method that draws on lean Six Sigma tools and its five-phase define, measure, analyze, improve and control method as a systematic approach to process improvement.

House of quality tool

In the define phase, the team used the house of quality tool to obtain insight into the voice of the customer (see Figure 1). Among critical-to-quality customer requirements, telephone interventions were identified as being the most important.

The team was confident that a project focused on telephone interventions directly supported corporate strategic objectives, specifically the ability to "Deliver on customer promises, and assure scaled delivery."

A drilling down to key inputs of the telephone process revealed the member contact rate—the effectiveness of a call—as the most important aspect of telephone interventions. Key stakeholders agreed Healthways could improve its member contact rate while supporting the company's business model and objectives.

The project was submitted to the quality committee for final approval. This committee ensures representation across the entire organization, using an impact and effort project scoring system that helps screen and select the projects that are most closely aligned with company strategies and goals.

The committee approved the project, and a core leadership team of stakeholders, suppliers and customers was assembled to ensure alignment and buy-in for improvement within Healthways.

Project charter tool

The team used a project charter tool to clearly define the scope and improvement opportunity for the project. The success metrics were established as clinician performance, clinician availability and call quality.

At Healthways, the word clinician is used to describe telephone workers who are typically registered nurses, but they also can be respiratory therapists, registered dieticians or licensed practical nurses. According to Mike Davis, vice president of quality for Healthways, they routinely interact with members and use evidence-based guidelines to provide health information and support designed to promote health behaviors.

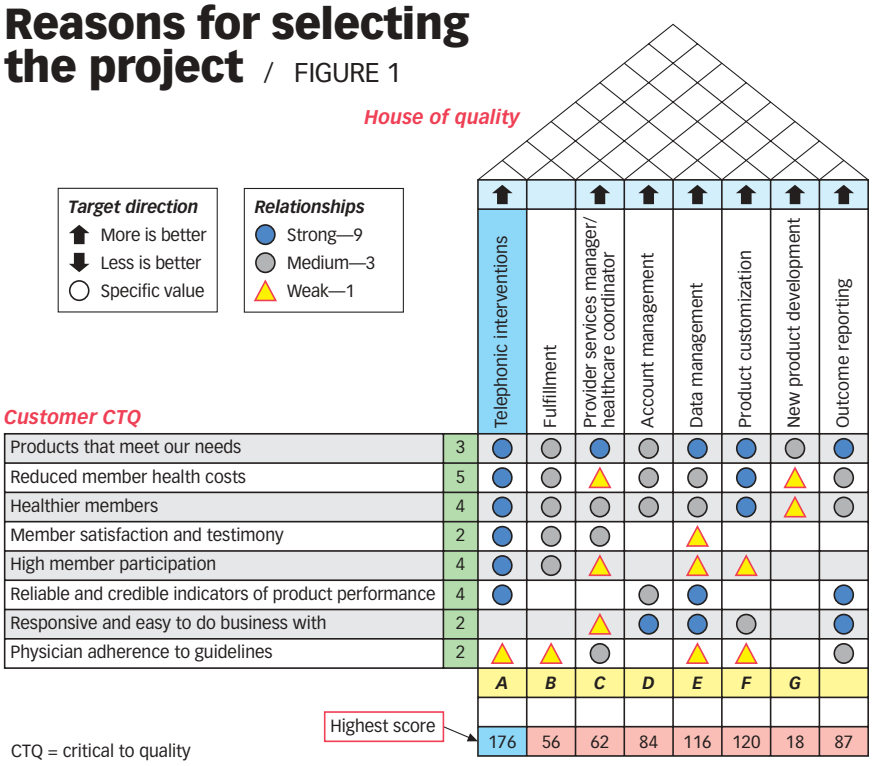
The two anticipated impacts were defined as increased member contacts that decrease healthcare spending for Healthways' member population and an estimated cost avoidance of $3 million related to improved efficiency of resources.

The team's target compared with the company's standard was 100% or better, but baseline data revealed current performance of key metrics at:

- Clinician performance: 60% of standard.
- Clinician availability: 97% of standard.
- Call quality: 84% of standard.

The team then conducted a high-level SIPOC analysis to identify the potential key internal and external stakeholders and to

Reasons for selecting the project / FIGURE 1



validate the process scope.

After assessing each potential stakeholder for level of involvement in each of the major process steps, the team identified types of potential stakeholder impacts, including strategic alignment, colleague morale, customer satisfaction and cost of execution. Stakeholder analysis then identified the project impact, change position and influence strategy on each key stakeholder.

Root cause analysis

To analyze the root causes of the current situation, the team used a variety of lean Six Sigma methods and tools: measurement system and stability analyses, normality test and *muda* (waste) walk.

The team's *muda* walk with its clinician focus groups identified a variety of wastes, including excessive documentation within member records.

To validate the accuracy of the reporting system, the team completed its measurement system analysis and compared data from the reporting application to actual observed telephone interaction (see Figure 2).

Stability analysis determined the mean and variation were stable and allowed the team to move forward in its analysis and process improvement initiatives. The team performed a normality test on the rate of calls per clinician per hour and verified the data had a normal distribution. This allowed the team to use statistical analysis tools designed for normal distributions.

Many stakeholders, each bringing a unique perspective, helped identify potential root causes. This set the stage for performing an overall process effectiveness test and determining that the biggest impact on improving the member contact rate could be made by focusing on the calls per clinician per hour.

Taking a deeper dive to understand the extent of the opportunity, the team performed a process capability test on its baseline data, comparing current performance with the desired standard. This analysis revealed only 7.7% of clinicians exceeded Healthways' standard expectation and that the current process was not capable of producing the member contact rate required to meet internal standard or customer expectations.

The team used a fishbone diagram to identify key inputs to the success metric of calls per clinician per hour, which included:

- Availability.
- Talk time.
- Time to end the call.
- Unsuccessful call management.

To validate its final inputs and contributing factors, the team went back to the house of quality tool to prioritize improvement initiatives. The significant contributors to productivity were clear performance expectations and visibility of data results using the right tools. Again, the team validated its findings with key stakeholders to see whether its list of contributors to productivity agreed with stakeholder needs. All stakeholders agreed the team was on target.

Potential solutions

To identify potential solutions, the team:

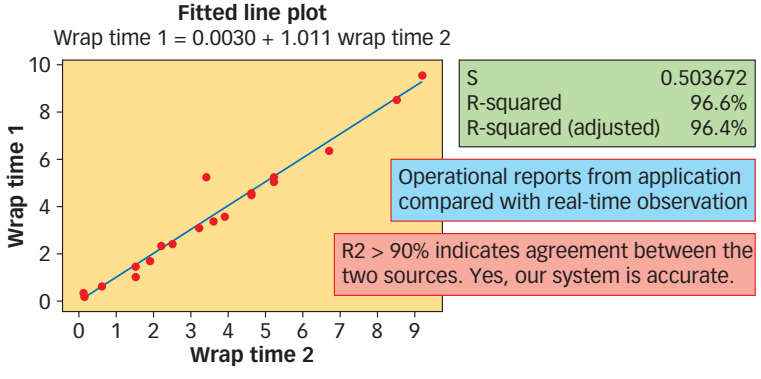
- Benchmarked other successful internal productivity improvement projects and interviewed involved team members to identify best practices and lessons learned.
- Conducted interview and brainstorming sessions with stakeholders to gain buy-in and identify potential improvement ideas.
- Took a five-whys approach to help identify root causes and provide insight into actions for improvement.
- Performed site visits to gain insight into other productivity initiatives across Healthways.

One identified root cause was related to ineffective computer skills during calls. This information led to the creation of an improvement initiative.

To select the final solutions, the team's criteria looked at impact on success metrics, ease of execution, impact on clinician satisfaction, likelihood of success and impact on corporate strategic objectives. Each metric was given a rank of high, medium or low.

The solutions with the highest scores were selected

Analysis of data to identify potential root causes / FIGURE 2



and included process guidelines, supervisor support tools and communication tools. The team enhanced and added details to its final solutions using methods such as:

- Process mapping to identify specific process guidelines that were needed.
- Process assessments to identify specific areas of need related to training, rewards and recognition, and reporting.
- A *muda* walk to help with specifics related to communication and supervisor support tools.

A capability analysis verified that the implemented solutions improved key process metrics. For the performance metric, 50.8% of clinicians exceeded Healthways' standard, compared with 7.7% at the beginning of the project.

Because the performance metric standard is a median of individual clinician performance, 50.8% equated to achievement of this standard. In addition, the two-sample t-tests supported that there was a statistically significant difference between the baseline and results for clinician performance and those following the improvement effort. The team verified this by a p-value equal to 0.0.

Stakeholder involvement in the final solution selection was based on subject matter expertise. Clinicians, for example, served as the subject matter experts for the clinician satisfaction criteria.

The process excellence team and quality committee provided input related to three key scoring criteria: ease of execution, impact on the project's success metrics and impact of strategic corporate objectives.

The team then defined specific improvement strategies and final solutions, including:

- Process guidelines.
- Supervisor support tools.
- Communication tools.
- Reporting templates.

Process guidelines, for example, included suggested

JUST THE START OF THE JOURNEY

I was honored to be the champion of the cross-functional member contact rate team from Healthways that received the silver award in ASQ's International Team Excellence competition.

The team's successful journey used the Healthways to Excellence improvement method, which includes lean Six Sigma tools, as part of a systematic approach to process improvement.

The majority of Healthways' services are delivered by telephone. Our data showed that in the area of member contacts, we had an opportunity to improve. The team needed to identify creative ways to do so to meet the needs of our customers and members.

A key success factor for this project was involving and receiving input from a wide variety of stakeholders including:

- Clinicians.
- Account managers.
- Executives.
- Customers.
- Call center management.

We benchmarked other internal improvements projects and interviewed team members to identify best practices and lessons learned. Without this support, many improvement ideas would not have been identified or implemented.

MEMBERS OF the Healthways team hold the trophy they won in ASQ's International Team Excellence Award competition are (from left) Peter Kapolas, Wendy Faust, Mike Davis and Mike McMillan.

In addition, the team studied operational data and conducted root cause analysis to develop a list of potential solutions. This allowed us to focus on factors that influenced our success metrics and pointed us to potential interventions to address these opportunities.

The project's success was outstanding and set the stage for a companywide rollout of these improvements across all of our care enhancement centers.

Preparing for and winning the Silver Award at the 2008 ASQ International Team Excellence Competition was a tremendous learning experience for all involved.

It brought great visibility to the project internally at Healthways and proved to us all that what we are doing in the area of quality and process improvement can compete against what anyone else is doing anywhere in the world.

At Healthways, our goal is to make the world a healthier place, one person at a time. The type of work done by the contact rate team is an important piece in making that a reality.

We are extremely proud of this accomplishment and look forward to competing again at this year's team competition during ASQ's World Conference on Quality and Improvement, May 18-20, in Minneapolis.

Mike Davis
Vice president, quality and process improvement
Healthways

call flows for specific call types and guidelines for the efficient use of the computer system.

The supervisor support tool is an example of a final solution (see Table 1) that provided close interactions between direct supervisors and their clinicians. Supervisors provided one-on-one coaching and call flow training over a specific time period.

Stakeholder team members validated the final solutions by assessing the impact of each solution on the project's success metrics, which covered tangible and intangible benefits.

Final solution and solution validation / TABLE 1

Final solutions	Expected benefits		
	Performance	Availability	Quality indicators
Process guidelines	X		X
Supervisor support tools	X	X	X
Communication tools	X	X	X
Reporting templates	X	X	X
Rewards and recognition programs	X		X
Training tools and information	X		X
Dialer strategy	X	X	

The team achieved nearly all project success metrics. Median calls per clinician per hour improved from 60% to more than 103% of the standard. In addition, Healthways saw an improvement in clinician availability to 98% of the standard. The team achieved its desired outcomes in terms of all four quality indicators, going from 84% of the standard to 100%.

In addition to achieving the project success metrics, the team realized the overall project goals, specifically:

- A 65% increase in successful member contacts within the project call center, with $3.3 million in cost avoidance.
- An increase from 49.2% to 88.3% in the overall process effectiveness.
- Call center quality improvement on all four major indicators.
- A strong correlation between the increase in call volume and a decrease in member hospitalizations and emergency room visits.

The project also resulted in the creation of new key processes, including streamlined standard call flows, transformation of supervisors to coaches and use of standard reporting templates and analysis processes.

Lessons learned

The Healthways team made procedure, system and other changes to implement the solution and sustain the results, learning that:

- Use of data and reports is essential.
- Documentation efficiency remains a challenge.
- Change is difficult for many, requiring the why to frequently be reviewed.
- Quality and quantity must be balanced to ensure positive impact on outcomes.
- Clinician buy-in is a key to success.
- Coaching and persistence are the only ways to sustain success.

The team's previous measurement system analysis confirmed that its reporting application was an accurate source for its key performance, availability and call-quality data. The data were tracked using control charts and bar graphs over weekly and monthly time frames.

A detailed response plan to ensure a timely correction of any process variance is an important element of the control plan. This plan uses standard reporting metrics to address results outside expectation and requires a drill-down to find root causes when targets weren't met. Action plans are then created to address any variances.

The tangible results for the project were a 67% increase in median calls per clinician hour, an improvement in clinician availability to 98% of the Healthways standard, and improvement or maintenance of all call-quality indicators. Research showed strong correlation between increased member contacts and improved member outcomes and return on investment.

Intangible results included a significant improvement in colleague opinion survey results, achievement of a lower employee turnover rate compared to previous years and presentation of clinician metrics in a real-time format that allowed them to see how they were performing.

Importantly, the initiative set the stage for future employee-led improvement projects at Healthways. QP

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For information on ASQ's International Team Excellence Award, go to http://wcqi.asq.org/team-competition/participants.html.

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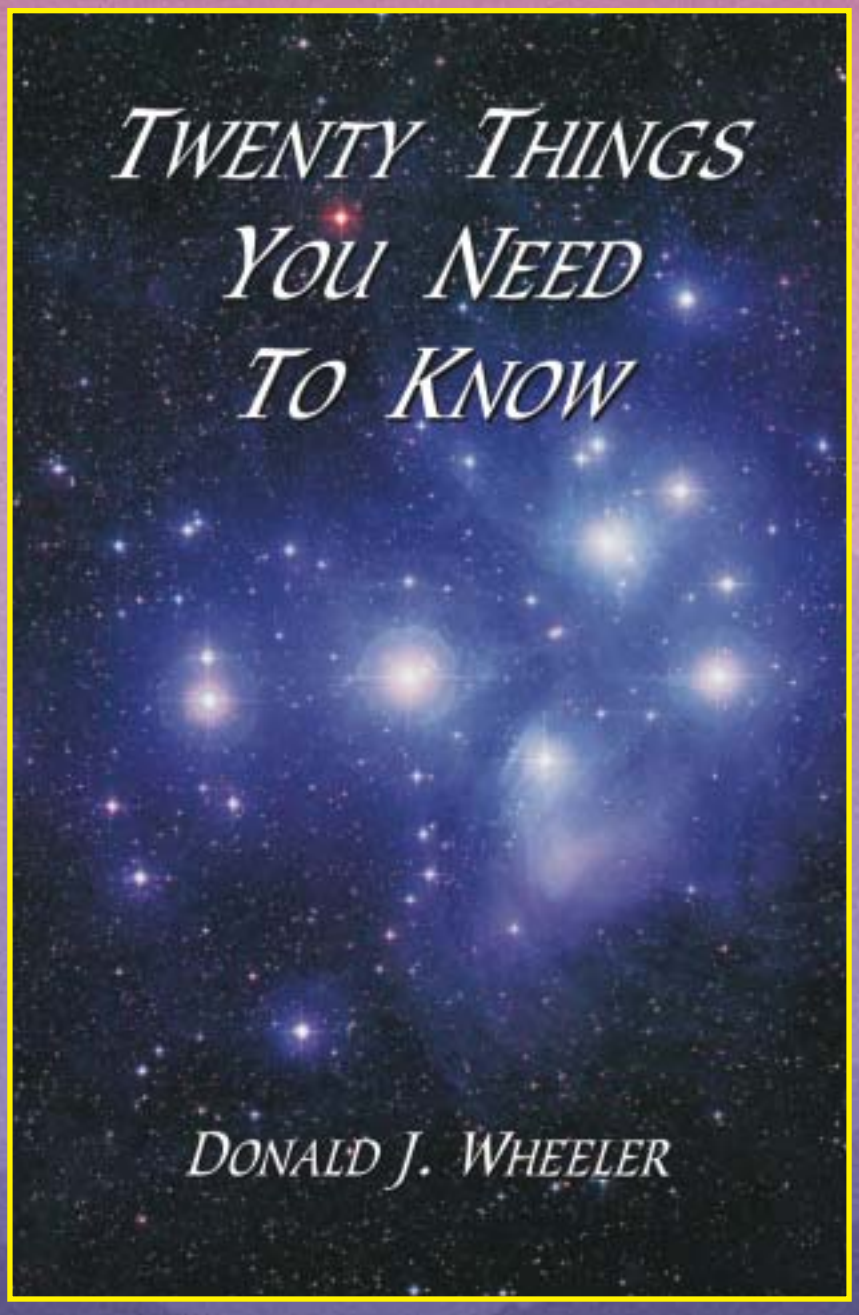

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From Class to Career

Course on TQL changes a Navy lieutenant's future

"STAUFFER, ON Monday morning, you will either be in that total quality leadership (TQL) class or in front of the captain, explaining why you were not there!"

With these words, my Navy division officer inadvertently put my life on a different course.

I had been involved in quality before. I worked at Ford for several years in the old, low-quality days of the 1970s. I actually drove a Volkswagen and a Toyota during that time. There, I watched a foreman follow an inspector and pull reject tags from transmissions that hadn't passed the stay-in-park test, because he "needed the numbers."

I took part in a recall of more than 100,000 Bronco transmissions because the plant industrial engineer (an English major with a two-year associate degree who was married to the plant manager's daughter) had signed an engineering waiver when we ran out of valve body filter screens.

Introduction to TQL

In the Navy, because I cared about how well things were done and how well they worked, I ended up as a quality auditor for a number of major projects. When I heard we would be doing TQL and that this was how auto manufacturers were improving quality, I was not impressed. And, when I heard from my Ford buddies that TQL was "Japanese management," I was even less impressed. So, the first few times my division officer scheduled the introductory fundamentals of a TQL seminar, I found excuses to be elsewhere. This time, though, she wasn't letting me off the hook. I called a trusted friend, expecting sympathy, but he said, "It's not what you think it is. Keep an open mind. I think you will like it."

The class didn't start well. There were videos of Ford executives and managers talking about quality problems at Ford and videos of some old bald guy railing about statistical control. Statistics? What could

statistics possibly have to do with anything? Then the instructors talked about systems, psychology, 14 points, driving out fear, reward systems and performance evaluations as harmful barriers. None of it made sense—until they began talking about variation.

The instructors said we didn't live in a mechanistic, deterministic world. This appealed to me because I had often felt that way and had spent most of my career fighting the feeling. Later, they brought out a container full of red and white beads, asking for volunteers to play a game. What followed literally changed my life.

Red bead experiment

W. Edwards Deming's red bead experiment had a profound effect on me.[1] That one exercise contained nuggets of new knowledge and offered answers to many leadership questions I had struggled with for years. Among them:

- Why couldn't we seem to make performance evaluation and ranking work?
- Why did internal competition always seem to fail or be harmful?
- Why was it impossible to actually do the impossible?

Suddenly, I wanted to know more about Deming, these management theories, systems, and even, incredibly, statistics.

The Navy offered numerous avenues to education. I took classes in statistical process control and basic statistics, and I signed up for 10 weeks of TQL training. I began putting together a plan to finish my bachelor's degree and went on to get a master's degree prior to retiring from the Navy.

I became a TQL coordinator, or director of quality, at a major overseas base, then went on to join the TQL Schoolhouse, a group of internal consultants for the entire Department of the Navy, where I worked as a lieutenant until I retired.

After retiring from the Navy, I joined a quality consulting group in Minneapolis, and now I have my own consulting practice.

I still conduct the red bead experiment in all my Six Sigma and statistical process control training and leadership development seminars, and I try to present it whenever I can at quality conferences. I've found that it provides a great foundation and is a conversation starter for any course in quality, statistics or leadership. QP

REFERENCE AND NOTE

1. W. Edwards Deming, red bead experiment. For more information about W. Edwards Deming's red bead experiment, visit www.asq.org/glossary/r.html.

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BY DILIP SHAH

In No Uncertain Terms

Find the meaning behind key words to get most out of guide

IN DECEMBER 2007, *ISO/IEC Guide 99:2007—International vocabulary of metrology—Basic and general concepts and associated terms* (VIM) was released. It replaces what is known in the metrology community as the second edition of the VIM, making it the equivalent to the third edition.

ISO/IEC Guide 99:2007 was developed by a joint committee that was comprised of representatives of: the International Bureau of Weights and Measures, the International Engineering Consortium, the International Organization for Standardization (ISO), the International Federation of Clinical Chemistry and Laboratory Medicine, the International Union of Pure and Applied Chemistry, the International Union of Pure and Applied Physics, the International Organization of Legal Metrology and the International Laboratory Accreditation Cooperation (ILAC).

It is worthwhile for those involved in the test and calibration business to obtain a copy of this guide.

Defining harmony

Because the guide harmonizes terms for many different industries, it is important to take a closer look at all the terms. In this column, I will examine measurement uncertainty and metrological (measurement) traceability. The notes after the definitions clarify several measurement scenarios for the user and provide guidance:[1]

1. Measurement uncertainty, uncertainty of measurement, uncertainty: Non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used.

Note 1: Measurement uncertainty includes components arising from systematic effects, such as components associated with corrections and the assigned quantity values of measurement standards, as well as the definitional uncertainty. Sometimes, estimated systematic effects are not corrected for. Instead, associated measurement uncertainty components are incorporated.

Note 2: The parameter may be, for example, a standard deviation called standard measurement uncertainty (or a specified multiple of it), or the half-width of an interval, having a stated coverage probability.

Note 3: Measurement uncertainty comprises, in general, many components. Some of these may be evaluated by type-A evaluation of measurement uncertainty from the statistical distribution of the quantity values from a series of measurements and can be characterized by standard deviations. The other components, which may be evaluated by type-B evaluation of measurement uncertainty, can also be characterized by standard deviations and evaluated from probability density functions based on experience or other information.

Note 4: In general, for a given set of information, it is understood the measurement uncertainty is associated with a stated quantity value attributed to the measurand. A modification of this value results in a modification of the associated uncertainty.

2. Metrological traceability: Property of a measurement result whereby the result can be related to a reference through a documented, unbroken chain of calibrations, each contributing to the measurement uncertainty.

Note 1: For this definition, a "reference" can be a definition of a measurement unit through its practical realization, or a measurement procedure that includes the measurement unit for a nonordinal quantity or a measurement standard.

Note 2: Metrological traceability requires an established calibration hierarchy.

Note 3: Specification of the reference must include the time at which the reference was used in establishing the calibration hierarchy, along with any other relevant metrological information about the reference, such as when the first calibration in the calibration hierarchy was performed.

Note 4: For measurements with more than one input quantity in the measurement model, each of the input quantity values should be metrologically traceable, and the calibration hierarchy involved may form a branched structure or a network. The effort involved in establishing metrological trace-

Traceability hierarchy and uncertainty / TABLE 1

Metrological traceability hierarchy	Combined uncertainty	Expanded uncertainty U (k = 2)
International Bureau of Weights and Measures	0.0025	0.005
National Measurement Laboratory	0.01	0.014
Reference metrology laboratory	0.05	0.06
Working metrology laboratory	0.2	0.23
General calibration	0.5	0.68
Process measurement	1	1.69

ability for each input quantity value should be commensurate with its relative contribution to the measurement result.

Note 5: Metrological traceability of a measurement result does not ensure the measurement uncertainty is adequate for a given purpose or that there is an absence of mistakes.

Note 6: A comparison between two measurement standards may be viewed as a calibration if the comparison is used to check and, if necessary, correct the quantity value and measurement uncertainty attributed to one of the measurement standards.

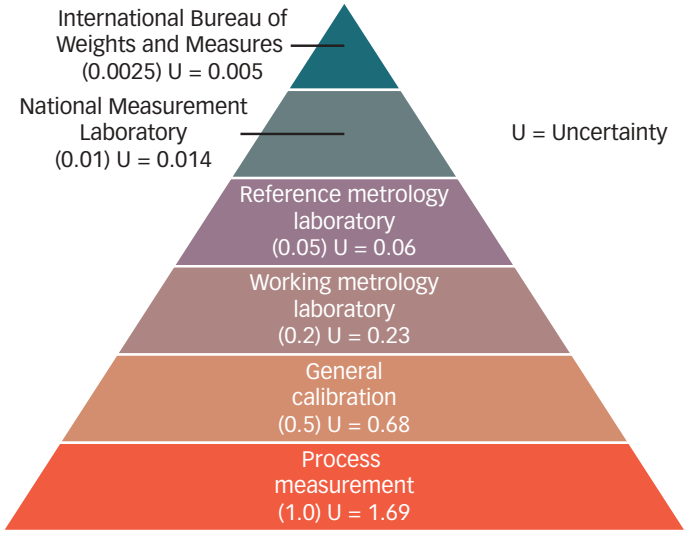
Note 7: ILAC considers the elements for confirming metrological traceability to be an unbroken metrological traceability chain to an international measurement standard or a national measurement standard, a documented measurement uncertainty, a documented measurement procedure, an accredited technical competence, metrological traceability to the International System of Units and calibration intervals.[2]

Note 8: The abbreviated term "traceability" is sometimes used to mean metrological traceability, as well as other concepts, such as sample traceability, document traceability, instrument traceability or material traceability, where the history (trace) of an item is meant. Therefore, the full term, metrological traceability, is preferred if there is any risk of confusion.

Perfect pair

These two definitions are important because of how intertwined they are. Without documented measurement uncertainty for a measurement parameter, we do not have metrological traceability. To estimate measurement uncertainty, documented calibration and measurement uncertainty data is required from the laboratories that calibrated the equipment to fulfill the "unbroken chain of calibrations" requirement.

Pyramid of uncertainty hierarchy / FIGURE 1



Laboratories claiming metrological traceability must have documented, unbroken chains of calibrations, each contributing to the measurement uncertainty. If calibration or test laboratories have doubts about having documented measurement uncertainty budgets, these definitions remove those doubts. For verifying metrological (measurement) traceability, you must have measurement uncertainty budgets.

We can illustrate these two definitions graphically in Figure 1 and Table 1. In Figure 1, each successive level of metrological hierarchy's combined measurement uncertainty includes the previous level measurement uncertainty. In Table 1, the measurement uncertainties are combined using the root sum square method, as outlined in the guide to uncertainty of measurement.[3]

Laboratories accredited to ISO 17025[4] must have documented measurement uncertainty budgets for each parameter under their scope of accreditation. Because ISO 17025-accredited laboratories are assessed by third-party accrediting bodies, their claims of metrological traceability are thoroughly verified and validated.

Unaccredited laboratories need to have measurement uncertainty budgets, along with documentation available to prove claims of metrological traceability, along with measurement uncertainty budgets. Traditionally, estimating and calculating measurement uncertainty is one of the more difficult tasks for laboratories preparing for ISO 17025 accreditation.

Many tools and techniques exist for estimating measurement uncertainty. A future column will outline a generic process to estimate, calculate and develop a measurement uncertainty budget. QP

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How to Get Hired

One hiring manager offers insight, advice to job seekers

AS AN EMPLOYEE, I have tons of insight on what the job hunt looks like from the seeker's point of view. This comes from my own and others' experiences. But I've often wondered what the process is like for the person on the other side of the hiring desk.

When a temporary office relocation put my desk next to a recruiter for a few months, I had a chance to find out. My work neighbor recruited and hired many IT projects in the department I worked in at the time. He talked with me about his experiences from the hiring manager's perspective.

JC: What tells you it's time to hire new people?

IT: I use a combination of short and long-term views. I have predictable seasonal demands that call for targeted additions to staff. I'm responsible for keeping up with the progress of all our projects. The required mix of skills changes with each stage of work. When a particular stage is on the horizon, I try to hire in preparation for it. Occasionally, we land work that calls for skills we do not have in-house, so I go to the market to satisfy those needs.

From a longer-term perspective, I try to find the optimum balance of new and experienced people. As people advance in their current assignments and move on to more demanding ones, I sometimes hire to handle the backfill created when they move up.

Turnover is a major concern in my industry. While we try to keep our people happy, they do sometimes retire or leave for other reasons. It is not unusual for me at any given time to be seeking very experienced people to compensate for attrition at the high end of the learning curve.

Internet leads

JC: How do you find new people?

IT: Particularly in my industry, the internet has completely changed how we do things. Our company website is the primary source for advertising and accepting applications. Some of the general job search websites pick up our listings as part of their routine sweeps of the internet.

We also use, to a lesser degree, newspaper ads, referrals from existing employees and contacts in our industry at other companies. On somewhat rarer occasions, I have been known to contact old college professors for referrals, especially when I am looking for something a new college graduate could fill.

> "Take the time to respond to the **specific wording and requirements** of the job listing."

We get periodic contacts from recruiters who scour our postings. If they send us a particularly strong candidate, we will consider him or her. If I had to guess, I'd say direct applications through our company's website are the source for half to two-thirds of our eventual placements.

Standout candidates

JC: What kinds of applicants stand out?

IT: I like people who take the time to respond to the specific wording and requirements of the listing. I guess about 10% to 15% of the applications are complete failures in that respect. I normally take that as a sign of the shotgun approach. Even recruiters are occasionally guilty, but far less frequently than individual applicants. If the applicant gives the impression my company doesn't deserve more than the shotgun approach, he or she shouldn't expect any special consideration from me.

JC: Are you flexible in how you review résumés?

IT: I have the benefit of the folks in HR

QUALITY CAREERS

At www.asq.org/careers, job seekers can post résumés, get career advice and explore career development opportunities, and employers can post jobs and search résumés.

who prescreen applications for me. So, almost all of the time what I see are the most promising candidates. We do not automatically rule out applications because they do not mention some predetermined set of keywords. The experience does not necessarily have to be a perfect match for what we are trying to fill, but the better the connection applicants make on their résumés, the better their chances of being hired.

JC: What's your opinion on mentioning salary?

IT: If the applicants insist on volunteering no information, they aren't doing themselves any favors. I have to at least make sure they are not completely outside the range I can offer for the position. I don't want to invest the effort a good hire requires only to find out I wasted my time as far as salary expectations are concerned. When it gets to the offer stage, we encourage the applicant to consider the whole salary and benefits package.

Upward mobility

JC: If you had to name one theme running through your selection criteria, what would it be?

IT: I would say promotability. We are most interested in people who can grow with our organization on a long-term basis.

JC: Do you have any suggestions for how to minimize negative surprises at the offer stage?

IT: Most of the negative surprises I can think of come from poor references. Applicants should make sure their references are current and able to address their qualifications for our job.

JC: Do you have any closing thoughts to offer job seekers?

IT: Don't be afraid to check out new opportunities in the marketplace even if you like your current job. Be careful about staying too long in your comfort zone and growing stale. Let the company see the real you during the interview. We can usually spot phonies, and they don't fit in well here.

Finally, don't accept an offer without getting reasonable answers to all your questions about duties and coworkers. Keep up to date on the industry so your training and skills are current. Strive to advance, but be flexible on the manner and timing. QP

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BY LYNNE B. HARE
AND KEITH EBERHARDT

Care and Feeding of Checkweighers

Statistics to help guard against release of underweight packages

MANY YEARS ago, during a tour of a production facility where packages of customer goods were being filled, a statistician colleague and I (Lynne Hare) stood transfixed by an end-of-line checkweigher. There was a red light on above a label that read, "Needs rezero." That didn't seem to bother anyone.

We watched as package after package progressed over the checkweigher's scale, some of them being kicked off into a bin by a pneumatic device. Then we weighed a large number of packages from the bin and found almost all of them were above the label-declared weight. Only a very few were actually below the label declaration by more than the law would allow.[1]

When no one else was around, my colleague announced he could do an excellent imitation of the checkweigher. Moving his head rapidly from side to side, he blinked his eyes repeatedly and said, "What was that? What was that? What was that?"

We laughed. It's easy to poke fun but more difficult to come up with something that is constructive—yet sufficiently simple—to use on a busy production floor.

If you start with questions that come immediately to mind, you might want to know what the checkweigher is targeted to reject, what the size of its zone of uncertainty is, and, given those things, what the chances are that a good package would be rejected and a bad package would escape detection.

Quantifying the uncertainty

Let's start with assessing the size of the zone of uncertainty, or the gray zone, as it is often called. It is common practice for operators or quality control specialists to run a package of known weight at machine speed several times over the checkweigher scale and record the resulting readings. A zone of target plus or minus 3 standard deviations of the resulting data might be used to provide an estimate of the size of the gray zone.

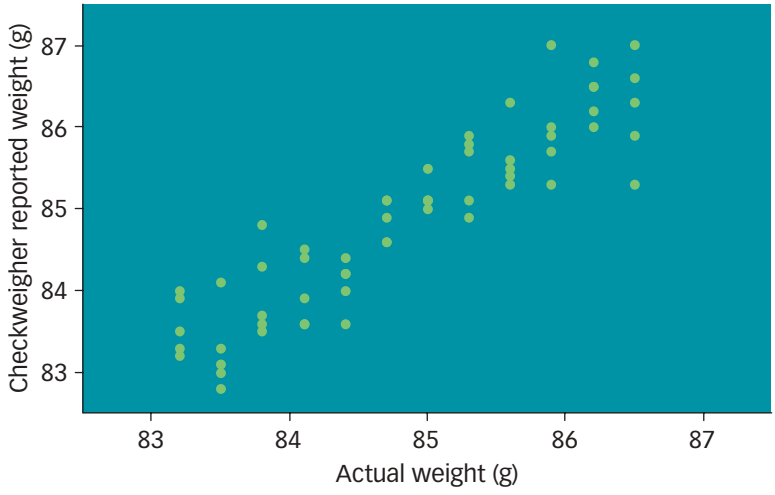
> "You can use multivariate statistics to learn **the probability that a package will be rejected,** given that its weight is acceptable."

That strategy gets you only part way there. We should be a bit more ambitious to ensure that the checkweigher's acuity is uniform over the weight range of expected performance and that the checkweigher reads accurately over that same range.

Here's a strategy that might help provide such assurances. Choose a range of weights likely to be experienced by the checkweigher. For example, one checkweigher study was designed to evaluate performance over weights ranging from 83.2 to 86.5 grams (g). The weight range in this case would be 3.3 g.

Next, divide the range by a convenient number to yield approximately 10 or more increments. Here, we use steps of 0.3 g to provide 12 weight increments of 83.2, 83.5, 83.8, … , 86.5 g. Then, artificially create 12 packages that weigh as close to these exact amounts as possible by using a static, calibrated analytical balance. Run these packages randomly over the checkweigher

Scatter diagram of checkweigher vs. actual weight / FIGURE 1



scale five times each, recording the stated weights and capturing the packages so you don't send tidy packages of birdshot, or whatever you have used to create the packages, out to your customers. Table 1 lists the data resulting from this exercise.

Next, of course, follow the first rule of data analysis: "Always, always, always, without exception, plot the data and look at the plot." Figure 1 is a scatter diagram of the raw data. At this point, you would make a rough visual assessment of the plot to determine whether the variation among checkweigher reported weights is the same among all the actual weights—that's "the acuity being the same over the weight range" part mentioned earlier. Then you would want to look at the plot to get some assurance the checkweigher-reported weights are roughly equal to the actual weights on average. That's the accuracy part mentioned earlier.

Of course, there are formal tests for these phenomena. To test for uniformity of variation among the five checkweigher readings of each of the 12 packages, we could use Bartlett's test. For these data, the test statistic is 9.92 and its probability is 0.537, clearly not small enough to persuade us that the standard deviations are different.

To ensure the checkweigher-reported values are the same within chance variation as the actual weights, we could look at the slope of the regression of those weights on the actual weights. For these data, the calculated slope is 0.978 and its standard error is 0.057. Because the calculated slope is less than one standard error away from the theoretical value of 1, we would say the slope does not differ significantly from that value. More formally, we could test the difference between the calculated slope and the theoretical value in light of the variation as a t-statistic:

$$t = \frac{b_1 - 10}{s_{b_1}} = \frac{0.978 - 1.0}{0.057} = -0.386$$

where b_1 is the estimated slope and s_{b1} is its standard error. The conclusion is the same: We cannot say the slope is different from 1.

Ideally, the regression line should have a zero intercept, and the formal test for that looks like the one for the slope. It turns out the calculated intercept for these data (1.914 with a standard error of 4.821) does not differ significantly from zero, but it should also be noted that our data are very far, in terms of multiples of variation, from weights of zero. So this test is a wild extrapolation (which doth taste of wormwood to statisticians).

Given that our checkweigher appears healthy from the perspectives of uniform acuity and a high degree of accuracy, we come back to the original objective of assessing the size of its zone of uncertainty, or gray zone. Pool the within-actual-weight standard deviations. A quick way to do that is to carry out an analysis of variance on the data using the actual weight as the source of variation. Take the square root of the residual mean square, and call it s_g. In this example, you should get $s_g = 0.442$. It has 48 degrees of freedom, more than enough to keep you out of too much hot water.

Checkweigher readings of packages of known weights / TABLE 1

Actual	Pass 1	Pass 2	Pass 3	Pass 4	Pass 5
83.2	84.0	83.2	83.3	83.9	83.5
83.5	83.1	83.0	83.3	84.1	82.8
83.8	83.6	84.8	84.3	83.7	83.5
84.1	83.6	83.6	83.9	84.5	84.4
84.4	84.4	84.2	83.6	84.0	84.2
84.7	85.1	84.9	84.6	84.6	85.1
85.0	85.0	85.5	85.1	85.1	85.1
85.3	85.1	85.9	84.9	85.7	85.8
85.6	85.6	86.3	85.4	85.3	85.5
85.9	85.9	86.0	85.3	87.0	85.7
86.2	86.5	86.8	86.5	86.0	86.2
86.5	85.9	86.3	85.3	87.0	86.6

Protecting against shipment of short-weight packages

What do you do with that? Well, suppose you wanted your checkweigher to prevent erratic weights from getting to the customer and getting your company in trouble. Further, suppose your label declaration is L grams. Look up the maximum allowable variation (MAV) corresponding to that label weight in *NIST Handbook 133*.[2] If you are willing to take only a α % chance that a package weighing at the label minus MAV would get to the customer, you would set the checkweigher reject point at X_c = Label – MAV + $t_\alpha(df)s_g$. Here, $t_\alpha(df)$ is the student's t-statistic that marks off α percentage of the distribution in the tail and has df degrees of freedom.

In our example, suppose the label declaration is L = 82 g. *NIST Handbook 133* shows a MAV of 7.2 g.[3] If we want only a 1% chance that a package weighing L – MAV = 74.8 grams will get out to the

STATISTICAL STUDIES

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customer, we should set the checkweigher at:

$$X_c = 82.0 - 7.2 + (2.407)(0.442)$$
$$= 75.864 \text{ grams}$$

Note that lighter packages will get to the customer even less often.

Protect against rejecting good packages

Your local, friendly plant manager is concerned about getting the product out the door. Production volume is one measure for which plant managers are rewarded. The manager's question will be, "How many good packages are being zapped by the checkweighers into the reject bin? They have to be reweighed manually, and that slows us down."

That question is not answered as easily as the question concerning the release of short-weight packages. To find the solution, you need to know the size of the checkweigher's gray zone, the checkweigher's setting and the MAV. But you also need to know the mean and the standard deviation of the package weights moving over the checkweighers. Given that information, you can use multivariate statistics to learn the probability that a package will be rejected, given that its weight is acceptable, for example, above the label minus MAV.

If you are not current in your multivariate statistics, you can rest assured that the larger the checkweigher's gray zone, the higher the percentage of good packages that will be incorrectly zapped. What do you do about that? Remember the red light above the label that says "Needs rezero"? Take it seriously and follow the manufacturer's instructions to rezero the checkweigher.

Or you can just stand there and say, "What was that?" QP

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3. Ibid.

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BY DALE K. GORDON

Risk and Quality Management

A holistic approach is necessary for organizational survival

THE MEDIA has made all of us aware of the global financial crisis caused by the assumption of risk by banks and speculators in stocks and commodities. Even ordinary people took on risk by buying homes in hot markets, hoping that they could quickly resell them and make a big profit.

What we have since learned is that many of these people, professionals and otherwise, did not understand or even consider the risks of the types of transactions or deals they were making. This caused significant losses for everyone.

In any organizational or business environment, we talk about risk all the time, with the understanding that we have to manage multiple aspects of risk every day. From an ownership and operational standpoint, as an organization gets bigger and more sophisticated, the one thing management learns to do is to manage risk.

Companies have always had to deal with different types of risk, be it financial, legal, or related to a product launch, merger or the threat of natural disasters. These risks are traditionally treated as silos:

- The CFO is responsible for understanding and making financial risk decisions.
- The IT department is responsible for the risk of losing data-processing capabilities.
- Legal counsel must understand and manage the company's legal issues.
- The quality department is tasked with the risk of shipping defective product.

Fragmentation in integration

This fragmented approach to risk is becoming more dangerous as companies with highly integrated processes and systems face risks that threaten their existence.

These risks come in the form of noncompliance with government regulations, information security threats, natural disasters, product liability and customer dissatisfaction resulting in loss of business.

It is important, now more than ever, for companies to develop and maintain a holistic risk management program that coordinates these silos because they all have the same overall goal: to protect the company and ensure its survival to the benefit of its stakeholders.[1]

It's time to identify **risk mitigation** as part of **QMS processes.**

The quality management system (QMS) of an organization exists as a framework for how the organization is going to ensure customer satisfaction through a set of operational requirements and quality management principles when the organization:

- Needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements.
- Aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.[2]

The word risk appeared nowhere in ISO 9001:2000. Yet the origin of quality, specifically quality control, was the application of statistical principles for managing risks (also known as probabilities) of delivering defective or nonconforming product to the customer (consumer risk).

There was a corollary risk of having too stringent a method of measurement and thus scrapping or wasting perfectly acceptable product that the customer would accept, thus potentially creating losses that would damage the organization's competitive position (producer risk).

It is only now, in the just-published ISO 9001:2008, that the word risk finally appears. The standard's introduction says that relative to the environment the organization has to operate in, which includes legal, regulatory and competitive forces, the adoption of a QMS should be a strategic decision of an organization.

The design and implementation of an organization's QMS is influenced by its organizational environment, changes in that environment and the risks associated with that environment.[3]

In adapting ISO 9001 to the industry-specific standard SAE AS9100, the aviation, space and defense industries always recognized the need to identify and manage risk as part of an acceptable, functioning QMS.

The word risk first appeared in AS9100 in terms of evaluating the risk of being able to deliver what the customer was asking for as part of reviewing require-

ments related to the product.

Many other sections of ISO 9001:2000 are all about managing and mitigating risks. They cover the following:

- Reviewing requirements.
- Establishing a robust design process.
- Looking at all aspects of customer use of the product.
- Management of the supply chain.
- Control of product or service operations.

Added to that list are the requirements for a nonconformance control process, feedback to management about risks uncovered in internal audits, and the corrective and preventive action processes that are supposed to be built into the system.

In fact, the entire standard could be considered a tool to mitigate the risk of poor customer satisfaction, with customer satisfaction considered essential for business continuation. But, we now don't really talk about risk in those terms.

Newest version of SAE AS9100

In the newest version of SAE AS9100, soon to be released as revision C, the use, importance and emphasis of risk is significantly enhanced.

Risk is used as an all-encompassing concept that can apply to all parts of the QMS and product life cycle. Risk is mentioned about 16 times and given its own definition: "An undesirable situation or circumstance that has both a likelihood of occurring and a potentially negative consequence."[4]

Some may argue that the products created and used by the aviation, space and defense industries have inherently greater risks than other types of products (think aircraft, spacecraft and weapon systems). I contend that any organization has to manage not only product risk to customers (from asbestos to ladders to toys) but also risks to the organization from likely events that could have negative consequences (think business disruption in a lean supply chain that could shut down a customer's operations).

The writers of the latest revision of the AS9100 standard not only identify risk as a concept but also identify risk management as an essential ingredient in the healthy functioning of the organization's QMS.

Clause 7.1 of the revised AS9100, which covers product realization and risk management requirements, includes establishing and implementing a process for managing risk that includes:

- Assignment of responsibilities for risk management.
- Definition of risk criteria (for example, likelihood, consequences and risk acceptance).
- Identification, assessment and communication of produce realization risks.
- Identification, implementation and management of actions to mitigate risks that exceed defined risk acceptance criteria.
- Acceptance of risks remaining after implementation of mitigating actions.[5]

Risk is not something that is treated lightly from an organizational standpoint. Organizations carry all sorts of insurance to mitigate risks to the business, such as liabilities from faulty products and faulty decisions by management. Organizations also carry insurance against the loss of physical assets of the organization and the loss of people.

What insurance are organizations carrying for scrap, rework, poor supplier performance or bad internal processes that delay shipments? How do organizations compensate for designs that are difficult to produce, machines with unacceptable variances, or new product or technology introductions with unknown variables? How do we compensate for the design and integration of complex technology and software so unintended consequences do not manifest in product failure or worse?

Customer dissatisfaction risk

Each and every risk in the preceding paragraph can and will lead to customer dissatisfaction, but it could also have dire effects on the organization's ability to continue as a viable concern.

In many articles about the current problems in financial markets, you will find repeated references to the fact that the personnel in those organizations did not understand or fully appreciate the risks associated with the kinds of investments or transactions they were making.

Many of these same organizations view their buying, selling, lending and financing as products, but they simply lacked or ignored the risk mitigation activities that should have taken place.

Many of these same organizations have fully functioning and certified QMS processes. Maybe it's about time we identified risk mitigation as part of our QMS processes.

Risk is not a bad thing or a dirty word. There is a lot of uncertainty in any endeavor that advances us. Risk is how we learn, innovate and open new frontiers and levels of understanding. There is no way we would have the societies and technology we have today without risk.

But let's be sure we understand what we are risking and whether we can afford to pay the price if the risk involved exceeds the potential benefit, or the ultimate outcome threatens a business's very existence. QP

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5. Ibid.

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QP TOOLBOX

Thickness measuring system ▶

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Call: 716-204-2388; visit: www.skyrayxrf.com.

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FKI Logistex's PL-950 Series hybrid in-line palletizer uses one or more robotic arms for pattern forming, making it suitable for handling small finished case sizes, multiple product formats and complex patterns. New patterns can be programmed from the Human Machine Interface, and it also gently handles products with minimal secondary packaging.

The PL-950 Series is available in two models, the PL-951 and the PL-952, each with the option of one or two robotic arms. The PL-951 features a single-layer accumulation zone for high-speed applications, while the PL-952 includes two layer accumulation zones.

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LMI Technologies' maestro allows engineers to design, install and start any machine vision solution, while reducing time, materials and costs by using two modules for all installations.

The P800 is the master controller that interfaces with the encoders and the input/output. It also delivers microsecond synchronization, power and safety. All timing, triggering, synchronization, sorting and reject activations are completed by this module.

The connecting piece to the maestro P800 is the C12 module. The C12 module powers and triggers any camera while providing synchronized, configurable, high-current pulses for light-emitting diodes or lasers.

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Microbial screening instrument

Celsis International has released RapiScreen, a rapid microbial screening instrument for dairy products. The screening test kit extends the Celsis Innovate platform to screen Ultra Heat Treated (UHT) and Extended Shelf Life (ESL) beverage products for microbial contamination.

RapiScreen is ideal for companies that produce beverage and dairy products. The kit works on everything from clear to pulpy juices and from broths to soups, with no filtering necessary.

Adenosine triphosphate bioluminescence is the industry standard for the rapid microbial screening of UHT and ESL beverage products.

Call: 312-636-5355; e-mail: jshields@outlookmarketinsrv.com.

Linear gauge sensor

Ono Sokki Technology has introduced the BS-112 miniature linear gauge sensor. The BS-112 can measure various dimensions, thickness, curvature, eccentricity, inner and outer diameter, displacement, height, depth, flatness, variation, run-out, roundness, distortion, deflection and position.

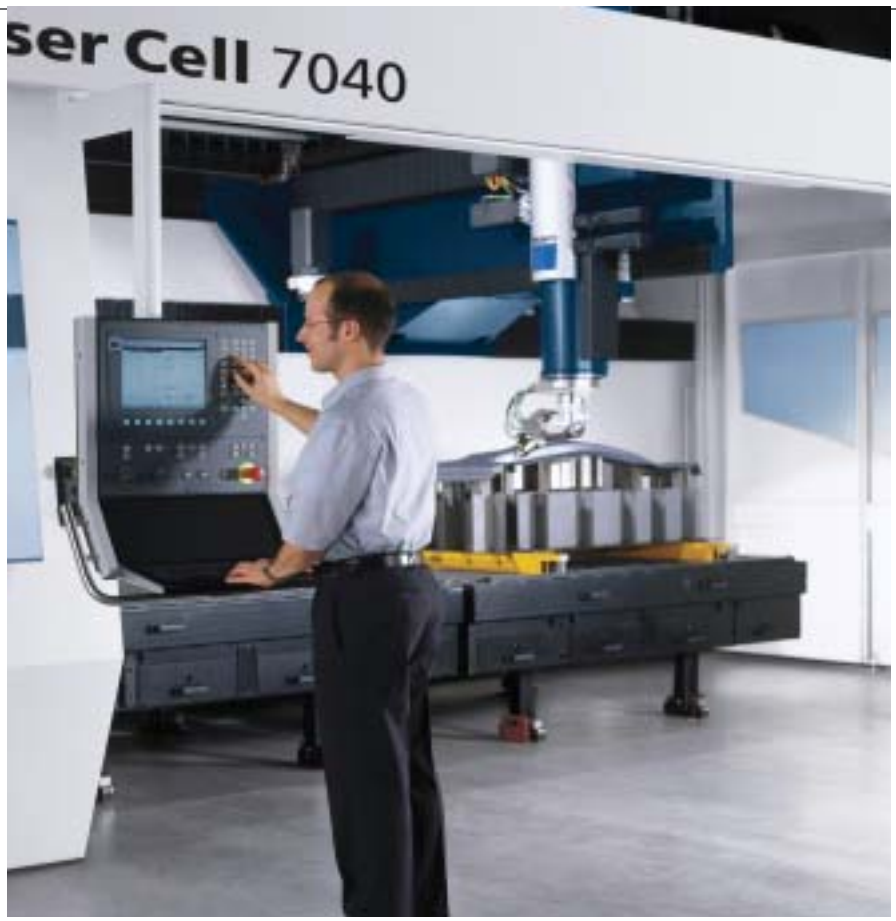
The sensor uses the precision glass scale. The main advantage of this principle is that you can maintain high, consistent accuracy throughout its entire range. The BS-112 was custom built to fit extremely tight quarters.

Call: 630-627-9700; visit: www.onosokki.net.

Contact data verification ▼

Melissa Data's Name Object 2.0 is an addition to the Data Quality Suite. Name Object 2.0 is a customizable application program interface that improves the quality and integrity of names that companies capture through their websites, e-commerce applications and call centers.

Name Object 2.0 comes with 140,000 names in its name table, and users can add names, prefixes and suffixes. They can also add ethnic names or names with which they have a particular domain expertise. The software parses multiple names and identifies the gender of each recipient.



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Laser system ▲

Trumpf has released the TruLaser Cell Series 7000 for processing 2-D and 3-D material. It allows users to adapt the processing program to reduce the positioning times of new parts. A smaller die diameter reduces the flow rate and process gas consumption. Compressed air can be used when quality is secondary to the cost per part.

The TruLaser Cell Series 7000 offers two axis modules for small and medium-sized rotation of symmetrical components that process a range of parts. A partition divides the work area for loading and unloading large parts simultaneously.

Call: 860-255-6424; e-mail: melanie.mcmillan@us.trumpf.com.

Electrostatic voltage sensor

Trek has introduced Model 875, an electrostatic voltage sensor designed for in-line monitoring of lectrostatic charge buildup.

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QP REVIEWS

Common Sense Project Management

Wayne Turk, ASQ Quality Press, 2008, 224 pp., $42 list, $25.20 member (book).

Common Sense Project Management is not strictly a how-to book, because most of what is written is, as the title suggests, common sense. Because common sense often can be an uncommon attribute, however, this book is useful to almost every project manager.

The book is broken into three sections. The first one addresses basic management—you can't be a good project manager if you aren't a good manager. The second and main part of the book deals with project management itself. The final section presents common project management mistakes and how to avoid them.

The main strength of the book is that it is well organized and written in a down-to-earth style that includes humorous chapters to make it easier to read. Moreover, the main ideas presented in each chapter are clearly arranged and presented schematically, surely due to the experience of the author.

The book has two main weaknesses. More editing would have enhanced its readability—in particular, inserting figures and tables would have helped. Also, at times there is too much overlap and redundancy between chapters.

Overall, this book provides an excellent explanation of project management from a project and management expert with more than 35 years of experience. It serves as a valuable resource for those lacking in project management experience, making it a highly recommended book for novice project managers or those looking to break into project management.

Reviewed by Martín Tanco
Tecnun (University of Navarra)
San Sebastián, Spain

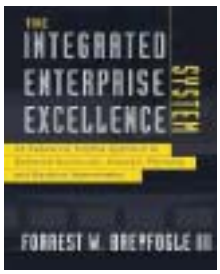
The Integrated Excellence Enterprise System

Forrest W. Breyfogle III, Bridgeway Books, 2008, 189 pp., $16.95 (book).

The *Integrated Excellence Enterprise System* (IEE) is the first in a series of books that introduces a business governance system that combines Six Sigma, lean and theory of constraints process and product-improvement methods with elements of the balanced scorecard or *hoshin kanri* styles of strategic planning methods.

By the author's estimation, the system enables managers to understand their businesses more completely and make better decisions. This book gives a high-level overview of the entire system and attempts to justify why the IEE system should be used.

Breyfogle is successful in showing how design for Six Sigma can be integrated with the process-level method of design, measure, analyze, improve and control (DMAIC) through the use of enterprise-level DMAIC.



The book contains an effective argument for why red-yellow-green scorecards are insufficient when determining the current state of a business and how IEE, through the use of probability plots and control charts, can do a better job. Whether management would accept the use of a probability chart as a dashboard item is questionable, though, because the tool requires some training in statistics to understand.

Breyfogle also makes the claim that the qualities of a good Black Belt are more inherent than learned, which may not be true. It would be interesting to see some data to back up that claim.

I wonder if it would have been better to use volume one of the IEE series to provide the overview and justification of the system rather than have it as a separate book. Overall, however, this book provides an effective, high-level introduction to what is an expanded version of the lean Six Sigma method and piques the reader's interest for what is to come in the other books in the series.

Reviewed by Brian Cocolicchio
Quest Diagnostics
Teterboro, NJ

The Best Practice

Charles Kenney, Public Affairs Books, 2008, 304 pp., $26.95 (book).

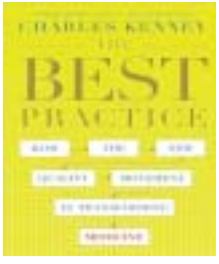
Author and former *Boston Globe* journalist Kenney, a quality and safety consultant to Blue Cross Blue Shield of Massachusetts, provides an excellent summary history of the quality movement in American healthcare.

In the mid to late 1990s, while treatment-related mortalities were the fifth-leading cause of death for Americans, healthcare practitioners decried attempts to standardize treatment. As healthcare quality professionals from this era will grudgingly remember, there were far too many preventable mistakes in a medical landscape that featured long waits in emergency rooms, interminable paperwork and increasing incidents of patients receiving the wrong medication or having the wrong limb amputated.

Those problems prompted a group of physicians to study the rapidly developing manufacturing concepts of quality improve-

ment learned from the Japanese that were being implemented in many American businesses. These visionary physicians began to apply these ideas and tools to the practice of medicine. This book tells their story and explains how what once was seen as heretical actions have blossomed into a healthcare quality movement that has brought the focus back to the patient.

The succinct chapters describe the early history of the quality movement in the United States, the birth and success of the Institute for Healthcare Improvement, the Annenberg Conference on error, how to set up methods to prevent human error, case studies, a forward-thinking perspective on the current state of healthcare quality and a viewpoint regarding further work that needs to be done.



This is a highly recommended book for all healthcare quality professionals and all university libraries that house a business curriculum.

Reviewed by Dale Farris
Groves, TX

Living on the Edge of Chaos

Karolyn J. Snyder, Michele Acker-Hocevar and Kristen M. Snyder, ASQ Quality Press, 2008, 345 pp., $60 list, $36 member (e-book).

At first glance, it appeared I erred in choosing this book to review, because I am not in the field of education. By the time I got through the first part of the book, however, I realized that if a reader substituted words such as regulators, schools, school districts, educators, teachers and students with words such as companies, governments, healthcare systems, management, managers, customers and workers, the insights, analogies and scientific evidence presented by the authors were not only phenomenal, but universally applicable.

With a central theme of reinventing education in a global age, the book is an exploratory journey that includes perspectives on the current education system and three views of change: the mechanistic view, the organic view and an emergent theory of change.

Concise and understandable explanations and examples are given for a plethora of theories applicable to understanding the current state and the emergent state of organizations within their environments. Several informative analogies are presented, and a model is included that outlines what students need if they are to succeed in a global village (those not in the academic field can substitute "workers" for "students").

This book is a must-read for any forward-thinking person aspiring to or involved in major change in his or her organization. In it, the authors provide the rationale for breaking away from the traditional command-and-control paradigm to an adaptive, collaborative organizational model. This can lead to success, the authors conclude, because the most meaningful changes occur at the edge of chaos.

Reviewed by Russ Westcott
R.T. Westcott & Associates
Old Saybrook, CT

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Smita Gopalaswamy and Venky Gopalaswamy, CRC Press, 241 pp., $139.95 (book).

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Improving a System

Add value by evaluating rework time and internal, external causes

WHEN WE think of nonconforming material, we think about scrapped and reworked material or products that directly cut into a company's bottom line. But a closer look shows that a nonconforming material system can provide a wealth of information.

Most of this information is already recorded for companies that use the ISO 9001:2000 standard or have a similar quality management system (QMS). The standard requires that nonconforming products be "identified, controlled, (preventing) unintended use and (recording) the nature of the nonconformity and any actions taken."[1]

Two pieces of information transform a system that meets or contains the elements of an international standard for a QMS into a dynamic system with additional benefits that readily support the QMS.

The first bit of information answers the question, "Was the nonconformity created in house or by component parts supplied from outside the organization?" This can be recorded in a check box on the nonconforming material form (see Online Figure 1 at www.qualityprogress.com), which separates products into internal and external causes. Internally caused nonconformances become input for continuous improvement projects. Those caused externally can be analyzed to ensure adequate information is provided to the supplier or to determine whether corrective action by the supplier is necessary.

While more difficult to obtain, the second piece of information is equally valuable: rework time caused by the nonconformance, which includes the time required by all departments involved in reworking or dispositioning the nonconformance. Rework can be analyzed in two ways: by time or money. To analyze by time, total the amount of rework time for the month and divide it by the total units produced to determine the amount per unit. To analyze by dollars, multiply the rework time per unit by the labor cost.

Illustrate the findings

A 12-month line chart showing these rework costs can be presented to management. Add a line to the chart that represents a three or four-month moving average to smooth out monthly variation and see the general trend in rework costs (see Online Figure 2). These measures support Section 8 of the standard: "measurement, analysis and improvement or similar elements for measurements in a QMS."[2]

To prioritize improvement efforts, create a Pareto chart using rework time or rework cost analysis for internally caused nonconformances. A Pareto chart of nonconformances from suppliers (external cause) can focus supplier communication where it is required.

A company that implemented this method saw a 55% reduction in rework cost per unit over a 12-month period. The results demonstrated the cost savings of improvement efforts and assisted in the prioritization of future continuous improvement projects.

Benefits of this additional information include reduced costs, focused problem solving, and increased management visibility, worker involvement, supplier communication and worker morale.

The softer benefits of increased worker involvement and morale are difficult to put a price tag on, but they can be the largest benefits. Workers usually stop ignoring issues that have been causing problems and frustration in normal tasks. When the nonconformances that have affected the workers are addressed, the employees become a valuable part of the system. Soon after including this additional information and taking action on it, an increase in reported nonconformances may be observed.

Measures from the nonconforming system are also valuable inputs into the management review system. Review of rework costs and sources of nonconformance by senior management creates buy-in and focus in these areas. The management review meeting also provides an opportunity for senior leaders to review not only specific action plans for reducing nonconformances and rework, but also their progress toward established goals.

Capturing a little more information about nonconformances and process rework can add a lot of value to an organization that focuses on doing it right the first time. QP

REFERENCES

1. *ANSI/ISO/ASQ Q9001-2000: Quality Management Systems Requirements*, International Organization for Standardization, 2000.
2. Ibid.

ROBERT PINTAVALLE is a senior process engineer with Watson Pharmaceuticals in Fort Lauderdale, FL. He earned his master's degree in mechanical engineering from Union College in Schenectady, NY. Pintavalle is an ASQ-certified Six Sigma Black Belt, quality engineer, manager of quality/organizational excellence and quality auditor. He is a senior member of ASQ.

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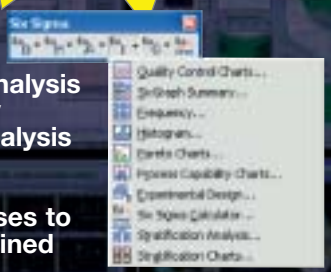

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