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QUALITY PROGRESS

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Contents

FEATURES

CUSTOMER SATISFACTION 16**The Right Move**

Advance toward your business goals and capture long-term profits by making the customer the centerpiece of your quality program. by Paulo F.P. Barcellos and Antony P. Mueller



SIX SIGMA **Progress Report**

A new scoring method lets you assess the maturity of your Six Sigma program and evaluate its strengths and weaknesses. bv Zhen He



New Frontiers

Statisticians found a new way to analyze data from customer satisfaction surveys and offer insight to management. by Ron S. Kenett and Silvia Salini



AWARDS **Watershed Moment**

A solid foundation in quality helped Cargill Corn Milling recover quickly from a natural disaster and earn a Baldrige award. by Brett Krzykowski



HEALTHCARE

Get Your Checkup A recent ASQ survey examines whether lean and Six Sigma are gaining traction in hospital settings.

by the ASQ Lean Six Sigma Hospital Study Advisory Committee





- More 'Frontier' Experience See additional figures on a new way to look at survey data.
- The Envelope, Please Updated listing of quality-related awards under "Tools and Resources."

Survey Says

Check out the complete "ASQ Hospital Study Data Report," the focus of "Get Your Checkup."

DEPARTMENTS

7 Inbox

 O'Neill's apt assessment of healthcare today.

8 Expert Answers

- Say "yes" to Likert scales.
- Auditing a QMS.

Keeping Current 12

- Healthcare institutions dominate Baldrige applications.
- Big Three's initial quality scores accelerate.
- Mr. Pareto Head 14
- **QP** Toolbox 64
- **OP Reviews** 66
- **QP** Calendar 68

COLUMNS

6 Upfront The Baldrige backbone.





Ouality in the First Person 51 Take emotion out of decision making.

- 3.4 per Million 52Choose the right measures for managing processes.
- 56 **Career Corner** Risk and rewards in career planning.
- **Statistics Roundtable** 58 Plot an experimentation strategy.
- **Standards Outlook** 60 Stick to global labeling requirements.
- One Good Idea 72 Using 5S in a lab setting.

NEXT MONTH **NEED A FIX?**

Addressing Six Sigma criticisms.

- PLAN AND PREPARE Handling the tough Baldrige questions.

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UPFRONT



Baldrige Backbone

The enduring role of quality's top honor

SINCE ITS INCEPTION in 1987, the Malcolm Baldrige National Quality Award has recognized U.S. organizations for achieving quality and performance excellence. This year, 70 organizations applied to be considered for the prestigious honor, and countless other organizations base their quality programs on the Baldrige framework. For a full breakdown of this year's applicants by category, turn to "Under the Microscope," p. 12.

We feature the tumultuous journey of a 2008 Baldrige award recipient in the article "Watershed Moment," p. 38. Assistant Editor Brett Krzykowski delves into how quality processes and practices can afford a level of resilience—even when it comes to a natural disaster. Cargill Corn Milling North America's Cedar Rapids, IA, plant was nearly wiped out by a devastating flood in June 2008, but the company's process focus helped it to reopen less than three months later and host a site visit by Baldrige examiners that October.

The success story illustrates the Teflon-like effect of having a strong and focused quality program.

In other Baldrige-related news, the first Future of Quality dialogue, a joint effort between ASQ and the Baldrige National Quality Program leadership, took place in June. Its purpose: to discuss new directions that quality and organizational performance excellence must take in the decade ahead to create a lasting positive impact in business, industry, healthcare, education and society.

Said Harry Hertz, Baldrige program director: "As we look to the future, the role of the quality professional and organizational performance excellence criteria is to help organizations face reality, think strategically, and implement efficiently and effectively, with the customer and other key stakeholders in mind.

"Success will not be defined by financial data alone. Success will be driven by how well we accept and address challenges of innovation, customer and employee engagement, globalization and societal responsibility."

A full report on the Future of Quality dialogue can be found here: www.asq.org/ knowledge-center/future-of-quality-dialogue.html.

QP has an archive of articles on Baldrige award recipients that can be found at www. qualityprogress.com. For more on the framework, the application process and past recipients, visit www.baldrige.nist.gov.

Finally, this month we updated our comprehensive quality awards listings, which include state-by-state, national, international and automotive awards, descriptions and information on how organizations can apply for them. The listings can be found at www. qualityprogress.com under the Tools & Resources tab. **QP**

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INBOX

Healthy savings

In response to the interview that appeared in the June 2009 issue of QP ("In a Perfect World," pp. 32-39), I believe former U.S. Treasury Secretary Paul O'Neill is right on target about the improvement opportunities in the healthcare industry.

The \$1 trillion of waste

in our healthcare system to which O'Neill refers can be attributed to data reported in a recent study by the New England Healthcare Institute. The research organization identified four major categories of waste that should be the targets for improvement efforts:

- Wide variations in patterns of care. A lack of physician adherence to clinical practice guidelines results in huge variations in patterns of medical care across the United States. Potential annual savings: \$600 billion.
- Medical mistakes. These errors include surgery on the wrong organ, preventable medication errors or avoidable infections acquired in the hospital. Potential annual savings: \$52.2 billion.
- Overuse of hospital emergency departments for non-urgent care. Potential annual savings: \$32 billion.
- 4. Underuse of drugs and other therapies. Potential annual savings: \$5.5 billion.

O'Neill's track record at the Pittsburgh Regional Health Initiative (PRHI) is proof positive that dramatic improvements in healthcare quality and significant cost reductions are not mutually exclusive.

What is equally remarkable is that the improvements were achieved without highpaid consultants, significant investment of capital, regulatory reform, new legislation or big committees. I often refer to PRHI's accomplishments during the Six Sigma



certification classes I teach at Emory University in Atlanta.

President Barack Obama should indeed raise the stakes for healthcare by challenging all key stakeholders to the kind of savings O'Neill espouses. As a quality professional, I would be glad to volunteer my time to such a noteworthy cause.

Peter J. Sherman Associate director, AT&T Lead instructor, Emory University Six Sigma Program Atlanta

Managing metrics

In his article in the June edition of QP ("Pyramid Power," pp. 40-45), Todd Creasy presented a different and useful perspective on the use of metrics to drive change.

Although many organizations resist the metrics dashboard, perhaps this perspective will encourage more use of metrics, which is commendable. By drawing a connection between foundational metrics and the capstone metric appropriately, Creasy enabled all levels of an organization to consider the business priorities and to focus on them.

People do not like metrics because they feel they cannot control them. What they fail to understand is that metrics require rigorous management to fully understand their value. Only then will anyone in the organization feel comfortable using them.

Likewise, management needs a set of tools to improve processes. Lean Six Sigma, 6TOC or any other approach must be understood, mastered and appropriately applied to the situation to get the most out of them. *Randall Johns*

> Vice president, Juran Institute Stafford, VA



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EXPERTANSWE

Likert scale: yes or no?

Q: Our company is redesigning its customer service surveys. To date, the question of whether the customer was satisfied with the service gave the option of answering yes or no, with a space provided for the customer to provide additional comments.

On the new survey, the company wants to start using a Likert scale of 1 to 10 so customers can indicate their level of satisfaction with the service, but it also wants to leave the yes-or-no question on the survey. It would be structured so customers would indicate yes or no as to whether they were satisfied, and then the company would have the customer indicate the extent of satisfaction or dissatisfaction by rating on a scale of 1 to 10. The ability to write additional comments would still be provided.

Is it redundant to have the yes-or-no aspect of the question in addition to the scale? I feel it is, but maybe I'm wrong. Also, if the yes-or-no question is eliminated, how should research and reporting be done across that dividing line between the historical data that has the yes-or-no question and the new data that will not have it? Leigh Comunale Quality analyst

Quality analyst Bradenton, FL

A: I strongly suggest you not use two ways to answer the same question. While the proposed approach seems simple and promises more information than you would get by using only one type of scale, there are two problems:

- Anything that seems even a little complicated will dissuade some people from completing the survey.
- 2. A fraction of people will be confused, and you will end up with questionable data.

Imagine your confusion if a respondent checked the "no" box, and then indicated a rating of 7 on the satisfaction scale. Does this suggest he or she wasn't sure how to use the scale and thought the 7 was the degree of dissatisfaction? Or maybe the respondent just wanted to send you a mixed message—that he or she was generally satisfied but was dissatisfied with some There is one exception to my preference for the Likert scale: It's obviously of little use for questions that can only have a yes-or-no response. For example, most political polls offer only two very distinct choices. Asking people to choose a candidate by using a Likert scale would not make much sense.

In choosing how broad a scale to use, there are many opinions among experts, all



portion of your service and couldn't answer yes. The problem is that you'll suspect some of your respondents were confused, but you won't know which ones.

As for which type of scale to use, I would definitely recommend the Likert scale. Just looking at the distribution of scores from a questionnaire that employs the Likert approach will give you a great deal more information than the percentage you will get from the same number of responses to a yes-or-no survey.

If you want to do a sophisticated statistical analysis, you will see that you can more quickly assess significant patterns if your data is captured on a Likert scale. The average of scores from Likert questions, along with their distribution of variation, gives you more information than the percentage you would get with yes-and-no responses. of whom have their reasons for selecting that range. You indicated that your company is considering using a scale of 1 to 10. I have always preferred 1 to 5—or at most a 1 to 7—because it's easy to fill out and gives the survey provider good information.

Years ago, I took a class from Joseph Juran, and he used a scale from 1 to 20 on his course evaluation survey. Perhaps his grades were so consistently high that he needed the broader scale to look for subtle changes.

In comparing new data to previously collected data, if you use a Likert scale from 1 to 10, the simplest approach is to consider all responses that fall between 1 and 5 as "no" and all responses from 6 to 10 as "yes." There may be some sophisticated rationale for doing it otherwise, but I'm not aware of what it is.

RS

Being able to audit for effectiveness **takes quite a bit of skill** and a good measure of **perspective**.

Some people insist on using a scale that has an even number of choices—for example, 1 to 6 or 1 to 10, thus forcing the respondent to choose an answer that leans toward a positive or negative direction. I prefer an odd number, which gives the respondent an opportunity to indicate that he or she is neutral on the question. Why force an answer that really doesn't mean anything?

In addition to the Likert scale, you should also allow a choice of "no opinion." This would let someone without enough information to indicate such while still answering the question. Thus, it would avoid skewing your data with people who should not count.

Finally, if space on your form permits, provide space after each question for open-ended comments. While these might not have much statistical validity, they would provide insight that otherwise could be missed.

> Joe Tunner Consultant Fort Collins, CO

FOR MORE INFORMATION

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on Customer Satisfaction," *Quality Progress*, July 2005, pp. 40-47.

Hayes, Bob E., "The True Test of Loyalty," *Quality Progress*, June 2008, pp. 20-26.

Real mature

Q: Is there a maturity model that shows how to gauge an organization's progress toward auditing the elements of a quality management system (QMS) or a standard from the International Organization for Standardization (ISO)?

Reviewing our audit-findings data from the last couple of years, document and record control (elements 4.2.3 and 4.2.4 in ISO 9001:2008) tend to be the most common areas of nonconformance. As a QMS process matures, I believe that findings would tend to move toward operational issues, such as ISO 9001 element 7.5.

Efrain Ruiz Quality assurance manager Marietta, GA

A: The short answer to your question of whether such a maturity model exists is no. However, you touch on an important issue relating to the purpose and evolution of a management system audit.

Like any process, an audit must add value. Any value an audit adds will change as the management system being audited matures. In a newly implemented management system, the focus of the internal audit program is conformance.

As the management system matures, however, conformance issues (including document control) should become less of an issue. Instead, the focus should shift toward the effectiveness of the system. For example, the audit should ask whether the processes accomplish planned results. If

ASKED AND ANSWERED

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not, it should then ask whether actions are being taken to resolve the issues.

Auditors should spend less time focusing on issues such as document and record control and more time evaluating process performance and metrics. That doesn't mean conformance issues such as document and record control should be ignored. It's just my opinion that less time should be spent looking for problems in these areas in the absence of serious historical issues relating to these processes.

Unfortunately, many auditors never leave the comfort zone of auditing for conformance, which is relatively easy and painless. Being able to audit for effectiveness takes quite a bit of skill and a good measure of perspective, and it often surfaces some sensitive (but quite important) issues.

For the audit program to continue to provide value in driving process performance, it must be performed thoroughly. *Joe Kausek*

Manager, operational excellence Rio Tinto Minerals Boron, CA

FOR MORE INFORMATION

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BALDRIGE

Under the Microscope Healthcare organizations continue to dominate Baldrige applications

Baldrige applications submitted to organizers were again dominated by healthcare institutions, but that doesn't mean they're the only ones using the criteria to improve their operations, the program's director contended.

For the second year in a row, the vast majority of applications came in the healthcare category, while just a handful of manufacturers and service providers submitted applications to be considered for a Malcolm Baldrige National Quality Award, considered the highest recognition for innovation and performance excellence in the United States.

Of the 70 applications submitted to the National Institute of Standards and Technology this year, 42 are from healthcare organizations. Nine applicants are education organizations, eight are nonprofits, two are manufacturers, four are service companies and five are small businesses.

Of last year's 85 applications, 43 were healthcare organizations, five were ser-

vice providers, three were manufacturers, 11 were from the education sector, 16 were nonprofits and seven were small businesses.

"It is troubling that we are not identifying as many role models from these sectors as in the past," said Harry Hertz, the director of the Baldrige National Quality Program.

"But it is worth remembering that the Baldrige program is more than just the Baldrige award. While the award and the recipients are our most visible centerpieces, our ultimate goal is for organizations to apply the criteria to the maximum extent according to their needs," he said.

There's been a surge of healthcare organizations applying for the Baldrige award since 2005, and state and local quality award programs are also seeing similar growing interest from the healthcare sector, Hertz said.

"We are told that many service providers and manufacturers still use the Baldrige criteria internally and that others see quality



as an embedded function, more functional than strategic," Hertz said. "Those companies who continue to use the criteria see (the criteria) as vital strategic ways that guide operations and long-term strategy setting."

The upswing in interest from healthcare organizations should continue for "at least the next few years," he added.

"We believe (the upswing) signals that the healthcare industry is seeing the challenges it faces and is willing to engage in the hard work necessary to address them in a positive way," Hertz said.

"The majority of our healthcare applicants describe starting their Baldrige journey several years prior to submitting an application to the Baldrige program, so the impact of the framework appears to be continuing to grow. Networks are developing for healthcare organiza-

tions to communicate their experiences and perceptions," Hertz said.

Of course, a high number of applicants from one category does not necessarily translate into a high number of award recipients from the same category.

Of the 85 applications last year, there were three Baldrige award recipients: one manufacturer, one hospital and one school. In 2007, from 84 applications, two healthcare organizations, two nonprofit organizations and one small business received Baldrige awards.

The Baldrige award review process continues through the end of the year with application reviews and site visits to the organizations that applied. Usually, organizers announce award recipients in December. Visit www.baldrige.nist.gov for more information about the award.

—Mark Edmund, associate editor

NT

AUTOMOTIVE

BIG THREE'S INITIAL QUALITY UP IN 2009

Initial quality of new vehicles sold by the Big Three has improved by an average of 10% compared to last year, according to a recent J.D. Power and Associates study.

The industry average for initial quality this year for domestic brands manufactured by Chrysler, Ford and General Motors is 108 problems per 100 vehicles (PP100). That's down from 118 PP100 in 2008. Initial quality has improved to an average of 112 PP100 this year, down from 124 PP100 in 2008.

Lexus leads the overall nameplate rankings, averaging 84 PP100, followed by Porsche, Cadillac, Hyundai and Honda in the top five.

"Even in the face of unprecedented challenges, the Detroit automakers are keeping their focus on designing and building high-quality vehicles, which is a precondition for long-term success," said David Sargent of J.D. Power and Associates.

The J.D. Power and Associates initial quality study is considered an industry benchmark for new vehicle quality measured at 90 days of ownership and has become a predictor of long-term durability. For more details on the scores, visit www.jdpower. com/corporate/news/releases/pressrelease. aspx?ID=2009108 (case sensitive).



Who's Who

NAME: S. Anil Kumar. RESIDENCE: Ranipet, Tamil Nadu, India.

EDUCATION: Bachelor's degree in engineering electronics and communica-



tion from the T.K.M. College of Engineering in Keraala. He has also obtained several quality-related certifications.

CURRENT JOB: Head of business excellence and quality assurance at Bharat Heavy Electricals Ltd. (BHEL) in Ranipet, India. Kumar has worked at BHEL for 25 years, helping his company obtain ISO 9001 certification in 1993. He was one of the first in the public sector to achieve this recognition. Other professional achievements include coordinating more

than 750 improvement projects during the last three years and developing internal quality management and Green Belt training programs.

INTRODUCTION TO QUALITY: Kumar was introduced to quality management when he started his career at BHEL as an inspection engineer, obtaining extensive quality training throughout his tenure.

ASQ ACTIVITIES: Among his many activities are: review board member of ASQ Quality Press since June 2003; paper reviewer for the World Conference on Quality and Improvement in 2008; proctor of ASQ certification exams in Chennai, India, since 2001; participant in e-section development; member of ASQ global transformation task force; and a contributor to the *Quality First* newsletter. Kumar also helped coordinate the first Quality-India Chennai meeting in 2006 and has been involved in many ASQ-Federation of Indian Chambers of Commerce and Industry activities.

OTHER ACTIVITIES/ACHIEVEMENTS: Kumar has been a senior examiner for the IMC-Ramakrishna Bajaj National Quality Award and an examiner for the Confederation of Indian Export-Import Award. He is also a Six Sigma training assessor for the Quality Council of India's National Registration Board for Personnel and Training.

RECENT HONOR: This year, Kumar became the first ASQ fellow from India. In 2005, he won the Qimpro Silver Standard Award.

PUBLISHED: Kumar has created hundreds of crossword puzzles related to quality management and Six Sigma and has had them published in magazines including QP, *Quality World* and *Informed Outlook*. He also has had many papers published and presented at national and international conferences.

QUALITY QUOTE: Quality is the manifestation of process interactions. It seeks a fine balance between systems and passion. Quality without innovation is stale, and innovation without quality cannot be sustained for long. Profound learning accelerates sustainable improvements.

KEEPINGCURRENT

Mr. Pareto Head BY MIKE CROSSEN







SHORTRUNS

THE MAJORITY OF HOSPITALS fail to meet patient safety standards that were recommended in a landmark report by the Institute of Medicine 10 years ago. The Leapfrog Group, a healthcare advocacy organization, said most hospitals surveyed don't meet medication error prevention standards or mortality standards, and many have failed to implement other efficiency standards known to improve quality and save lives. For more details on the survey, visit www.leapfroggroup.org.

THE AMERICAN NATIONAL STAN-DARDS INSTITUTE, coordinator of the U.S. standards and conformity assessment system, began accepting applications last month for certification bodies seeking accreditation under the new Toy Industry Association Toy Safety Certification Program. The program was created to improve toy safety, help restore stakeholder confidence in toy products and comply with new federal requirements that toys be tested by a qualified lab and certified for meeting rigorous national safety standards and regulations. For more information about the program, visit www.toycertification.org. THE AMERICAN NATIONAL STAN-**DARDS INSTITUTE (ANSI) Certificate** Accreditation Program (ANSI-CAP) has selected ASTM E2659-09, Standard Practice for Certificate Programs, as the standard against which certificate programs will be evaluated for potential accreditation. The ANSI program seeks to accredit organizations that issue education and training certificates to U.S. workers. ANSI is also asking those organizations that issue education and training certificates to U.S. workers to apply for the institute's pilot ANSI-CAP. Call 202-331-3621 for more information about the pilot program.

ENGINEERING JOBS are the toughest to fill in the United States, according to a recent report from Manpower, an employment services agency. More than 2,000 U.S. employers were surveyed to find out which positions are the most difficult to fill. Following on the list are nurses, skilled trades, teachers, sales representatives, technicians, drivers, IT staff, laborers, machinists and machine operators. To view the 2009 Talent Shortage Results Report, visit www.manpower. com/research/research.cfm.

HEALTHCARE WISCONSIN RANKED FIRST IN HEALTHCARE QUALITY

The state of Wisconsin ranked No. 1 in healthcare quality last year, according to a recent report by the federal Agency for Healthcare Research and Quality.



The agency scored each state based on 250 quality measures drawn from more than 30 sources. Minnesota and Massachusetts were ranked second and third, respectively, in this year's survey, and New Hampshire and Michigan rounded out the top five.

The lowest performing states were Louisiana, Mississippi, Nevada, Arkansas and New Mexico.

Wisconsin was also ranked No. 1 in 2006, but dropped to second behind Minnesota in 2007.

A complete report on the findings and detailed information on each state's scores can be found at http://statesnapshots.ahrq.gov.



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 the most recent Quick Poll:

"What do you find most difficult to communicate to management?"

- That quality must be an organization-wide effort.
- The value of quality—in monetary terms.
- The need for sustained resources dedicated to quality.
- That quality is proactive as well as reactive.

Visit www.qualityprogress.com for the most recent poll question posted:

"What has the biggest impact on customer satisfaction?"

- Quality of the product or service.
- Price of the product or service.
- Current economic climate.
- · Competition's offerings.

ASQNEWS

TRAINING PROGRAM LAUNCHED ASQ has launched a new education and training program for quality professionals. The ASQ Learning Institute (www.asq.org/ learninginstitute) features ASQ's learning offerings and integrates training resources among ASQ headquarters, member communities, education professionals and members. There's also a learning management system that lets users create a profile and learning plan and track their learning history.

IAQ AWARD Ira M. Millstein was awarded the Marcos E.J. Bertin Quality in Governance Medal by the International



Academy for Quality MILLSTEIN

(IAQ). Millstein was recognized for "raising our global sensitivity to the imperative of a strong quality focus in the governance of organizations," award organizers said. Bertin is a past-chairman and honorary member of IAQ and is considered the father of the Argentine quality movement. ASQ administers IAQ.

39.6%

26.4%

22.6%

11.4%

SR REPORT Three major corporations featured in a panel discussion on social responsibility (SR) at ASQ's World Conference on Quality and Improvement earlier this year have been profiled in the latest ASQ Quarterly Quality Report. The report details SR approaches taken by Target, Ecolab Inc. and 3M. For more details, visit www.asq. org/quality-report/reports/200906.html.

ASQ IN MEXICO CITY ASQ has opened an office in Mexico City as part of its plan to expand quality's reach around the globe. The new office employs two people. There are more than 600 ASQ members in Mexico. ASQ already operates offices in Beijing and New Delhi. An opening celebration will be held in the fall. Visit www.asq. org/global/countries/mexico.html for more details about ASQ activities in Mexico.

NEW TAG MEMBERS Two technical advisory groups (TAG) recently held elec-

CAPITOL



ASQ has submitted comments to the National Coordina-

tor for Health Information Technology about a proposal to establish a national network of regional health IT extension centers that would assist healthcare providers in their efforts to adopt new information technologies. In the letter, then-ASQ president Roberto Saco said ASQ believes quality principles can ensure the money is wisely spent and process improvement tools and quality methods can make implementation go smoother and quicker. For more details on the correspondence, visit www.asq. org/advocacy/issues-actions/20090626electronic-health-records.html.

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

tions, and new members were selected to hold TAG positions. Those elected to the social responsibility TAG were: Mary McKiel (chair and government expert), Linda Golodner (consumer expert), Heidi Hijikata (government observer), Rolf Schneider (industry expert), Bruce Tackett (industry observer), Jason Morrison (nongovernmental organizations expert), Rochelle Zaid (nongovernmental organizations observer), Dorothy Bowers (service, support, research and others expert) and Sonny Maher (service, support, research and others observer). The newly elected members of TAG 207, who start their duties in 2010, are: Susan Briggs (chair), Joe Cascio (vice chair) and Thea Dunmire (secretary).

THE Right NOVE

SHORTCOMINGS IN MEASUREMENT systems and traditional methods for assessing customer satisfaction affect the ability of most firms to directly link quality improvements to changes in financial performance.

With respect to the revenue side, manufacturers and service providers must find the best path to satisfy, retain and attract customers if they want their businesses

In 50 Words Or Less

- Market-oriented quality management links longterm profitability to a company's ability to create customer value.
- Quality measurement must consider that quality depends on customer perception, which is based on the utility of the product or service.
- Quality cannot be defined separately from the value of the final product.

to survive and grow. They also must be able to determine the return on their quality initiatives.

That path to survival, growth and profitability begins by developing quality programs through the identification of critical quality dimensions as dictated by the market. By doing so, firms can concentrate their scarce resources where they are most valued by their customers, and management's efforts can be focused on long-term objectives rather than short-term profits. Those tactics will depend mostly on customer satisfaction as the key driver for increasing the net value of the company's customer base.



by Paulo F.P. Barcellos and Antony P. Mueller

Market-oriented quality management leads to long-term profits

A market-oriented approach is essential for developing an effective marketing and product development strategy. Market-oriented quality management will also increase company profits, similar to how business profitability and growth are driven by customer loyalty and customer retention, which are natural outcomes of customer satisfaction.

Gauging satisfaction

An effective strategy begins with measuring customer satisfaction properly. Customer-satisfaction measurement is needed at the microeconomic level—at which a company's quality efforts reside—and the macroeconomic level—at which the quality of goods and services of particular sectors of an economy can be found.

The Swedish Customer Satisfaction Barometer¹ and the American Customer Satisfaction Index (ACSI)²⁴ are two good examples of customer satisfaction measurements that illustrate how the quality of goods and services can be evaluated from the demand side using a market-oriented perspective.

To establish and maintain profitability, private and state-owned companies must know the worth of a loyal customer, particularly in economies exposed to recent deregulation processes and where monopolies are being challenged by globalization and privatization.

A few years ago, for example, the Brazilian government launched a process to deregulate some monopolies, including state-owned public utilities and telecom services. These actions, paralleling privatization of the economy, were aimed at creating a more competitive national marketplace.

Hotel chains in Rio de Janeiro conducted a pilot project in 1999 and 2000 measuring their quality of service using the ACSI method. One of the conclusions of the project was that the ACSI method proved valid for applications in Brazil.

The pilot—a benchmarking project involving seven hotel chains based in the United States (Holiday Inn, Hilton, Hyatt, Marriott, Starwood [Sheraton, Westin, and Days Inn], Promus and Ramada⁵)—fostered improvement in the hotel industry at the macroeconomic level. At the microeconomic level, the project improved the quality initiatives of Rio de Janeiro's hotel chains.

The importance of these projects is enhanced by the fact that business survival and growth stem from customer satisfaction, which impacts customer retention, profitability and competitiveness.^{6,7}

Satisfaction and performance

In an article from the journal *Managing Service Quality*, Ton van der Wiele, Paul Boselie and Martijn Hesselink wrote: "The relationship between customer satisfaction (as a result of service quality) and business performance is not always very clear."⁸ They also presented three major challenges to measuring the relationship:

- 1. Time between measurements of customer satisfaction and profit improvements.
- 2. Other variables that influence company profits (such as price, distribution and competition).
- Other behavioral variables that could explain the causality between customer satisfaction and business results.

According to the trio of authors, the findings of some researchers pointed to evidence of the direct relationship between customer satisfaction and organizational performance.

Other research by Christopher D. Ittner and David F. Larcker revealed four common mistakes made by companies trying to measure nonfinancial performance:⁹

- Failing to link measures to strategy.
- Failing to validate the links.
- Failing to set the right performance targets.
- Measuring incorrectly.

They also recommended areas for companies to focus on to improve performance: selection and staffing of new hires; employee satisfaction; employee empowerment and accountability; customer satisfaction; and customer buying behavior.

Focusing on those areas, they said, leads to sustained profitability and shareholder value: "For example, a major finance company found that, in ascending order of importance, employee satisfaction, quality (the number of processing mistakes) and customer satisfaction were the fundamental drivers of financial performance."¹⁰ If nonfinancial measures can improve financial results, they should be used to make decisions.

In the Journal of Marketing, Eugene W. Anderson, Claes Fornell and Sanal K. Mazvancheryl empirically documented "a positive association between customer satisfaction and shareholder value. Given the overall estimate of the association between ACSI and Tobin's q of 1.62, a 1% change in customer satisfaction (as measured by ACSI) is associated with an expected 1.016% change in shareholder value (as measured by Tobin's q)."¹¹

This finding has important implications. While the "study does not provide diagnostic guidance for man-

Satisfied customers are **economic assets** with **high returns and low risks**.

agers seeking ways to improve customer satisfaction or specific guidelines for implementing customer satisfaction programs, it does provide a strong rationale: Firms that actually achieve higher customer satisfaction also create more shareholder wealth."¹²

Fornell emphasized this point as evidence of his research conclusions: "We might even have stumbled upon the holy grail for managers, as well as investors: Satisfied customers are economic assets with high returns and low risks. That is, you don't have to take high risks to get high returns. This is contrary to what most financial analysts believe. It is also contrary to what many in business believe: 'Be bold. Take risks. No risk, no reward. Nothing ventured, nothing gained."¹³

Quality as customer satisfaction

Defining quality as customer satisfaction must take into account that the satisfaction a customer expects to receive is not a constant. Instead, it depends on the customer's situation.

Similarly, the perception of quality differs among customers, and the same individual will apply different quality standards according to his or her specific situation. Therefore, quality as customer satisfaction must be conceived as the endeavor of the seller to meet the changing perceptions of the customer as they occur.

From this perspective, quality management consists of the art of anticipating changes of perception and putting them into the context of competition.¹⁴ Therefore, quality measurement needs to take into account that quality is customer perception based on utility, which is subjective and depends on that customer's situation.

Because the valuation of a product, including all intermediate stages of its production, is based on the utility of the final product, quality standards will change with the variability in the consumers' tastes. Although the consumer decides only whether to purchase certain goods, his or her valuation of the product is the root of valuation in the production process.

Through the act of buying or not buying, the consumer transmits his or her valuation to all preceding stages of the production process. Quality accounts for this element of subjectivity that rests with the consumer. The observance and maintenance of high technical standards must not be confounded with meeting those quality standards because they are derived from a market-oriented approach to quality management.

The value of any product in the production process, from natural resources to final consumption, depends on the value the consumer places on the product. In other words, production goods have value only insofar as they contribute to providing a good for consumption.

The economic value of technological knowledge and resources, therefore, is derived from the value the buyer places on the final product. This means there are no definite standards of quality regarding the production of goods outside the buyer's valuation of that product. As a result, quality cannot be defined without the value of the final product.

Customer satisfaction is a means toward the company's goal of profitability. It follows that the profitability of a company's operations serves as the prime criterion of whether the adequate quality standards have been achieved.

Falling profit rates do not necessarily suggest the quality standards that have been pursued are too low; they might very well be too high because customer satisfaction will always include price. A lower-quality product may, in fact, meet an individual's customer-satisfaction criteria if he or she believes the price is right. The pursuit of quality standards needs to be congruent with the customer's willingness and ability to pay.

Taking into account that beauty is in the eye of the beholder, simplicity can be a virtue. In this way, simplicity represents an element of quality. One of the most basic errors of quality management is to confuse quality with complexity—or, even worse, higher production costs—and to believe that a more elaborate product is always better than a simpler version.

Brand name

Established quality standards—as they are transmitted through branding—reduce uncertainty, form a relationship of trust with consumers and increase market transparency.

From a quality perspective, branding can be defined as reliability by standardization of a differentiated product. Quality defined in this way serves as a tool for companies that serve a mass market. The task of quality management is to watch for the slightest deviations from the established quality standards.

Modern branding is a way to transmit information about quality levels to the customer. As such, branding provides a good example of what is meant by marketoriented quality management.

For example, McDonald's and Coca-Cola do not carry customer expectations of a gourmet meal or an exquisite beverage. On the other hand, customers who see the Mercedes and Lexus brands expect that the products' higher-priced products will be matched by high quality standards. In this respect, quality contains the meaning of reliability that comes with the brand.

Back to burgers: Although the McDonald's brand does not conjure images of a white-tablecloth, fine-dining experience, the level of quality the brand delivers is reliable. Quality in this sense, as it is used in branding, serves as a means of communication between seller and buyer. It is a form of establishing definitive customer expectations. The primary task of management is to ensure expectations will be met under any circumstances.

The establishment and branding of quality standards reduces uncertainty for the buyer. When standards are not being met, the buyer's confidence in the seller is in jeopardy. In this regard, quality standards form the basis of a relationship of trust between seller and buyer. It is not necessarily high quality but a specific degree of quality that forms the basis of the relationship.

In contrast to producers of mass-market brands, makers of custom products cannot standardize their products. Instead, they must strive to transfer the aspect of reliability within the personal relationship between seller and buyer. Along with the product, the dimension of quality refers not only to the product itself, but also to the effectiveness of communication between seller and buyer about the details of the product.

In the area of custom-made products, quality standards refer mainly to the responsiveness of the producer to the demands of the customer. In this relationship, the producer must become educated about the customer and convince the customer about the utility of certain features of the product.

A dynamic approach

Regardless of the size of the organization, the implementation of market-oriented quality management entails a shift of perception that calls for the systematic application of quality criteria in all stages of the production process. By adopting a market-oriented approach to quality management, the company applies quality standards that are derived from the dynamics of the market process.

With the market process serving as the source of quality standards, management will achieve flexibility without losing the anchor, which is directly linked to customer satisfaction. **QP**

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PROGRESS Report

Learn something about your Six Sigma program's maturity

by Zhen He

In 50 Words Or Less

- Six Sigma's use in a variety of industries has resulted in a focus on successful deployment.
- Assessing the maturity of program implementation, however, is often overlooked.
- By establishing assessment criteria, an organization can ensure continuous improvement.

SIX SIGMA HAS been a hot topic discussed and implemented globally in the business world, nonprofit organizations and even governments. It has also been an important academic research area in recent years (see sidebar, "Six Sigma in Print," p. 26). There is comparatively less research, however, into how to assess the maturity of Six Sigma implementation.

In a recent article, Prasad Raje outlined the five levels of Six Sigma development: launch, early success, scale and replication, institutionalization and culture transformation.¹ He also described the characteristics of each level from viewpoints such as leadership support, training, people, project selection, financial impact and software.

In doing so, he established a general framework for Six Sigma maturity assessment, but not a detailed one. For example, the framework didn't provide a measuring system to evaluate Six Sigma maturity. Six Sigma deployment within a business is a complicated process, and a maturity assessment requires systematic design from overall business perspectives.

IX SIGMA RATING Exceptiona Exceeds Re Meets Requi Needs Im August 2009 • QP 23

In 2006, I, along with other members of the School of Management at Tianjin University in China, surveyed 106 companies that implemented Six Sigma in China. We further investigated six companies that successfully implemented Six Sigma: Bao Steel, Taiyuan Iron & Steel Co. (TISCO), Haier, TCL Corp., Shanghai Hitachi Electrical Appliances Co. and Aviation Industry Corp. of China. We also conducted site visits to three foreign-invested companies and joint ventures: Motorola China, Dell China and Jiangling Motor (a joint venture with Ford).

As we analyzed the companies that used Six Sigma to achieve broad-based innovation and superior financial performance, we identified several distinguishing characteristics of their approaches that set them apart from those with a traditional operational improvement mind-set. Successful companies had:

- A strategic vision based on customer and market insights. Leaders crafted a compelling vision—not just from a Six Sigma perspective, but companywide—based on a keen understanding of market demands and their own capabilities.
- Leadership committed to continuous improvement. Senior business leaders played active and enthusiastic roles.
- Alignment across the extended enterprise. The strategic vision was used as a unifying force to align strategic and operational goals and to influence supplier and customer relationships.



Integration through the extended enterprise. Operations were characterized by processes that were repeatable and regularly evaluated for change and improvement in collaboration with other affected business units. Efficiencies across units were sought and achieved through analysis, innovation and sharing. Processes and measures tracked progress on key strategic and operational goals.

Based on the survey, analysis and face-to-face talks with Six Sigma Champions, Black Belts (BBs) and Green Belts (GBs), we discovered it's important to establish a set of Six Sigma maturity assessment criteria. That way, benchmarks can be created regarding where the company stands in terms of Six Sigma deployment, and strengths and weaknesses can be evaluated.

Finding a purpose

Like the Malcolm Baldrige National Quality Award criteria, the main purpose for an organization to establish Six Sigma maturity criteria is self-assessment. The program should be focused and collaborative to determine how best to integrate, align and deploy Six Sigma in an enterprise. As a result, it is an attractive tool for organizations looking to improve their performance over time and to continue the never-ending journey for performance excellence.

The maturity criteria can also provide an analysis of an enterprise's cultural transformation toward Six Sigma and help it:

- Improve Six Sigma deployment performance by understanding the big picture of Six Sigma management from the strategic to the operational level.
- Benchmark best practices and clearly understand where the company stands.
- Locate areas for improvement through gap analysis.
- Pinpoint specific steps to close the gaps.
- Identify an organization's strengths and weaknesses.

Establishing your values

To set up a Six Sigma maturity assessment model, it's important to clarify the management philosophy of Six Sigma. Previous studies show that what sets Six Sigma apart from prior quality management approaches isn't the underlying philosophy or the quality tools and techniques employed, but rather the manner of organizational implementation.²

Six Sigma is far more than a quality improvement program; it is a continuous improvement strategy and

an integration of contemporary management ideas, principles and tools. Its goal is to achieve continuous improvement by conducting Six Sigma projects that result in improved customer satisfaction, bottom-line costs or profits.

Six Sigma adopts the key principles and philosophies of ISO 9000, total quality management and the Baldrige criteria. It reflects the following core values, which should be fully understood by the executives of the organization that implements Six Sigma:

Commitment from high-level management. Six Sigma deployment is a top-down process. To deploy Six Sigma successfully within a company, management executives should have a long-term vision and must set up the needed infrastructure. SWOT (strengths, weaknesses, opportunities and threats) analysis and balanced scorecards can be used to align business strategy with Six Sigma and identify opportunities or critical areas for business improvement.

Customer-driven decisions and improved customer satisfaction. The ultimate objective for pursuing Six Sigma is not just to reach a high-level quality goal, but also to meet customer requirements. Organizations must go beyond customer satisfaction to customer delight via breakthrough business process improvement. Focusing on the voice of the customer (VOC) is a major tenet of Six Sigma, which requires that all business processes be customer-driven.

Organizational learning. Six Sigma is an effective way to push organizational learning. The actionlearning process of Six Sigma combines classroom training with projects and aligns employee learning, performance improvement, knowledge management and organizational learning.

Management by facts and data. Six Sigma methods focus on rigid data analysis. The processes of define, measure, analyze, improve and control (DMAIC) and define, measure, analyze, design, optimize and verify (DMADOV) are data-driven problem-solving processes. A business culture of data-based decisions can be cultivated through deployment of Six Sigma.

Cross-functional teamwork and breakthrough improvement. In general, Six Sigma breakthrough improvement can be achieved only if the project team is cross-functional. Traditional functional and organizational structure encourages people and departments to function alone, without collaboration. The fact is, most key business processes flow across many functional departments, and total business process optimization requires collaboration.

Focusing business results and value creation. The reason many companies invest money in Six Sigma is that its return on investment (ROI) is very high— Motorola University claims it ranges between 10:1 and $50:1.^3$ But most people believe the prevailing reason for an organization to implement Six Sigma is to cut costs or boost profits. Even though bottom-line profit or cost savings is very important for Six Sigma deployment, the benefits go beyond those areas to include customer satisfaction, human resource development, internal business process and supply chain improvements, and corporate culture transformation.

Building a framework

When drafting the criteria for Six Sigma maturity assessment, we adopted the Baldrige criteria and Motorola corporate quality system review (QSR) guidelines.⁴ A team of 24 people (including Six Sigma Champions, Master Black Belts and BBs) from industry and academia joined the meetings to discuss the framework, reached consensus and categorized the core values of Six Sigma:

- 1. Leadership.
- 2. Strategy.
- 3. Customer focus.
- 4. Infrastructure.
- 5. Project management.
- 6. Evaluation and motivation.
- 7. Business results.

Figure 1 depicts the framework and how the categories relate to one another. Leadership is the most important input for a successful Six Sigma deployment, and business results are the output.

Because Six Sigma is a customer-focused continuous improvement program, strategy is based on a customer focus. Using that strategy, the organization implements a project. Through the project review, evaluation and motivation system, the organization maintains the momentum of the program and continuously finds new opportunities for improvement. At the bottom is infrastructure, which provides systematic assurance of long-term success.

Exploring the criteria

The criteria consist of seven categories, 26 items and 47 areas for assessment, all of which contribute to a

1,000-point scale (see Table 1). Companies are divided into four categories: poor (a score less than 400), marginally qualified (400 to 600), qualified (600 to 800) and excellent (more than 800).

To facilitate the assessment process, we posed a question regarding how each area was evaluated. Then, we presented detailed considerations about the question.

For each question, the assessment team scored the result from 0 to 5—very poor (0), poor (1), fair (2), marginally qualified (3), qualified (4) and excellent (5)—followed by specific descriptions. The results were categorized as strengths or opportunities for improvement, and a total maturity score was obtained.

In addition, we developed an Excel worksheet with macros to help the assessment process. For example, for area 4.1.b (project selection procedure), the question, considerations and performance levels were described as follows:

SIX SIGMA IN PRINT

The Six Sigma body of knowledge grows by the day. For more information on Six Sigma deployment, check out the following:

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Question: Does the organization have a well-defined systematic and documented Six Sigma project selection procedure?

Considerations:

- There exists a well-defined systematic Six Sigma project selection procedure based on improvement opportunities.
- Improvement opportunity is determined through analysis of VOC or voice of the business.
- Six Sigma project selection is a top-down process involving the organization's executives or champions.
- The scope of the Six Sigma project is in line with SMART (specific, measurable, achievable, relevant, time-bound) objectives.

Performance levels:

- Very poor (0): There is no systematic Six Sigma project selection procedure. Six Sigma projects are selected by BBs or GBs without involvement of management executives or champions. Most of the project failures are due to poor project selection.
- Poor (1): There is no systematic Six Sigma project selection procedure. Six Sigma projects are selected by BBs or GBs. Projects are approved by management executives or Champions, but some are not closely aligned with organization strategy. Some project failures are due to poor project selection.
- Fair (2): There is a documented Six Sigma project selection procedure. Six Sigma projects are topdown and are selected with some involvement of management executives or champions. VOC and voice of the business are partly used in project selection. Inadequate management participation in Six Sigma project selection leads to inappropriate project scope or objectives.
- Marginally qualified (3): There is a documented Six Sigma project selection procedure. Six Sigma projects are top-down and are selected from business strategy with involvement of management executives or champions. VOC and voice of the business are utilized in project selection.
- Qualified (4): There is a well-defined and documented Six Sigma project selection procedure. Six Sigma projects are top-down and are selected based on business strategy, with strong involvement of management executives or Champions. VOC and voice of the business are fully used in project selection. Most Six Sigma projects are in line with SMART objectives.

Categories, items and areas for assessment / TABLE 1

Categories (with score)	Items (with score)	Areas (with score)				
1. Six Sigma	1.1 Organization vision and core values (20)	a. Vision (10) b. Core values (10)				
Leadership (100)	1.2 Executive leadership (80)	a. Visible resource support (40) b. Participation in Six Sigma (40)				
2.Customer focus (80)	2.1 Voice of the customer (VOC) and organization's response to customer requirements (40)	a. VOC and organization's response to customer's requirements (40)				
	2.2 Customer satisfaction (40)	a. Customer satisfaction metrics (20) b. Customer satisfaction measurement (20)				
3. Six Sigma strategy (80)	3.1 Six Sigma strategy development (40)	a. Strategy development process (20) b. Six Sigma and organization strategy alignment (20)				
	3.2 Six Sigma strategy deployment (40)	a. Deployment process (20) b. Key performance metrics (20)				
4. Six Sigma project management (170)	4.1 Project selection (30)	a. Opportunity identification (15) b. Project selection procedure (15)				
	4.2 Project team (30)	a. Team building (15) b. Teamwork (15)				
	4.3 Problem-solving procedure and tools (40)	a. Problem-solving procedure (20) b. Problem-solving tools (20)				
	4.4 Project plan and execution (40)	a. Project plan (20) b. Project process review (20)				
	4.5 Project evaluation (30)	a. Project evaluation (30)				
5. Evaluation and motivation (100)	5.1 Performance evaluation system (40)	a. Team performance assessment (30)b. Performance of people in charge of Six Sigma deployment (10)				
	5.2 Motivation (60)	a. Award and recognition (30) b. Career development (30)				
6. Six Sigma infrastructure (230)	6.1 Six Sigma deployment structure (40)	a. Structure (20) b. Objectives, responsibilities and resource allocation (20)				
	6.2 Six Sigma management system and procedures (40)	a. Six Sigma management system and procedures (40)				
	6.3 Six Sigma training system (30)	a. Training system and management (10)b. Body of knowledge (10)c. Contribution of training to Six Sigma projects (10)				
	6.4 Communication and employee involvement (30)	a. Communication (5) b. Exchanging with outside organization (5) c. Employee involvement (20)				
	6.5 Data management (30)	a. Quality and availability of data (20) b. Data-processing system (10)				
	6.6 Information system and sharing (30)	a. Support of information system (10) b. Knowledge management and sharing (20)				
	6.7 Six Sigma in supply chain (30)	a. Deployment in supply chain (20) b. Deployment with strategic partners (10)				
7. Business results (240)	7.1 Customer satisfaction results (40)	a. Customer satisfaction results (40)				
	7.2 Financial results (60)	a. Financial results (60)				
	7.3 Human resource development (40)	a. Talent cultivation (20) b. Employee satisfaction (20)				
	7.4 Internal business process improvement results (40)	a. Internal business process improvement results (40)				
	7.5 Supply chain improvement results (30)	a. Supply chain improvement results (30)				
	7.6 Corporate culture transformation results (30)	a. Corporate culture transformation results (20) b. Corporate social responsibility results (10)				

Maturity assessment scores / TABLE 2

Category											
Company	1	2	3	4	5	6	7	Total	Number of years since implementing Six Sigma		
Α	82	72	60	124	74	152	164	728	3.5		
В	76	80	68	148	76	199	202	849	6		
С	80	52	68	128	66	158	162	714	3		
D	82	52	52	134	70	140	162	692	2.5		
E	68	64	48	129	76	152	138	675	2.5		
F	78	48	40	125	80	142	132	645	2		
G	80	64	52	136	64	174	188	758	5		
Average (a)	78	61.7	55.4	132	72.3	159.6	164	723			
Full score (b)	100	80	80	170	100	230	240	1000			
Percentage (a/b)*100	78	77.1	69.3	77.6	72.3	69.4	68.3	72.3			

• Excellent (5): There is a well-defined and documented Six Sigma project selection procedure. Evidence shows the procedure is followed, with continuous improvement. Six Sigma projects are top-down and are selected in a team environment, with very strong involvement of management executives or champions. VOC and voice of the business are fully utilized in project selection. Six Sigma projects' scopes are in line with SMART objectives.

The scoring method for each area is very straightforward. For example, the full score of area 4.1.b is 15. If the performance level for 4.1.b is level 4 (qualified), then the final score of 4.1.b is (4/5) * 15 = 12.

Time to apply

From 2007 to 2008, seven Chinese state-owned enterprises were assessed using the criteria. These enterprises are leading companies in their industries, including iron and steel, home appliance, mining and aviation.

The companies, which had at least two years of experience implementing Six Sigma, asked the China Association for Quality (CAQ) to conduct field assessments to find strengths and opportunities for improvement. The field assessment process included face-toface talks with high-level management, Champions,

MODEL OF MATURITY

Let us know how your organization tracks the development of its Six Sigma projects (or whether it does) by logging on to www.qualityprogress.com and using the comment tool on this article's page. BBs, GBs and frontline workers; project review; and a review of the relevant Six Sigma documents, including training materials and Six Sigma project management files.

The assessors provided results and documented feedback about the companies' strengths and opportunities. The total scores and category scores for each company are in Table 2. From the results, you can see Company B scored "excellent," while the others were "qualified." The maturity level was positively correlated with the number of years since implementing Six Sigma.

Based on the current state of Six Sigma deployment in China, we propose a set of Six Sigma maturity assessment criteria that adopts facets of the Baldrige award and Motorola QSR. The criteria can be used for self-assessment and third-party assessment of Six Sigma deployment maturity. The ROI for conducting the assessment will be the result of improving the process of Six Sigma deployment.

Currently, more than 20 Chinese companies have adopted the criteria for self-assessment. Some companies also set up their own self-assessment criteria based on the criteria we proposed. A book about the criteria was published by Standards Press of China in 2007.⁵ That same year, the CAQ began to use the criteria to award businesses exhibiting Six Sigma excellence. **OP**

ACKNOWLEDGEMENT

This article is supported by the Natural Science Foundation of China and the Korea Science and Engineering Foundation. The development of the criteria was a result of relentless teamwork. It was first proposed by the CAQ and the School of Management at Tianjin University. Several companies—such as Bao Steel, China National Aero-Technology Import and Export Corp., TISCO and Dell China were involved in the development of the criteria. Yizhong Ma, a professor at Nanjing University of Science and Technology, and Xiaoming Gong of the CAQ also contributed to the development of the criteria.

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New FRONTERS

In 50 Words Or Less

- A Bayesian network can graphically represent cause and effect relationships between variables and provide management with insights that help guide improvement and follow-up actions.
- To demonstrate their effectiveness, Bayesian networks were applied to analyzing an annual customer satisfaction survey and a public opinion survey about utilities in Europe.

Bayesian networks give insight into survey-data analysis

by Ron Kenett and Silvia Salini

SELF-DECLARED OR interview-based surveys are a prime research tool in many application areas, such as risk management, customer satisfaction tracking and social science research. In such surveys, target individuals are requested to complete questionnaires, which can have anywhere from five to more than 100 questions.¹

Take, for example, an annual customer satisfaction survey directed at customers of an electronic product distributed worldwide. The survey assesses satisfaction levels regarding different features of the product and related services. The questionnaire is composed of 81 questions, including demographics and overall satisfaction.

An important output of the survey is to find out which aspects of the product and services influence overall satisfaction, recommendation level and repurchasing intentions. Demographic variables that can help profile customer responses include country, industry type and age of equipment.

As a second example, consider the Eurobarometer public opinion surveys regarding utilities conducted by the European Commission each spring and autumn throughout the continent.²

To derive answers and management insights from the data collected in these two surveys, we applied Bayesian networks, which, so far, have been rarely used in analyzing survey data.^{3, 4} Such techniques provide new frontiers in survey data analysis.

Bayesian networks

A Bayesian network is a graphical model representing cause and effect relationships between variables.⁵ In the case of a customer satisfaction survey, variables are typically measured on a scale, and the Bayesian network shows how the distribution of responses to one question affects the responses to another question.

This dependence is determined from tables of conditional probabilities derived from the survey data. The model can be used for diagnostic or predictive purposes. In the case of the customer satisfaction survey, the Bayesian network shows the type of responses from those who highly recommend the product, in contrast to the profile of responses from others who do not.

Bayesian networks are gaining popularity within a wide range of application areas, such as risk management, web data analysis and management science. Availability of software for analyzing Bayesian networks is further expanding its role in decision analysis and decision support systems. Some popular software implementations of Bayesian networks include GeNIe from the University of Pittsburgh, Hugin Decision Engine from Hugin Expert in Denmark, SPSS's Clementine and the bnlearn R-package.

Annual customer satisfaction survey

A Bayesian network was applied to data collected from 266 companies (customers) participating in the electronic product company's annual customer satisfaction survey, which was described earlier.

The data was analyzed using a basic Bayesian network implemented in the GeNIe version 2.0 software, presented in Figure 1. The network of cause and effect was generated automatically using specific learn-

Bayesian network of customer satisfaction survey data / FIGURE 1







ing algorithms. If needed, manual interventions to the network configuration are possible so that expert opinions can be used to either force a specific link or eliminate learned relationships.⁶

In the first part of the questionnaire, there is a set of questions grouped according to topic: equipment, sales support, technical support, training, supplies and media, customer portal, administrative support, site planning and installation, terms and conditions, and prices.

For each topic, there is an overall evaluation question. The topic with the highest level of satisfaction was training and the one with the lowest level was terms and conditions, and prices. We consider in the Bayesian network analysis presented here only the evaluation of overall satisfaction from each topic.

The second part of the questionnaire evaluates overall satisfaction from the company, with a score ranging from one (very low satisfaction) to five (very high satisfaction). Repurchasing intention and recommendation level both are measured with a score going from one (very unlikely) to five (very likely).

We observed that 59.5% of the customers are highly satisfied (level four or five), and 64.9% are very likely to purchase products from the company again.

Note that the topics that influence overall satisfaction, recommendation level and repurchasing intention were suppliers, equipment and technical support. The other topics appeared independent of one another. Moreover, overall satisfaction, recommendation and repurchasing were influenced by the customer's country. A bar plot representation of the distribution of responses to questions mapped by the Bayesian network is shown in Figure 2 (p. 33).

On the basis of the network, we can perform diagnostic checks. Figure 3 presents distributions of responses to questions for customers who indicated they are very likely to recommend the product to others. Observe that overall satisfaction and repurchasing changed in the same direction as recommendation. Note also that in Figure 2, the distribution of responses to overall satisfaction from technical support was 7%, 13%, 16%, 38% and 26% to scores of one, two, three, four and five, respectively; and 5%, 8%, 9%, 42% and 37% in Figure 3. So, high level of recommendation corresponded to high satisfaction level from technical support.

Specifically, 26% of customers are very satisfied with technical support, but when considering customers who would recommend the product, the number



Diagnostic distributions / FIGURE 3

Note: Based on the recommendation being at its highest level.
The Bayesian network shows how the **distribution** of **responses** to one question affects the responses to **another question**.

increases to 37%. This information has practical relevance because an intervention to improve technical support by increasing the number of very satisfied customers by 10% will significantly increase recommendation levels, along with repurchasing intentions and overall satisfaction.

Public opinion survey

In the second example, we used Bayesian networks to analyze the opinion of Europeans about utilities. The Eurobarometer public opinion surveys have been conducted each spring and autumn since 1973 on behalf of the Directorate General for Education and Culture of the European Commission.

An identical set of questions is asked to a representative sample of the population more than 15 years old in the European Union. In each household, the respondent is drawn at random. All interviews are face to face in people's homes and in the appropriate national language. The sample size is about 1,000 people per country.

In our application, we considered four services: fixed telephone, electricity supply, gas supply and water supply. For each service, we examined three aspects: accessibility, price and quality.

The data set we analyzed consisted of 12 dimensions: Accessibility of the fixed telephone service (SGIaccT), the accessibility of the electricity supply service (SGIaccE), the accessibility of the gas supply service (SGIaccG), the accessibility of the water supply (SGIaccW), the price of the fixed telephone service (SGIpriT), the price of the electricity supply service (SGIpriE), the price of the gas supply service (SGIpriG), the price of the water supply (SGIpriW), the quality of the fixed telephone service (SGIquaT), the quality of the electricity supply service (SGIquaE), the quality of the gas supply service (SGIquaG) and the quality of the water supply

(SGIquaW). We had three levels for accessibility (not accessible, difficult to access and easy to access), three levels for price (excessive, fair and low) and four levels for quality (very bad, fairly bad, fairly good and very good).⁷ The Bayesian network for this data is presented in Online Figure 1 at www.qualityprogress.com.

We noticed that country seemed to influence only electricity supply service, which affected all the other services. Year influenced electricity supply service and fixed telephone service. Relating to the aspects of service, accessibility was connected to quality and price, and quality was connected to price for all services.

It also was evident that services were not independent of one another. For example, the price of fixed telephone service (SGIpriT) also depended on access, quality and price of all the other services. A bar plot representation is shown in Online Figure 2.

On the basis of the network, as in the previous case, we can perform various diagnostic checks. Online Figures 3 and 4 present distributions of different variables based on results from Italy and Ireland, respectively.

Generally, the opinion in Ireland was better than in Italy. For example, the percentage of those who thought the price of gas services was fair was 75% in Ireland versus 52% in Italy; for the price of fixed telephone service, 66% fair in Ireland and 46% fair in Italy. For the quality of water, only 19% of Italians think that it is very good versus 62% in Ireland.

Online Figure 5 presents distributions of price of fixed telephone service based on the quality and access of fixed telephone service being at their highest level. Good quality and easy access positively influenced the opinion about price.

In fact, the distribution of price of fixed telephone service changed from 58% fair, 31% low and 11% high to 73%

MORE ONLINE TO FIGURE OUT

Check out Online Figures 1-6 for results from the authors' analysis of a survey of Europeans regarding public utilities. Visit this feature article's page at www.qualityprogress.com and click on "online-only content."

fair, 21% low and 7% high. This is important evidence for suppliers and legislators who may be involved in regulating utilities.

Online Figure 6 presents distributions of attitudes to price of fixed telephone based on the price of the other services being at their lowest level. With 100% of prices considered low in other services, the distribu-



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tion of price considerations of fixed telephone will be 19% fair, 76% low and 5% high.

Raising awareness

Analysis of survey data can be improved by using several recent advances in data analytics, data mining and statistical techniques, such as cluster analysis, deci-

sion trees, structural equation models and neural networks.

Bayesian networks and analytical hierarchical processes can be used to more effectively analyze survey data. More application of such techniques, with more details and more examples, are presented in two upcoming issues of *Quality Technology and Quantitative Management*. We hope this article will help further raise awareness of such techniques in analyzing data from surveys. **QP**

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In 50 Words Or Less

- The June 2008 flood that ravaged Cedar Rapids, IA, damaged 700 businesses, including Cargill Corn Milling's facility.
- Thanks to a qualityfocused system, the company resumed operations less than three months later.
- Its emphasis on best practices and robust processes helped the company earn a 2008 Baldrige award.

by Brett Krzykowski, assistant editor

> FLOODWATERS FROM THE Cedar River submerged Cargill Corn Milling's facilities in Cedar Rapids, IA—along with the rest of the city—in June 2008. (Photo courtesy of Jeremy Baker)

A Baldrige recipient's nature-defying approach to improvement

it decides to subject itself to the rigors of the Malcolm Baldrige National Quality Award review process. The site visit alone is enough to shoo away any company that doesn't approach quality with steadfast dedication.

During the course of a week, a team of six to eight examiners and a member from the Baldrige National Quality Program staff descend on as many of the applicant's locations as time allows. Any questions team members have about the application need to be answered, and information is verified as the organization is scrutinized in a manner normally reserved for Supreme Court nominees.

Cargill Corn Milling North America (CCM) approached its site visit in October 2008 with the same level of preparation and seriousness any organization would, but also with a perspective few possess. After all, not many applicants find themselves in the middle of a natural disaster the same year they apply for —let alone receive—the award. On June 13, 2008, the Cedar River crested at 31.2 feet—20 feet above flood stage—and engulfed Cedar Rapids, IA. The event defied the Titanic-like confidence of the 120,000 residents who boasted that the city "would never flood."¹ It even spat in the face of statistics.

CCM's Cedar Rapids facility sits on the outskirts of downtown and on the edge of the city's 500-year floodplain. The designation means that in any given year, there is a 0.2% chance of flooding. Anyone betting against those miniscule odds lost in 2008, when the surging waters damaged or destroyed 700 businesses

Best practices model / FIGURE 1



and 5,390 homes, 1,300 of which needed to be razed as a result.² CCM was not immune to the swath of destruction, as it sustained an estimated \$100 million in damages to its facilities.³

Just four months later, as part of the companywide assessment of CCM, Baldrige examiners toured the restored plant, which was back to its previous capacity and then some, after adding two new product lines. A month later, CCM President Alan Willits received a phone call from U.S. Commerce Secretary Carlos Gutierrez, who informed him of the company's Baldrige honor.

"It was a really powerful message to me about how you can use Baldrige effectively, as well as the power of robust processes," Willits said. "What I mean by that is if you have robust processes, they adapt to the situation."

Setting the stage

Of course, CCM didn't go from submerged to celebrated in five months. Its commitment to quality reaches back to the mid-1980s, when it began to implement the principles of total quality management and process controls. An early adopter in the Cargill family, CCM applied for—and won—several company awards, which contributed to Cargill creating its own quality department and adopting the Baldrige criteria as a companywide strategy.

Given its past success, Willits recalled, CCM anticipated little trouble getting its arms around this new set of criteria and adding to its already impressive cache of company awards. Much to the surprise of management, however, CCM didn't even merit a site visit when it first applied for the Cargill Chairman's Quality Award, which mirrors the Baldrige criteria.

Confident the oversight had to be the result of a clerical error or some other administrative issue, CCM's leadership met with Cargill President Gregory R. Page on Nov. 6, 2002, and were spoon-fed a giant helping of humble pie.

"We were kind of expecting redemption and to find out, 'Yeah, Corn Milling is great," Willits said. "He basically said, 'If you're as good as you think you are, get to work and prove it.' For our leadership team, that was really a defining moment, where we said, 'Oops, we're not as good as we think we are, and we really need to change how we're doing things.' Effectively, we had to become a process-honoring culture. It was really at that point that we decided to take a different approach to how we run the business."



DOWNTOWN CEDAR RAPIDS' highways became waterways June 13, 2008, when the Cedar River crested at 31.2 feet and damaged 700 businesses, including Cargill Corn Milling's facility.

That wasn't going to be easy for CCM, which had to change the culture of nine manufacturing facilities primarily located east of the Mississippi River and 11 distribution terminals that extend from California to Florida, as well as a pair of sales offices (see "CCM Fact Sheet," p. 42). As Willits put it, "The challenge is turning the ship, or in our case the fleet of ships, and getting everyone headed in the right direction. That's a tough thing to do."

It's even more difficult when the ships in that fleet chart their courses independent of one another and, on occasion, open fire on their own.

At that time, Willits said, CCM's system encouraged plants to compete against one another—a fragmented approach that worked well enough for the enterprise to boast of a well-stocked trophy case. But a holistic effort was necessary to achieve a higher level of success.

All the best

That effort included a renewed emphasis on the implementation of common processes across the company and a deployment method CCM calls its Best Practices Model (BPM), both of which eventually contributed to the resurrection of the Cedar Rapids facilities.

"We didn't want to just have best practices well deployed at a particular facility," Willits said. "Times had changed, so we had to move beyond that. That required structure change, process change, a lot of time communicating our expectations to our people, putting incentive systems in place—all of the things that go with having a systematic approach like Baldrige."





A major part of that approach is the nine-step BPM (see Figure 1, p. 40), a blueprint for CCM's Process Development Groups (PDGs) that can be found throughout the enterprise. The sole purpose of the PDGs is to identify best practices and quickly—sometimes violently, Willits said, half-jokingly—implement them across the system.

The result is a symbiotic relationship between the PDGs and the BPM. While it's important to have a unit devoted to improvement, Willits said, it's crucial in a complex manufacturing environment to identify a tool capable of driving that improvement. By the same token, he continued, quality tools aren't nearly as effective without a team that knows how to wield them properly.

Knowing that a slapdash approach would simply perpetuate the lone-wolf structure that had been in place, CCM set up the PDG system in such a way that it would standardize procedures and best practices across the enterprise. Each group is comprised of at least one employee from each of CCM's manufacturing facilities, in addition to the PDG leader, to encourage collaboration among the company's facilities, functional areas and product lines.

This cross-functional strategy has been wildly successful for CCM, which has seen the savings resulting from PDG activities more than double from fiscal year (FY) 2003 to FY 2008 (see Figure 2, p. 41).

All told, CCM has recorded hundreds of millions of dollars in cumulative savings since establishing the PDG process in 1999. But the PDGs can only claim partial credit for that bump to the bottom line. To achieve those results, they needed help from more than 2,000 contributors who also double as CCM's total workforce.

Wanting to include every employee in its improvement efforts, CCM established its "idea to innovation" (i2i) process, which uses a computer-based system to collect and track suggestions to improve efficiency and help the company meet its business goals. In the process:

- 1. Ideas are entered into the i2i system by CCM employees.
- 2. All ideas are reviewed by cross-functional innovation review teams (IRTs).
- 3. The IRTs analyze ideas using an idea prioritization matrix or the team's first-hand knowledge of the idea's feasibility or potential effectiveness.
- 4. Idea mentors are assigned to see the idea through to its realization or to inform the originator of the idea why it is not being advanced.

CCM FACT SHEET

Cargill Corn Milling North America (CCM) is a business unit of Cargill Inc. that manufactures and markets corn and sugarbased products. Its products include corn syrup, high-fructose corn syrup, sugar, corn oil and dry corn ingredients; gluten feed and meal; and ethanol, acidulants (substances added to food or beverages to lower their pH) and industrial starches. CCM supplies 60-plus products to more than 3,000 customers in the food, feed and fermentation markets.

With revenues of more than \$1 billion and 2,321 employees, CCM's headquarters is in Wayzata, MN. It has eight manufacturing facilities in seven states (Illinois, Indiana, Iowa, Nebraska, North Dakota, Ohio and Tennessee), 11 distribution terminals in seven states (California, Florida, Maryland, Massachusetts, Tennessee, Texas and Washington) and two sales offices in Coral Gables, FL, and Naperville, IL.

Highlights from Baldrige application

- Earnings after tax tripled from fiscal year (FY) 2003 to FY 2007.
- Maintained an error-free delivery rate of about 99% from FY 2005-2008.
- From FY 2004-2008, increased its overall employee engagement score from 37% to 65%.
- Complaints per shipment were less than 0.2% in FY 2008.
- Third-party audits of food safety, sanitation and quality processes have resulted in scores of more than 900 (superior) from FY 2003-2008. B.K.

"We had **all the processes** in place. We were simply able to use them to react to a **very significant and difficult event."**

In FY 2008, savings from employee ideas topped \$5 million, while the suggestion rate exceeded 0.9 ideas per employee (see Figure 3).

"Since we rolled this out, we've had thousands of suggestions and millions of dollars in real-value creation," Willits said of the i2i process. "But, most importantly, it really helps validate our employees, because they understand they're being heard and that their ideas really matter and have an impact. That's how we make continuous improvement everyone's job."

Helping the recovery

Fostering a work environment in which everyone feels included has allowed CCM to identify problem areas and roll out improvement in every facet of its activities, Willits continued. And never was that body of knowledge more needed than during the floods of June 2008 and the months that followed, when the company called on any and every expert it could identify to revive its Cedar Rapids facility.

The floodwaters crested on a Thursday, and by the following Tuesday, Willits recalled, CCM re-established its presence in the plant to evaluate the damage. In the end, 600 motors, 500 pumps and more than 100 blowers needed to be removed and reconditioned.⁴ Seven days after the flood, CCM had about 500 people in the plant, including all 200 employees, working to get the facility up and running again—a process made considerably less arduous by the business culture already in place.

"We didn't need to go back and ask how we were going to manage this project," Willits said. "We didn't need to ask how we were going to do procurement. We didn't need to ask how to communicate to customers in an emergency. We didn't need to ask how to respond to a community that's in the middle of this major event. We had all the processes in place. We were simply able to use them to react to a very significant and difficult event. That's when you see the light and that these processes are truly powerful because they can adapt to things you frankly never thought would happen."

It wasn't just about a return to normalcy, though. In addition to the two new product lines, the 40-year-old plant received a facelift to integrate the latest technological advances, an effort that involved a 900-member workforce at the peak of CCM's four-month efforts. The company also constructed 12 temporary buildings on site that served as project headquarters and paid its employees throughout the entire recovery process.⁵

Less than three months after the flood, operations resumed at the Cedar Rapids facility. By November, the same month CCM was recognized for its robust processes, those same processes had the plant running at full capacity again.

"It was a matter of trying to address our customers' needs. We needed to get that plant up and running as soon as possible," Willits said. "That's an example of having everyone in the business involved as far as knowing how they can help the organization. We've had feedback from external people who were involved who said they had never seen any company in any setting be able to marshal the resources and bring them to bear like this." **QP**

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UPDATED AWARDS LISTINGS

For an extensive listing of quality-related awards, including a state-by-state breakdown, log on to www.qualityprogress.com and look under the "Tools & Resources" menu.

^{5.} Ibid.

GET Your Checkup

ASQ study looks at hospital deployment of lean and Six Sigma

In 50 Words Or Less

- A recent ASQ survey looked at why hospitals are driven to pursue lean, Six Sigma or both.
- The study also examined deployment, targets and specific tools.
- The results offer a range of benchmarks and a first look at the possible future of healthcare improvement efforts.

by the ASQ Lean Six Sigma Hospital Study Advisory Committee

FOR NEARLY 20 YEARS, lean and Six Sigma improvement initiatives have been in the quality spotlight, helping thousands of organizations in the United States and elsewhere. But are hospitals across the United States truly embracing the lean and Six Sigma movement, and if so, are these efforts making a difference?

Lean is based on long-held practices advanced by the Toyota Motor Corp., with an emphasis on removing waste from organizations while focusing on and delivering more value to customers. Six Sigma focuses on variation reduction in processes, products and delivered services. Although both methods are applicable in a wide array of industries, they have received the most attention in manufacturing. In the last decade, however, these two distinct improvement approaches have moved—independently or together—into many nonmanufacturing fields, such as service, insurance and financial businesses.

Healthcare professionals, too, have sought to apply the principles and tools of lean and Six Sigma in their organizations, with many examples and case studies of successes, such as Virginia Mason Hospital/Medical Center in Seattle, the Mayo Clinic in Rochester, MN, and Massachusetts General Hospital in Boston.

While anecdotal success stories provide promise and incentive to organizations considering these initiatives, there's been little substantive proof of the efficacy of these methods in healthcare institutions. Last year, ASQ attempted to identify the level of adoption of lean or Six Sigma practices at U.S. hospitals and, if possible, assess the correlation of these improvement initiatives with management, operational and financial performance.

The questionnaire

ASQ sent an online questionnaire to a list of hospitals and to ASQ members participating in the healthcare sector, with 77 hospitals responding. The questionnaire consisted of 31 questions, accounting for 246 variables.

Respondents to the "ASQ Hospital Study" were predominantly senior-level executives: 70% of responses came from titles of CEO, COO, CFO, VP, chief medical officer, chief quality officer or lean/Six Sigma leader.

The study attracted the attention of only a small percentage of the approximately 5,000 hospitals nationwide. It is, therefore, not surprising that the most basic of the study variables at full participation provide a confidence interval of approximately ± 11 at 95% confidence level. Subquestions related to those hospitals deploying only lean or Six Sigma are even less statistically significant.

Nonetheless, all study analysis provides a range of benchmarks that have been lacking to date for hospitals considering lean or Six Sigma.

Hospital deployment / TABLE 1						
	Lean	Six Sigma	Lean Six Sigma			
No deployment	47.2%	57.5%	62.9%			
Minor deployment	44.4%	26%	27.1%			
Moderate deployment	4.2%	8.2%	4.3%			
Full deployment	4.2%	8.2%	5.7%			

Deployment

Many U.S. hospitals are now keenly aware of the need for improvements in core processes and are deploying lean and Six Sigma to address this need: 53% of study hospitals report some level of adoption of lean, 42% some level of adoption of Six Sigma and 37% some level adoption of the hybrid approach of lean Six Sigma.¹

Study hospitals that have deployed lean, Six Sigma or both cite the following as the most frequent criteria for targeting an area or areas of their facilities for improvement.²

- Lean: Throughput need (73% of hospitals), business or cost need (68%) and quality need (56%).
- Six Sigma: Business or cost need (69%), quality need (62%) and throughput need (41%).

Among the study hospitals where deployment has not begun, it's generally not for lack of interest or belief in the concepts. Of the nondeployers of lean, Six Sigma or lean Six Sigma, none indicated that they don't need it or don't believe it works, and only 11% of respondents indicated they didn't know what these methods were.³

Respondents indicated the chief reasons for nondeployment are lack of resources (59%), not enough information to deploy (41%), lack of buy-in from leadership (30%) and lack of deployment talent (22%). Other reasons not listed are cited by 26%.⁴

The survey's deployment findings should be encouraging to those looking for ways to change how their hospitals operate. The findings indicated that a high percentage of healthcare facilities are beginning to use these tools and concepts. But "beginning" is the operative word. For example, although 53% of study hospitals reported they have deployed lean, 44% identify deployment as minor, 4% as moderate and 4% as full. The other approaches were similarly limited in effort (see Table 1).

Minor deployment efforts usually occur in one of two ways within organizations:

- One or two departments apply a palette of improvement tools to upgrade performance (frequently referred to as creating islands of excellence in an organization). Often, these efforts fail to impact overall hospital performance and are difficult to sustain without the momentum of a wider, deeper effort within the organization.
- There is focus on only minor areas (such as housekeeping) or minor tools (such as visual management) and on attacking low-hanging and often lowimpact fruit within the organization.

It can be argued, however, that even minor deployment is necessary to gain any type of improvement foothold. And starting—where, how and with whom—can be the most challenging aspect of improvement, frequently followed by an ability to sustain improvements.

The inability to sustain improvement was cited by 68% of study hospitals as the greatest challenge to achieving successful lean deployment and by 53% of hospitals as the greatest challenge to achieving successful Six Sigma deployment (see Table 2). Other challenges include competition from other initiatives, level of leadership commitment and availability of resources.⁵

Targets and success

The study sought to identify the locations or departments in hospitals that are most frequently targeted for deployment of lean or Six Sigma initiatives. The study asked respondents to identify whether lean or Six Sigma had been deployed in an area and to report on the general rate of success with the deployment.

The sample size of hospitals responding to these questions was relatively small—about 30 to 40 hospitals for the deployment portion, with many of those responders indicating that the success rate portion of the question was not applicable, thus further reducing

Greatest challenges to successful deployment / TABLE 2

	Lean	Six Sigma
Sustaining improvements	68.3%	52.6%
Competition from other initiatives	58.5%	47.4%
Leadership commitment	53.7%	52.6%
Availability of resources	51.2%	55.3%
Building employee knowledge	34.2%	42.1%
Motivating employees	31.7%	39.5%
Expertise	22%	26.3%
Scaling up the effort	14.6%	29%
Other	2.4%	2.6%
No challenges	0%	2.6%

the number of hospitals that indicated success. So, while these data are not statistically significant, they nonetheless provide insight into popular deployment targets among the study sample.

Based on the responses, departments within clinical areas of study hospitals are more likely to be selected for lean deployments than ancillary services or nonclinical support services. This isn't surprising because throughput and quality are typical objectives for lean deployments and are core to hospitals' successes or failures.

But consider: Because nonclinical areas actually

Donloved in Not Somewhat Highly

Lean deployment locations and successes / TABLE 3

an	and successes / TABLE 3		area	successful	successful	successful
		Surgery and operating room	60.5%	5%	75%	20%
ical	Emergency	60%	13.6%	77.3%	9.1%	
	In-patient (not mental health, rehabilitation or intensive care unit)	52.8%	15.8%	78.9%	5.3%	
	Outpatient and ambulatory (not mental health or rehabilitation)	50%	5%	75%	20%	
- 5		In-patient intensive or critical care	28.6%	16.7%	75%	8.3%
Ŭ		Home health	16.7%	14.3%	71.4%	14.3%
		Rehabilitation	11.8%	33.4%	66.7%	0%
		Mental health	11.1%	25%	75%	0%
cillary support vices	Admissions and discharge	42.9%	5.6%	77.8%	16.7%	
	se s	Radiology and imaging	42.9%	12.5%	68.7%	18.8%
	ž	Pharmacy and pharmaceutical services	28.6%	30.8%	53.9%	15.4%
AP	Se S	Sterilizing and reprocessing	27.8%	11.1%	77.8%	11.1%
	5	Patient transportation	19.5%	20%	70%	10%
		Purchasing and supply	36.1%	21.4%	64.3%	14.3%
nclinical/ upport	Information systems	24.3%	11.1%	77.8%	11.1%	
	Administration	24.3%	12.5%	37.5%	50%	
	Accounting	19.5%	25%	50%	25%	
NOI SI		Maintenance	11.4%	16.7%	83.3%	0%
		Other	57.1%	0%	71.4%	28.6%

Note: Deployment percentage subtracts from 100% of the hospitals that answered "not applicable: department or function does not exist at this hospital," "no deployment or projects underway" and "deployment not underway, but planned." Success-rate percentages are prorated based on the hospitals indicating success and excluding "not applicable: department does not exist or deployment not underway."

resemble the processes targeted by traditional lean deployments in other industries, it's surprising that more isn't being done in these areas—especially given the large number of case studies and benchmarks offering guidelines for successful implementation.

Hospitals were asked to indicate the state of lean deployment for each area and to indicate the general rate of success of those distinct efforts (see Table 3, p. 47). Targets and success rates for lean deployments with hospitals were:

- Clinical: The most popular targets for lean deployment in clinical areas were operating rooms (61% of hospitals), emergency (60%), and in-patient areas, not including mental health, rehabilitation or intensive care units (53%). The highest percentages of success (combined percentages for somewhat successful or highly successful) were found in operating rooms (95% of hospitals that indicated lean success there), outpatient and ambulatory (95%) and emergency (86%).
- Ancillary and support services: The most popular targets in ancillary services for lean deployment were admissions and discharge (43% of hospitals), and radiology and imaging (43%). The highest percentages of success were admissions and discharge

(94% of hospitals that indicated lean success there), sterilizing and reprocessing (89%), and radiology and imaging (87%).

• Nonclinical support: The most popular targets for lean deployment in nonclinical areas were purchasing (36% of hospitals), information systems (24%) and administration (24%). The highest percentages of success were found in information systems (89% of hospitals indicated lean success there) and administration (87%).

Departments within clinical areas of hospitals were more likely to be targeted for Six Sigma deployments than ancillary services or nonclinical support services. Hospitals were asked to indicate the state of Six Sigma deployment for each area and the general rate of success of those distinct efforts (see Table 4).

Targets and success rates for Six Sigma deployments with hospitals were:

• **Clinical:** The most popular targets for Six Sigma deployment in clinical areas were emergency (72% of hospitals), surgery or operating rooms (66%) and in-patient areas, not including mental health, rehabilitation or intensive care units (59%). The highest percentages of success were found in operating rooms (95% of hospitals indicated Six Sigma suc-

Deployed in Not Somewhat Highly

Six Sigma deployment locations and successes / TABLE 4

			Dopioyou in		ouroopooful	
			area	successful	successful	successful
		Emergency	71.9%	12.5%	66.7%	20.8%
		Surgery and operating room	65.6%	4.5%	81.8%	13.6%
		In-patient (not mental health, rehabilitation or intensive care units)	59.4%	5%	80%	15%
ica		In-patient intensive and critical care	39.4%	14.3%	57.1%	28.6%
ij		Outpatient and ambulatory (not mental health or rehabilitation)	53.1%	10.5%	73.7%	15.8%
0		Home health	25%	22.2%	44.4%	33.3%
		Mental health	18.2%	16.7%	50%	33.4%
		Rehabilitation	15.6%	28.6%	42.9%	28.6%
Ľ		Admissions and discharge	56.3%	10%	80%	10%
ary ses	. Se	Radiology and imaging	53.1%	11.1%	50%	38.9%
cill	ž	Pharmacy and pharmaceutical services	50%	11.8%	64.7%	23.5%
Ab	Sel	Sterilizing and reprocessing	21.9%	12.5%	62.5%	25%
al		Patient transportation	25%	20%	50%	30%
~		Purchasing and supply	53.1%	12.5%	62.5%	25%
inical/ port	Ч	Information systems	24.2%	9.1%	72.7%	18.2%
		Maintenance	21.9%	11.1%	66.7%	22.2%
upl upl		Administration	15.6%	0%	50%	50%
2	07	Accounting	15.2%	14.3%	42.9%	42.9%
		Other	57.1%	0%	71.4%	28.6%

Note: Deployment percentage subtracts from 100% those hospitals that answered "not applicable: department or function does not exist at this hospital," "no deployment or projects underway" and "deployment not underway, but planned." Success-rate percentages are prorated based on the hospitals indicating success and excluding "not applicable: department does not exist or deployment not underway."

Respondent demographics / TABLE 5

	For-profit	5.2%
Is this hospital for-profit or nonprofit?	Nonprofit	94.8%
Is this hospital independent or part of a	Independent	49.4%
hospital system?	System	50.7%
If part of a hospital system, how	Median	11
many hospitals are in the system?	Average	23
In this a tapphing bosnital?	Yes	23.7%
	No	76.3%
	Less than \$25 million	8.3%
	\$25 million to \$100 million	23.6%
What was your hospital's approximate	\$101 million to \$250 million	23.6%
gross revenue in 2007?	\$251 million to \$500 million	29.2%
	\$501 million to \$1 billion	11.1%
	More than \$1 billion	4.2%
How many staffed hade?	Median	161
How many staned beus?	Average	231
Llow mony boonital admissions in 20072	Median	8,402
How many nospital aumissions in 2007?	Average	11,441
How many total hospital days of patient	Median	38,691
care in 2007?	Average	59,936
	Private payers	28.2%
What is your hospital's payer mix (based on	Government payers	59.5%
average responses to each payer group)?	Self-pay	6.5%
	Other	5.9%
	Staff physicians, medical scientists and research associates	204
Please report hospital staffing levels	Residents, fellows and students	20
for 2007 (based on average	Administration and support personnel	774
	Other staff	867
	Total staff	1,865
What is the approximate age of the	Median	30
majority of your physical plant?	Average	28.5

cess there) and in-patient areas, not including mental health, rehab or intensive care units (95%).

- Ancillary and support services: The most popular targets for Six Sigma deployment in ancillary services were admission and discharge (56% of hospitals), radiology and imaging (53%) and pharmacy and pharmaceutical services (50%). The highest percentages of success were admissions and discharge (90% of hospitals indicated Six Sigma success there), radiology and imaging (89%) and pharmacy and pharmaceutical services (88%).
- Nonclinical support: The most popular targets for Six Sigma deployment in nonclinical areas were purchasing (53% of hospitals), information systems (24%) and maintenance (22%). The highest percentage of success (combined percentages for somewhat successful or highly successful) were found

in administration (100% of hospitals indicated Six Sigma success there) and information systems (91% of hospitals).

Half (median 50%) of lean deployments cut across hospital departments and, similarly, 50% (median) of Six Sigma deployments cut across hospital departments.⁶

In addition to deployment by location, those who participated in the study were asked to identify what areas of improvement hospitals were targeting when they deployed lean and Six Sigma hospitalwide. For lean, the highest percentages were turnaround time (63% of hospitals), productivity (59%), capacity use (49%), quality of care (46%) and staff use (46%).

The highest percentages for Six Sigma were turnaround time (63% of hospitals), productivity (56%), quality of care (54%), capacity use (51%) and staff use (44%).⁷

A majority of hospitals have applied the following

specific lean and Six Sigma tools in their organizations:8

- Value-stream mapping (84%).
- 5S (80%).
- Failure mode effects analysis (80%).
- Define, measure, analyze, improve and control (75%).
- Pareto analysis (73%).
- Statistical process control and control charts (73%).
- Project charters (71%).
- Plan-do-check-act/adjust (59%).
- Five whys (55%).
- Seven or eight wastes elimination (55%).
- Visual management or organization (55%).

The figures on deployment (locations, criteria and specific tools) highlight significant lean and Six Sigma activity within many hospitals. What we found sobering were the findings indicating the cost of lean and Six Sigma at study hospitals deploying the initiatives in 2007: \$25,000 (median) for lean and \$96,485 (median) for Six Sigma.⁹

While lean has always been heralded as a low-cost improvement activity, the lean and Six Sigma investment figures were surprisingly low for the size of these healthcare facilities (see the survey demographics in Table 5, p. 49).

Impact

Correlating lean and Six Sigma deployments of hospitalwide improvement projects is hardly a straightforward exercise. Correlation is complicated by a variety of factors in the study data and the hospitals responding to the study:

- A relatively small percentage of deployment with any one improvement initiative and, thus, small beginning samples for cross-tabulations of data.
- Even smaller percentages of moderate or full deployment with any one improvement initiative, where strong correlations with improved performance would be expected.
- A high percentage of hospitals, especially those without lean or Six Sigma deployments, that don't track many relatively common operational metrics (length of stay and patient complaints, for example) and financial metrics (cost per patient and total asset turnover, for example) that appeared on the study.

Given these considerations, it's not surprising the correlation between deployment of improvement methods within study hospitals and improved operational and financial performance appeared equivocal.¹⁰

Based on those findings from a small sample, it would also be easy to question whether lean and Six Sigma have real, broad impact across hospitals nationwide, rather than just in isolated departments, or any ability to close the gap between good and bad metrics.

Yet, based on the success of these methods in other industries and on an increasing number of anecdotal hospital case studies, the real questions may be:

- What would the results be if hospitals deployed lean and Six Sigma at deeper and broader levels and for longer periods?
- What would the real results be if hospitals, especially those without lean or Six Sigma deployments, tracked the common operational and financial metrics that appeared on the study?
- How would hospitals without lean or Six Sigma deployments compare with those hospitals that did deploy the methods?
- What if other hospitals—those oblivious to lean or Six Sigma, or those that had the need for improvement in general—had participated in the study?

The "ASQ Hospital Study" provides an intriguing first look at a more efficient healthcare future. It suggests the next step toward improvement for most hospitals is a broader deployment of lean and Six Sigma and rigorous tracking of their results. **QP**

NOTES

- Three separate questions were used to assess the deployment levels of the three improvement methods, with respondents able to select "no deployment," "minor deployment," "moderate deployment" and "full deployment."
- 2. Hospitals were presented an array of criteria and allowed to select more than one response.
- 3. Hospitals could select one or more responses from an array of factors.
- 4. Hospitals could select one or more responses from an array of factors.
- 5. Hospitals could select one or more responses from an array of factors.
- Hospitals were asked, separately pertaining to lean and Six Sigma, what percentage of their deployments and projects cut across hospital departments.
- 7. Hospitals could select one or more responses from an array of criteria.
- 8. Hospitals could select one or more responses from an array of tools.
- For lean and Six Sigma spending, one respondent indicated \$0 on the deployments.

10. Data are available at www.qualityprogress.com.

EDITOR'S NOTE

This article was prepared by the ASQ Lean Six Sigma Hospital Study Advisory Committee, which included ASQ members and subject matter experts. Results of the survey were compiled by a partnership of two independent research organizations, the MPI Group and Industry Insights, which also assisted ASQ in designing the study. The complete study, "ASQ Hospital Study Data Report," is available at www.qualityprogress.com.

Call to Order

Useful technique for removing emotion from the equation

IN SUMMER 2001, I was working as a quality engineering manager in New Hampshire. While living there, I became involved in local government—much to the chagrin of my patient wife.

Among other positions, I was serving as a member of the town's budget committee, when the budget committee chairs and school board members asked me to serve on a new high school site-selection committee as the budget committee representative. I had not been active on this subject and thus was viewed as impartial. I accepted after much arm-twisting and ego-stroking.

This was a highly controversial topic



in the town. High-school students from an adjoining town attended our high school, resulting in overcrowding. The cost of building the new school would be funded by both towns.

In addition, the current high school was a bit outdated and needed capital improvements if it was going to continue to be used. An apparent slight majority in town thought we should build a new school. A vocal minority felt students from the adjoining town should simply go somewhere else. The town had been through a couple of years of failed efforts to build a new school due to the need for a super-majority for passage of the capital improvement.

A meeting of foes

The time came for our first meeting. The committee was made up of five of the most vocal opponents and supporters of the need for a new school—and me.

The first order of business was to select a committee chair. The group of opponents nominated a member from the sup-

> porter groups to act as chair, and visa versa. Each time, nominees turned down the opportunity, stating they had been so vocal in the past that it was unlikely the committee's work would be viewed as impartial if they were selected chair.

After going back and forth, I was the only one who had not directly turned down the offer. I accepted the nomination on the

condition we would strictly follow Robert's Rules of Order¹ and use a data-driven method of my choosing for determining our recommendation for the site. The members unanimously (minus me) agreed, and I reluctantly became the chair. We selected a secretary for the committee and reviewed our charter from the school board.

Our next meeting was on the evening of

Sept. 11, 2001. We wanted to get to work to respect those who fell that day. The meeting started solemnly with prayer, and it moved forward from there.

I proposed we develop and use the Kepner-Tregoe decision analysis technique. I had used the technique in the past, and it had proven extremely effective in significantly reducing the emotional aspects of a decision by determining quantifiable musts and wants in advance and then using data to populate the matrix.

Our musts were specific lot size, transportation access and an owner who was willing to sell.

Making a recommendation

Our meetings were cordial and productive despite it being a gathering of foes. We identified three land plots as meeting our musts. As a committee, we walked each lot and ranked them against our wants. In the end, the committee voted unanimously to select one of the three as the recommendation from the committee.

In the end, the purchase failed at election time, but this was a great experience for me. It proved once again that the Kepner-Tregoe decision analysis tool is an excellent method for getting a group of foes to agree on a solution without creating anger and resentment. In the end, it was a positive experience for all. **QP**

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3.4 PER MILLION BY T.M. KUBIAK

Perusing Process Performance Metrics

Selecting the right measures for managing processes

OFTEN, I HAVE students ask for clarification about the subtopic level in the 2007 Six Sigma Black Belt body of knowledge (BoK) that deals with process performance metrics. Perhaps the students are confused because of the sheer number of metrics or maybe because of some subtle differences among the metrics.

I hope this article can resolve a lot of the confusion surrounding the various process performance metrics. Based on my review of the literature, I'm offering my interpretation of these metrics. I suspect many differing opinions will continue to exist, however, and there may be a flurry of letters to the editor after this appears.

Before I attempt to clear things up, it's worthwhile to revisit each of the process performance metrics identified in the BoK, explore the relationships among the metrics and look at examples of each. The performance metrics include:

- Percentage defective.
- Defects per unit (DPU).
- Defects per million opportunities (DPMO).
- Parts per million (PPM).
- Rolled throughput yield (RTY).
- Process sigma.

Before examining each metric, however, it's important to define "defect" accurately to provide a foundation for interpreting these metrics in a meaningful way.

Building the foundation

To use the defect-based metric effectively, it is important to answer:

- What is a defect?
- How can a defect occur?

What is a defect? I have always lived by the mantra that "anything not done correctly the first time is a defect." Of course, this means understanding what it takes to "do it right the first time." Simply put, a defect occurs during any process (for ex-



ample, assembly, manufacturing, chemical or paperwork) when the outcome of the process is not the expected outcome. Of course, expected outcome means the conditions of a defect are specified in advance.

It's important to hold true to these definitions. For example, if a unit was declared defective because it met the criteria, but a material review board later found it to be usable, the unit's classification as defective should remain. Some organizations are reluctant to embrace this position because it adversely affects their quality numbers. Because a unit is usable, some organizations conclude it must not be defective. A defect may or may not affect usability.

For example, a new car may contain surface imperfections. By definition, the car is defective because it contains one or more defects, but it is still usable. Reclassifying a defective unit as a nondefective does nothing to help resolve the underlying cause of the defect.

How does a defect occur? To address this question, many organizations have compiled a list of defect families and defect types within families. Such a list should be as complete as possible in identifying all possible defect types. Also, each defect type should be independent and mutually exclusive of others. This allows you to recognize the occurrence of multiple defects on any given unit.

Furthermore, avoid the temptation to exclude known defect types because they happen infrequently. In other words, if a defect family or type is known to occur, include it on your list. In addition, it is useful to have a defect family or type deemed "other" because there may be a lack of foresight or wisdom to define everything in advance.

As you develop your list of defect types, it is often useful to define them in pairs (for example, too high and too low, or too long and too short), particularly when you are examining physical, mechanical or electrical characteristics. You might argue that a type such as "too long" or "too short" should simply be defined as one defect (for example, the wrong length). This is a viable argument and worth considering. I would suggest, however, looking beyond the defect to the action the defect creates.

For example, if the "too long" defect results in a unit requiring further trimming and rework, and "too short" requires the unit be scrapped, the consequences of the defect occurrence are different. Different consequences may require identifying and tracking different defect types. Classifying the defect occurrence as two different defect types allows for future root cause analysis.

Defining the metrics

When selecting meaningful metrics, consider the audience and how the metrics will drive action. In the following example, the PPM metric might be more understandable to an organization's management that compares processes at a high level. A quality engineer who has oversight responsibility for the process, however, may consider the DPU metric to be more actionable at the specific process level.

As you read through each of the process performance metrics below, consider how they may apply within your own organization.

Percentage defective

The percentage defective is simply defined by the following equation:

 $\frac{\text{Total number of defective units}}{\text{Total number of units}} \ge 100$

Example of rolled throughput yield / FIGURE 2



Of course, a defective unit is any unit containing one or more defects. Note that the ratio,

Total number of defective units

is known as the fraction defective.

Consider a process in which the output is normally distributed with a mean of 0 and a standard deviation of 1. Specifications are set at +/- 3. The fraction defective for the process is shown by the tail areas in Figure 1. The total fraction defective is the sum of the tail areas, or 0.0027. Therefore, the percentage defective is 0.27%.

DPU

The DPU metric is a measure of capability for discrete (attribute) data defined by the following:

> Total number of defects Total number of units

For example, a process produces 40,000 pencils. Three types of defects can occur. The number of occurrences of each defect type is:

Blurred printing:	36
Too long:	118
Rolled ends:	11
Total number of def	ects: 165
A straightforward app	plication of the
DPU formula provides th	nis:

DEBATE ON PERFORMANCE METRICS

Recently, ASQ's Six Sigma Forum discussion board has hosted lively exchanges on the confusion over DPU, PPM and DPMO vs. Sigma level. Read the topic thread at www.asq.org/discussionBoards/thread.jspa?threadID=8655&tstart=0&forumID=37.

 $\frac{\text{Total number of defects}}{\text{Total number of units}} = \frac{165}{40.000} = 0.004125$

DPMO

The DPMO metric is a measure of capability for discrete (attribute) data found by:

> (Total number of defects)(1,000,000) Total number of opportunities

The DPMO metric is important because it allows you to compare different types of product. Developing a meaningful DPMO metric scheme across multiple product lines, however, can be very time consuming because it is necessary to accurately determine the number of ways (or opportunities) a defect can occur per unit or part. This can be an enormous task, particularly when dealing with highly complex products and subassemblies, or even paperwork.

Continuing with the pencil example, let's calculate the number of opportunities. First, determine the number of ways each defect can occur on each item. For this product, blurred printing occurs in only one way (the pencil slips in the fixture), so there are 40,000 opportunities for this defect to occur.

There are three independent places where dimensions are checked, so there are (3) (40,000) = 120,000 opportunities for this dimensional defect.

Rolled ends can occur at the top and the bottom of the pencil, so there are (2)(40,000) = 80,000 opportunities for this defect to occur. Thus, the total number of

3.4 PER MILLION

opportunities for defects is:

40,000 + 120,000 + 80,000 = 240,000. Likewise, the total number of opportunities per unit is:

1 + 3 + 2 = 6

Applying the DPMO formula, you can readily determine the DPMO metric:

 $\frac{\text{(Total number of defects)}(1,000,000)}{\text{Total number of opportunities}} = \frac{165,000,000}{240,000} = 687.5$

PPM

In a typical quality setting, the PPM metric usually indicates the number of times a defective part will occur in 1 million parts produced. By contrast, the DPMO metric reflects the number of defects occurring in 1 million opportunities. It is important to note that some authors say the PPM and DPMO metrics are identical. If we follow the definitions above, however, this would only be true when the number of opportunities for a defect per unit or part is 1.

Perhaps additional confusion can surround the PPM metric because of a laxness in the terminology applied. In the Six Sigma context, PPM is also referred to as the PPM defect rate. Similarly, 3.4 PPM is often stated as 3.4 defects per million parts. In both examples, however, when we say defects, we are really referring to defectives.

PPM is also used to refer to contaminants. For example, suppose 0.23 grams of insect parts are found in 25 kilograms of product.

$$\text{PPM} = \left(\frac{0.23}{25,000}\right) \times 1,000,000 = 9.2$$

Finally, in the more traditional scientific context, PPM may simply refer to the various ratios of components in a mixture. For example, the oxygen component of air is approximately 209,000 PPM. In this case, the idea of "defective" isn't even a consideration.

Table 1 illustrates the links among multiple metrics, including PPM, sigma level, percentage in specification and percentage defective. The familiar 3.4 PPM corresponds to a 6-sigma level of quality, assuming a 1.5 shift of the mean. Sigma level of a process and the 1.5 shift of the mean will be addressed later.

RTY

The RTY metric represents the percentage of units of product passing defect free through an entire process. It is determined by the multiplying first-pass yields (FPY) from each subprocess of the total process as follows:

$$RTY = \prod_{i=1}^{n} FPY_{i}$$

Note that n = number of subprocesses, and FPY_i = first-pass yield of the *i*th subprocess.

Similarly, the FPY represents the percentage of units that completes a subprocess and meets quality guidelines without being scrapped, rerun, retested, returned or diverted to an offline repair area. The FPY is calculated as:

 $\frac{\text{Number of units entering the}}{\text{Number of units entering the process}} \times 100$

Note the FPY and RTY values are often expressed simply as the fractions or probabilities.

The concept of the RTY is best illustrated by the example given in Figure 2, (p. 53) which depicts an overall process comprised of four subprocesses. Suppose the FPY of each subprocess is 0.95. Then, the RTY is easily computed as:

RTY =
$$\prod_{i=1}^{4} FPY_i$$
 =
(0.95)(0.95)(0.95)(0.95) = 0.81 or 81%

Although individual subprocess yields are relatively high, the total process yield has dropped significantly. A significant advantage of using the RTY metric is that

The relationship among several process performance metrics / TABLE 1

Without sigma shift (centered)				With 1.5 sigma shift			
Sigma level	Percentage in specification	Percentage defective	РРМ	Sigma level	Percentage in specification	Percentage defective	РРМ
1.00	68.2689	31.7311	317311	1.00	30.2328	69.76721	697672
1.50	86.6386	13.3614	133614	1.50	49.8650	50.13499	501350
2.00	95.4500	4.5500	45500	2.00	69.1230	30.87702	308770
2.50	98.7581	1.2419	12419	2.50	84.1313	15.86869	158687
3.00	99.7300	0.2700	2700	3.00	93.3189	6.68106	66811
3.50	99.9535	0.0465	465	3.50	97.7250	2.27504	22750
4.00	99.9937	0.0063	63.3	4.00	99.3790	0.62097	6210
4.50	99.9993	0.0007	6.8	4.50	99.8650	0.13499	1350
5.00	99.99994	0.00006	0.6	5.00	99.9767	0.02326	233
5.50	99.999996	0.000004	0.04	5.50	99.9968	0.00317	31.7
6.00	99.9999998	0.000002	0.002	6.00	99.9997	0.00034	3.4

PPM = parts per million

it provides a more complete view of the process. Subprocess yields that run high aren't likely to garner the attention necessary to drive improvement. Often, it is only when the total process yield becomes visible does real action occur.

Process sigma

When there's talk of the process sigma of a process, you'll often hear it described as a 3-sigma or 4-sigma process or something similar. Sometimes you'll hear it described as the sigma level of a process. What does this mean and how do you interpret it in the context of Six Sigma?

Assume the output of a process is operating as a standard normal distribution with a mean of 0 and standard deviation of 1, with an upper specification limit (USL) and lower specification limit (LSL) set at +/- 3, respectively. This is depicted by the blue curve in Figure 3. From basic statistics, you know that:

 $P(Z \ge 3 = USL) = 0.00135$ (the area to the right of the USL and below the blue curve in Figure 3).

 $P(Z \le 3 = LSL) = 0.00135$ (the area to the left of the LSL and below the blue curve in Figure 3).

This gives a total fraction defective 0.0027 or percentage defective of 0.27% as we determined previously.

The underlying philosophy of Six Sigma, however, assumes a 1.5-sigma shift of the mean either to the right or left over the long term. If you assume the shift is to the right as shown in Figure 3, the process distribution is normal with a mean of 1.5 and a standard deviation of 1. Applying basic statistics again, you know that:

 $P(Z \ge 3 = USL) = 0.0668072$ (the area to the right of the USL and below the red curve in Figure 3).

 $P(Z \le 3 = LSL) = 0.0000034$ (the area to the left of the LSL and below the red curve in Figure 3).

Note that the area is small and there-

fore difficult to depict graphically.

This results in a total fraction defective of 0.0668106, a percentage defective of 6.68106% and a PPM level of 66,811. From Table 1, we can see these values equate to a 3-sigma level.

If you extend the same approach as above, you can quickly generate the values shown in Table 1.

A quick review of Table 1, along with understanding the

1.5-sigma shift, explains why Six Sigma uses 3.4 PPM for a 6 sigma process, and not 2 PPB.

In addition to the use of Table 1, the sigma level associated with the 1.5-sigma shift can be approximated based on the PPM metric using the following formula:

Sigma level = $0.8406 + \sqrt{29.37 - (2.221) \ln (ppm)}$.

The above equation very closely approximates the actual sigma value when the PPM is below 309,000, or when the sigma value is expected to exceed 2.

The subject of the 1.5-sigma shift is highly controversial. You may or may not accept its validity. The intent of this section was simply to explain how the shift relates to PPM and associated process sigma level.

Choices abound

Clearly, there are a lot of process performance metrics to consider. Though they take different forms, some of them are equivalent. Selecting the appropriate ones for your organization depends on your audience and how the metrics will be used to drive improvement actions.

Some metrics are more understandable



than others, while some have more of an emotional impact. For example 66,811 PPM may be more startling to management than using a corresponding 3-sigma level. Regardless of which metrics you choose, each one must be based on a clear operational definition of a defect.

By the way, I've had numerous students ask me what happens to the defective products shown in Figure 2 (p. 53). I tell them they are packaged as complex derivatives and other high-quality securities and sold on the world financial markets. Some just sit there and wonder. Others think, "Good idea!" QP

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Risks, Relationships and Rewards

Use your quality toolkit to make wise career decisions

EMPLOYERS, EMPLOYEES and independent contractors alike have been affected by the turbulent economy. We see it all around us, whether at firms we own, organizations at which we work or businesses we patronize. Nonprofits are experiencing the same types of challenges as for-profits.

All organizations can benefit from the knowledge of quality professionals. Our careers are rooted in problem solving, risk analysis, out-of-the-box thinking and managing based on lean principles. career. She started a part-time business, and the financial and time risk paid off when she was able to grow her side business to the point at which it became her full-time career.

Another woman was in an unstable industry. She took a risk and temporarily relocated to another state to put her secondary skills to work. She left her home, family and life's work behind to take a chance on a better future. After eight months, her reward came in the way



Three examples

The road to rewards is paved with potholes of risk. What matters is how prepared you are to avoid the risky potholes and find the reward at the finish line. Consider the three women chronicled in the article "You're Hired" from the May 2009 *Woman's Day* magazine. These three women all took significant risks and started new careers.

One had a relatively stable job in a field she enjoyed but saw a need for a service business totally unrelated to her current of a promotion within a growing industry. The situation also resulted in her spouse finding a job in the new location and a better life overall for her family.

The third woman was working but not happy with what she was doing. She decided to leave the security of her parents' business and made her

way into unfamiliar work territory by volunteering and "freelancing for free" to get her name known in a new field. Within a year, she built a good network of happy clients, one of whom hired her.

Risk management tools

Have you, as an employer or employee, considered what makes up your unique mix for success? It is difficult to leave your comfort zone, especially when you are not forced to do so by circumstances beyond your control. Consider using the risk management principles from your quality toolkit and apply the same ideas to your career decisions.

What happens if you leave the job for a better one? What happens if you start your own business? What plan do you have if your industry, profession or organization ceases to exist? Evaluating the risks—and the rewards—will help you make the right choice.

Even if you still have a job in shaky times, a risk assessment and a plan are good preventive measures in case the work runs out. The rewards take many forms, especially the relationships made along the way, whether they be with other organizations or fellow employees.

Build relationships

Career consultant Andrea Kay's "Careers" column discusses just how beneficial relationship building is, particularly in turbulent economic times.¹ She tells of a woman who went well above and beyond what was required for her client.

The woman helped the client arrange for delivery and setup of a product and clarified the product's instruction manual—all functions that were part of her job. But, she went further. In talking with the client, the woman learned the client had just moved to the area, where her favorite cereal was not sold. The woman had a year's supply of the cereal sent to her client as a thank you for doing business with her. That client, in turn, sent the woman's business additional customers. Relationships matter.

Perform a **risk assessment** of **your own career**.

Did you take a risk or build a relationship that benefited your career? Share your

"Quality in the First Person" success story with QP readers. E-mail editor@asq.org.

Sometimes, relationships unrelated to jobs can benefit your career. Consider the first woman chronicled in *Woman's Day*. She started her part-time business with just one customer garnered from a relationship with the customer's mother.

Now more than ever, the relationships we have will pull us through any crisis. Don't wait until you are faced with job loss or other career crisis. Continue relationship building, or get started if you haven't done so.

TELL US YOUR SUCCESS STORY

Get started now

Perform a risk assessment of your own career. Don't just limit yourself to the industry you know; consider something that is your passion. Tough economic times lead people to rethink their careers and their work.

As HR consultant Chris Posti of Posti & Associates writes, "Office managers start pet-sitting businesses, nonprofit administrators get real estate licenses," because they made lists of their capabilities, interests and all the jobs that excited them.²

They took risks to make their passions pay off. You have the power, you have the passion, and you have the network. What are you waiting for? **QP**

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STATISTICS ROUNDTABLE BY LYNNE B. HARE AND MARK VANDEVEN

Drudgery to Strategy— A Statistical Metamorphosis

A strategy of experimentation can point you toward success

THINK BACK to your Stats 101 course. You entered the first session laden with apprehension—induced by survivors' horror stories—and your worst fears were confirmed. Early on, the professor said, "OK, boys and girls, today we're going to discuss t-tests and confidence intervals." And you sat there thinking you'd rather visit the dentist.



Tools and occasional toy (artificial) problems characterize many introductory statistics courses. To be sure, the professors are gifted, enthusiastic lecturers; many have great humor and human kindness in their veins. But still, the class dealt with statistical tools suitable for fixed occasions. At semester's end, you knew about a bunch of tools you could resurrect if the right occasion ever arose.

It never did.

There's no getting around the fact that statistics is a difficult subject. The thinking is different from that of many other disciplines: It acknowledges uncertainty, whereas others profess determinism. It runs counter to everything we are taught in algebra: "Solve for x, a fixed but unknown quantity."

Further, statistical applications require following mathematical formulas of which there are relatively few in political science, English, history or philosophy. Even pure mathematics claims closure (not always true), which is absent in statistics. The semester usually ends before the professor scratches the surface. And because the first semester lacks a happy ending, many students are reluctant to proceed to a second.

On the rise

Over the last two decades, we've noticed statistical stock is rising at some companies. They may be in the minority, but some top executives have begun to see statistics' strategic value.

We believe this occurred because those executives witnessed very positive (read: dollars to the bottom line) results, especially when scientists and engineers used statistical methods to guide projects from highly uncertain project beginnings to solid, successful and sustainable products and processes. To their internal statisticians, executives are saying, "I want more of that. Make it happen." "Egad," says the internal statistician. "Now what do I do? All that my colleagues learned from their statistics course was not to take another one. The only statistical methods they use come at the end of a project, when they compare the new prototype against the current product. And now I have to change the organizational culture so people not only use the methods, but also use them upstream in the development process for guidance. I'd rather visit the dentist and have root-canal surgery!"

Well, this is not an appeal for long lines at dentists' offices. Positive results can emerge from some lessons learned, if only by osmosis, in Stats 101. An appeal to intuition reduces resistance to the notion that the t-test used to compare a sample mean to some hypothesized value is analogous to signal-to-noise, for example. Build on this to show that a reduction of noise makes it easier yet to hear the signal. Build on it further to show that the test can be expanded to compare two sample means as in Stats 101, chapter 3, but it's still signal to noise.

It is a bit of a leap from there to compare more than two treatment means, but it can be shown that the guiding principle remains akin to signal to noise. Then, if you want to compare multiple treatment means, wouldn't it be wise to economize by running half the experimental treatment combinations on one material and the other half on another? Doing that introduces a two-way classification painlessly—almost. The discussion with colleagues dredges up their unpleasant memories, true, but at least they form a base for intuitive appeal.

If you can study multiple treatments and multiple materials, why not add multiple speeds? Now you have a three-way classification. Conceivably, you could add other factors, such as ingredient levels, machines and locations. Whoa! Wait a experiment to find which factors are most likely to drive success. We can hone in on levels in subsequent experiments."

This is the great leap or paradigm shift—we move from comparing treatment or material A and B to estimating something called an "effect." The question has changed from "What factor level is best?" to "Which factors are most important?"

The **strategy of experimentation** puts data behind your decisions so you **know the path to take**.

minute and those experiments will get big in a hurry. Big experiments cost big bucks, and they are logistically hard to control. Fugetaboutit!

To the rescue come the two-level designs and their fractions. Don't do multiple factor levels. Examine only two levels per factor, and make those levels the extremes. "Absurd," you say, "some of those levels could be best!"

"Right," we say in appropriately humble rejoinder, "but we don't even know which factors are important right now. Let's "You mean I have to do more than one experiment?" you ask. Yes. The first one or two identify which factors or combinations of factors are important. The next experiments help identify best levels among the important factors. It is a strategy for experimentation, and it has a higher success rate than competitive approaches to experimentation such as spray and pray, try everything, and try your best hunch and hope you get lucky.

We see other advantages to the strategy of experimentation, especially as it is used to drive decision making upstream in the research process. For one, the competitive method of giving it your best shot and testing at the end simply tells you if you were successful. If you weren't, you don't know why.

The strategy of experimentation puts data behind your directional decisions so you know, early in the experimental process, what path to take; there are no blind alleys. You gain product and process knowledge along the way.

The strategy of experimentation also provides trade-offs. If practical constraints block the path to using one combination of factors and their levels for success, there may be another combination that comes close. The data point you in the direction toward success.

We've found that those who use the strategy are successful and they feel liberated. To go back to the old methods would be like having more oral surgery. **QP**



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HARE TODAY AND YESTERDAY

DVIS

YOUR

Check out the Statistics Roundtable columns Lynne B. Hare has written since 1999 by visiting www.qualityprogress.com.

Are you in a bind at work? Are you looking to clarify a term or methodology? Have you run into a problem where nobody seems to have the answer? Do you wish you had a quality mentor? Someone you could turn to when you run into a roadblock? You do.

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World of Confusion

Challenges abound when distributing medical devices globally

U.S. MANUFACTURERS of medical devices must comply not only with U.S. Food and Drug Administration (FDA) labeling requirements, but they also face the challenge of labeling in multiple languages if they want to sell their products in the global marketplace.

Section 201(k) of the Federal Food, Drug and Cosmetic Act (FFDCA) defines a label as any "display of written, printed or graphic matter upon the immediate container of any article," and labeling as "all labels and other written, printed or graphic matter upon any article or any of its containers or wrappers, or accompanying such article" at any time while a medical device is held for sale after shipment or delivery for shipment in interstate commerce.¹ not the manufacturer, the firm information must be qualified by an appropriate statement, such as "manufactured for" or "distributed by."

- Intended use. If a packer, distributor or seller intends a device for uses other than those intended by the person from whom it received the device, these parties must furnish adequate labeling in accordance with the new intended use. If a manufacturer knows or has information indicating the device is to be used for conditions or purposes other than what it intended, the manufacturer is required to provide adequate labeling in accordance with such other uses.
- Adequate directions. "Adequate directions for use" means directions that

The **simplicity and comfort** of English-only labeling **is history**.

So far, this is not too difficult to decipher: If it's on the device, it's a label; everything else is labeling.

U.S. regulations

For medical devices distributed in the United States, clarification of the definitions and more specific requirements are identified in the FDA's 21 CFR 801 and include:

• Name and place of business. The label of a device must contain the name and place of business of the manufacturer, packer or distributor, including the street address, city, state and ZIP code. The firm's street address can be omitted if it is in the local telephone directory. If the firm listed on the label is enable the layman to use a device safely and for the purposes intended. These include statements of all purposes for which and conditions under which the device can be used, the quantity of dose for each use and usual quantities for persons of different ages and physical conditions, frequency of administration, duration of application, time of administration in relation to other factors, the route or method of application, any preparation necessary for use and information on exemptions from adequate directions-for-use requirements.

• False or misleading statements. A device is misbranded if it makes a false or misleading statement with respect to

another device or includes claims that cannot be substantiated.

- Prominence of statements. A word, statement or other required information may lack the required prominence and conspicuousness: if it fails to appear on the part or panel that is displayed under customary conditions of purchase; if the package contains sufficient space, and the required information fails to appear on two or more panels, each of which is designed to render it to be displayed under customary conditions of purchase; if required labeling fails to extend over package space provided; if there isn't sufficient label space for required labeling due to placement of nonrequired labeling on the package; or if smallness or style of type, in sufficient contrast between labeling and package background or designs that obscure or overcrowd labeling render it unreadable.
- **Exemptions.** Exemptions may be granted when device labeling lacks sufficient space for required labeling, provided that existing label space is not taken up by including nonrequired information or by giving prominence to a portion of the required labeling, and existing label space is not used for any representations in a foreign language. All labeling must be in English with the exception of products distributed solely within Puerto Rico or a U.S. territory where the predominant language is not English. In these instances, the predominant language may be substituted for English. If any representation on the device label or labeling appears in a foreign language, then all required labeling must also appear in that foreign language.

Speak their language(s)

If a medical device manufacturer wants to distribute its products globally, it must overcome other sets of labeling hurdles. One of the main challenges today is multilanguage labeling.

Before the enactment of the European Union Medical Device Directives (MDD), there were no requirements to include multiple languages on medical device labels. The impetus to offer more than one language was driven by individual countries and customers. Manufacturers would compete for market share in another country and label their products in that country's language. Most manufacturers labeled their products in English, and an international version of their product would be labeled in two to three other languages.

In 1993, when the European Union MDD (93/42/EEC) stipulated that medical device packaging include instructions for use in the packaging for every device in the languages of the countries in which it would be placed on the market, the simplicity and comfort of English-only labeling became history.

There was a five-year transition period to implement the MDD, but most companies either had no clue about the requirements or waited until the last minute to become compliant.

As additional member countries join the European Union (EU) and other regions around the world implement their own labeling requirements, the roles of packaging engineers and regulatory professionals are not to be envied. Requirements mandated by the MDD for labeling include:

- Device name.
- Name and address of manufacturer.
- Name and address of authorized representative.
- Statement indicating in vitro use (when appropriate).
- "Use before" date.
- Batch code preceded by lot or serial number.

- The words "for performance evaluation only" (when appropriate).
- The word "sterile" and method of sterilization (when appropriate).
- The words "self-testing" (when appropriate).
- Intended purpose (if not obvious to user).
- Special storage, handling or operating instructions.

Today, there are 27 member states in the EU and at least another three candidate countries. These countries and their official 24 language requirements can be found in Table 1. As other countries become part of the EU, there will be additional language requirements.

Other European language requirements include countries in the European Free Trade Association (EFTA). Liechtenstein requires translation into German, and Switzerland has requirements for translations into its official languages: German, French and Italian. Multiply those requirements for Asia, and it becomes clear a company will need a package that is at least four feet long to include everything that is required if it wants to sell its device around the world.

Symbolic gesture

Aside from the space limitations of most medical device packaging, manufacturers face several other challenges. It now takes much longer to implement a labeling change because everything must be translated and certified. Those translations are not cheap, and translation expenses become a large item in a company's annual budget. It might take a year or longer to get a minor labeling change out to customers.

One way to address this problem is through the use of symbols, thus reducing translation time and costs while saving valuable packaging real estate. Symbols visually enhance the label and allow for the addition of languages without major redesign to the printing software or the actual label itself. With the FDA's decision to allow symbols only, there is some relief from the onerous requirements and sheer volume of text that had once been necessary. Some of the most commonly recognized and accepted symbols defined in the harmonized section of EN 980 ("Symbols for Use in the Labeling of Medical Devices") are shown in Table 2 (p. 62).

Practices make perfect

Recommended best practices include understanding the requirements, developing a global labeling strategy, developing a long-term language strategy, designing

EU language requirements / TABLE 1

Member state	Official language(s)			
Austria	German			
Belgium	Dutch, French and German			
Bulgaria	Bulgarian			
Cyprus	Greek			
Czech Republic	Czech			
Denmark	Danish			
Estonia	Estonian			
Finland	Finnish			
France	French			
Germany	German			
Greece	Greek			
Hungary	Hungarian			
Ireland	English			
Italy	Italian			
Latvia	Latvian			
Lithuania	Lithuanian			
Luxembourg	French, German and Luxembourgish			
Malta	English and Maltese			
Poland	Polish			
Portugal	Portuguese			
Romania	Romanian			
Slovakia	Slovak			
Slovenia	Slovenian			
Spain	Spanish			
Sweden	Swedish			
The Netherlands	Dutch			
United Kingdom	English			

STANDARDS OUTLOOK

appropriate labels, translating intelligently and carefully, and ensuring appropriate tools and support.

Understanding the requirements. Successful device manufacturers emphasize satisfying the regulatory and the derived requirements. Even though a country may not stipulate the translation of labeling, end users may require it.

Understand your market entry strategy, and consider market opportunities. This includes understanding how many markets are under consideration, what labeling requirements exist or are likely to be enacted and what your competitors are doing. Developing a global labeling strategy. The best strategy is to use symbols whenever possible. This has become a lot easier since FDA recognized the use of symbols without text. Coupled with the use of symbols, determine the best approach for your company, which could include:

- Using the same label for all markets. This may not, however, be possible because of limited print space.
- Using single-language labels for each country. This will often solve the space problem but will have tremendous cost, manufacturing and inventory implications.

Medical device labeling symbols / TABLE 2

Symbol	Used for	Symbol	Used for
(\mathfrak{A})	Do not reuse	$\sum_{i=1}^{n}$	Use by YYYY-MM-DD or YYYY-MM
LOT	Batch code	SN	Serial number
	Date of manufacture	STERILE	Sterile
STERILE EO	Sterilized using ethylene oxide	STERILE R	Sterilized using irradiation
STERILE	Sterilized using steam or dry heat	REF	Catalog number
\triangle	Caution, consult accompanying documents	STERILE A	Sterilized using aseptic processing technique
	Manufacturer	EC REP	Authorized representative in the European community
S	Contains sufficient for < n > tests		For in vitro diagnostic performance evaluation only
IVD	In vitro diagnostic medical device		Upper limit of temperature
	Lower limit of temperature		Temperature limitation
ĺ	Consult instructions for use	Ś	Biological risks

- Keeping inventory unlabeled until an order is received, and then labeling it according to the requirements for the order. But this is time-consuming and expensive, and it has the potential to create inventory discrepancies and could result in misbranding of the medical device.
- Using a combined approach by printing three languages on the label and leaving space for a fourth language that can be applied as a separate label at the time of order. This is called "overlabeling." There isn't one correct strategy. You

need to determine what is best for your company. Regardless of the approach that you select, however, don't forget about additional future languages.

Developing a long-term language strategy. Consider country-by-country sales for each product, along with market entry plans and competitive pressures.

Designing appropriate labels. Design effective labels that are easy to use, beginning with standard templates that can be used across products, configurations and markets. This will result in a consistent look and feel on labels and will assist the customer with product selection.

Use icons and symbols, preferably harmonized symbols, whenever possible. Text that alternates between languages is confusing and irritating to users. So, when possible, text for one language should be grouped and appear in the same place from package to package. Use fourthgrade vocabulary and simple declarative sentences. Minimize the use of medical terminology. Keep things simple, but don't overlook branding implications.

Translating intelligently and carefully. Consider developing a labeling database. Don't guess at the spelling or word use of text you don't know. Remember that each language behaves differently in different contexts. You don't want your labeling to contain typos or look as if a machine translated the text.

When submitting labels for translation,

batch them whenever possible to minimize charges. Translate labels with package inserts or instructions for use to ensure consistency of the translated text and to minimize the potential for introduction of linguistic inconsistencies.

Provide the translators with PDF files or other proofs of the formatted label to make it easier to understand what you want the label to say. Looking at only a few words pulled from the label makes it difficult for the translator.

Ensuring appropriate tools and support. Be certain databases, websites and e-mail systems can handle non-English characters. Communication among marketing, regulatory affairs, translation subcontractors and printers need to be frequent, clear and consistent.

Japan's new PAL

Following the implementation of the new Pharmaceutical Affairs Law (PAL) in Japan, companies registering and marketing their products there face new regulations, including the requirement to appoint a marketing authorization holder (MAH) and changes in the labeling of medical devices.

Under PAL, the Ministry of Health, Labor and Welfare (MHLW) requires the following new information be listed on the product insert for all medical devices:

- The classification of the medical device.
- The address of the MAH.
- The contact information, which must be the location where the marketing of the product is handled.
- The location of the manufacturing site for all devices manufactured overseas.

Complying with international labeling requirements is laborious but not impossible. Good communications, appropriate planning and common sense will significantly reduce the burden and will keep your products from potentially being misbranded. **OP**

REFERENCE

1. Food and Drug Administration, "Federal Food, Drug and Cosmetic Act," www.fda.gov/RegulatoryInformation/ Legislation/FederalFoodDrugandCosmeticActFDCAct/ default.htm.



LES SCHNOLL has 30 years of experience in industries regulated by the U.S. Food and Drug Administration and is vice president of quality and regulatory affairs for ThermoGenesis Corp. in Rancho Cordoba, CA. He is a senior member of ASQ and is an ASQ-certified quality engineer, auditor and manager. A member of the U.S.

technical advisory group to ISO technical committee 176, Schnoll wrote The Regulatory Compliance Almanac (Paton Press, 2001, 2008).



QPTOOLBOX

Laser scanning ►

Hexagon Metrology has announced a combination laser scanning metrology package, which combines a Brown & Sharpe Global Performance bridge coordinate measuring machine, a Romer Infinite 2.0 7-axis portable arm and a ScanShark V4ix laser scanner that is plug-and-play swappable between systems.

Companies can invest in a single scanner that can be adapted to the strengths of the different types of measuring platforms. Shared systems can do double duty as inspection systems, as well as performing reverse engineering and 3D point-cloud gathering tasks.

The machines are also capable of performing point-to-point inspection without the scanner attached. This means they can be used simultaneously, regardless of which one uses the laser scanner.

Call: 920-906-7514; e-mail: william. fetter@hexagonmetrology.com.

Absolute encoder v

Heidenhain has incorporated absolute technology to a multi-substrate scale tape linear encoder design with its LIC 4000 encoder. Absolute encoders, which provide the current position immediately upon switchon, offer high reliability and safety because they perform without reference runs. Absolute encoders are well suited for use on direct drives. Together with the current position, the computation offset is known immediately upon switch-on, and the motor can be provided

> with power immediately and held in the control loop. Critical operating states, such as switching on a vertical axis with direct drive or retraction after an emergency stop, are safely controlled.

LIC 4000 encoders measure up to 27 m and are resistant to contamination. The dimensions of the LIC 4000 match those of Heidenhain's LIDA 400 incremental linear encoder. This makes it possible to retrofit machine tools to absolute measurement technology by exchanging the encoders. Only the subsequent electronics must be adapted.

Call: 847-490-1191; visit: www. heidenhain.com.

Routing mileage software

ALK Technologies has released the PC Miller 23 routing and mileage software that includes carbon emissions and intermodal analysis functionality. Intermodal analysis calculates alternative rail intermodal routes for truck shipments and runs quick comparisons of truck and intermodal mileage, fuel consumption and carbon emissions. Meanwhile, the points of interest database displays small, medium and large intermodal ramps in the United States and Canada.

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This tool predicts and manages operating and transportation costs. It reduces out-of-route mileage, saving time, tolls and fuel. For example, PC Miller 23 offers capabilities in toll calculation to include tolls determined by weight and truck axles. It calculates weight-based tolls in specific categories and rates applied by each individual toll authority, with rates up to 136,000 pounds.

Users can enter a vehicle's height, length, width and weight when generating routes. The application will generate mileage and directions, taking those factors into account.

Call: 609-252-8160; e-mail: kelly@alk. com.



Heated optical glass **A**

Abrisa has introduced LuxVu heated optical windows for cameras and displays that operate in rugged, wet or cold outdoor environments. The LuxVu line is designed to keep optical glass free from moisture and fog. The heated windows also aid in deicing in extreme weather conditions.



The LuxVu heated front glass window provides a transparent, conductive coating that can be combined with custom display enhancements and coatings. Abrisa also

> offers additional glass fabrication and optical coating services, such as screen printing, busbar, epoxy, glass strengthening, etching and special masking.

> Call: 877-622-7472; visit: www. abrisa.com.

Remote monitoring system ▲

Onset Computer has announced that its web-based HOBO U30 remote monitoring systems are now compatible with NorthWrite's Energy Expert software platform.

The Energy Expert software converts raw building energy and environmental data collected with

HOBO U30 system's graphical "smart models" to predict building energy consumption. The information, delivered online, provides building managers, energy service consultants and others with real-time feedback on building energy use.

The HOBO U30 remote monitoring systems measure and record up to 15

channels of high-accuracy energy and environmental data. The systems feature a NEMA 6-rated enclosure designed for harsh environments and can transmit data via GSM-cellular, Wi-Fi and Ethernet communications. Sensors are available for a wide range of measurements, including kilowatt hours, voltage, current, air temperature and relative humidity.

Call: 800-564-4377; visit: www. onsetcomp.com.

Corrosion monitoring

Corrosion and maintenance costs can be reduced with Cosasco's Side-Stream Assembly for corrosion monitoring. This system ensures piping assets are properly monitored to prevent corrosion damage.

The Side-Stream Assembly installs quickly to provide information on metal loss, corrosion rate, erosion rate, pressure, temperature, flow and bacterial activity in pipelines. It is configured to meet specific commercial requirements. The assembly includes multiple, easily connected, 1-in. tees. Each tee is configured with a choice of corrosion management and process monitoring technologies.

Call: 562-949-0123; e-mail: sales@ cosasco.com.

QPREVIEWS

Process Improvement Using Six Sigma

Rama Shankar, ASQ Quality Press, 2009, 110 pp., \$31 list, \$18 member (book).



Shankar's book provides a general outline of the five phases of the Six Sigma quality initiative of define, measure, analyze, improve and control (DMAIC).

The purpose of this book is to provide the practitioner with the necessary tools and techniques with which to implement a systematic approach to process improvement initiatives using Six Sigma.

The book has five main parts, each of which corresponds to one phase of DMAIC. For each phase, the purpose is clearly explained, and the tools that can be used to carry out the activities of each phase are outlined. Generally, Shankar includes examples to clarify concepts and calculations. Finally, a checklist is provided at the end of each chapter.

The main strength of the book is its clear, down-to-earth language that makes individual concepts easy to understand and the book as a whole easier to read. Moreover, the examples provided use Minitab software for calculations and graphs, further easing the learning process.

The main weakness of the book is its length. Shankar aimed to explain many statistical tools in as little space as possible. Consequently, practitioners won't find this book useful as a guide or reference when problems arise during data analysis.

This book best serves as an introduction to the DMAIC aspect of Six Sigma. I would recommend it to Green Belts and to quality practitioners who are looking for quick insight into DMAIC to help carry out their improvement projects.

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

The Integrated Enterprise Excellence System, Vol. III

Forrest W. Breyfogle III, Bridgeway Books, 2008, \$124.95 (book).



This is the fourth and final installment in Breyfogle's set of books introducing his integrated enterprise system (IEE). Although it's part of a series, the book

could be used as a standalone reference.

This volume covers the details of how an improvement project should be undertaken in the IEE system and is suitable for Master Black Belts (MBBs) and Black Belts (BBs). It is divided into seven parts that introduce the IEE system and cover the DMAIC sequence at the project level. Each part is then divided into chapters that cover the theory and practical application of the project management, lean and statistical analysis tools necessary to complete each phase of the DMAIC cycle.

If there is one word to describe the book, it's encyclopedic. It's 1,180 pages long (including the index) and describes all of the pertinent Six Sigma, project management and lean concepts in enough detail to ensure the reader can understand each one. In addition, there are exercises at the end of each chapter that can be used to reinforce the concepts discussed. This makes this volume quite useful as a textbook. The statistical analyses are performed using Minitab software, and there are numerous charts and tables within the book that show what the Minitab output for a given task will look like. The book also contains roadmaps that can take a BB step by step through what needs to be done in each DMAIC phase.

If there is a weakness to the volume, it lies in its sheer size. This volume is too large to be read cover to cover as you would other books. By attempting to be encyclopedic in its coverage, some sections of the book may not provide enough details for some readers. But, overall, this is an excellent book (on par with *The Six Sigma Handbook* by Thomas Pyzdek) that can serve as a reference text and a textbook. MBBs and BBs would do well to have it in their professional libraries.

> Reviewed by Brian Cocolicchio New City, NY

Stakeholder-Driven Strategic Planning in Education

Robert W. Ewy, ASQ Quality Press, 2009, 123 pp., \$40 list, \$24 member (book).



Using two decades of experience, Ewy has crafted an effective how-to guide and an ideal reference tool for in-process strategic planning and operations in education.

The book starts with an overview, followed by procedures for surveying stakeholders, assessing current performance, strategic plan development, defining and developing strategies and the strategy map, establishing and using the balanced scorecard, and using timelines to guide activities.

The table of contents presents a working outline of the process, and the detailed index provides support for those looking for specific information. Ewy also includes sample press releases that announce longrange planning projects and examples of invitations to potential project participants. This makes the book an excellent reference for a strategic planner.

The inclusion of tools and resources that can be of use in the planning process is particularly helpful. For example, in the fifth chapter, "Developing the Strategy Map," Ewy needs fewer than three pages to provide strategies for finding the strengths, weaknesses, opportunities and threats faced by a project (also known as SWOT analysis). He also shows how to integrate the analysis results into the stakeholder's strategy map.

The book is packed with ideas for simplifying strategic planning, demystifying planning processes and presenting strategic plans to authority groups, such as school boards, legislative bodies or accreditation teams.

Whether the lessons are applied in a K-12 or post-secondary setting, this book can serve as a process guide for anyone new to strategic planning and as a reference for experienced planners.

> Reviewed by Gerald Brong Ellensburg, WA

Inspire!

Jim Champy, FT Press, 2008, 150 pp., \$22.99 (book).

Written by the co-author of Reengineering the Corporation and other best-selling books, Inspire! is the second book in a series of three compact volumes on the topics of strategy, marketing, managing people and operations.

Outsmart!, the first in the series, described and analyzed the strategies of successful, fast-growing organizations. Inspire! picks up where that one left off, showing how those organizations have been able to increase their market share. The third in the series, Deliver!, which will be released



in 2010, will focus on how organizations achieve true operational excellence. While these books are part of a series, each can be read as an independent offering.

In an era of commoditization and dwindling customer loyalty, Champy's aim is to show how to keep customers coming back. Customer satisfaction is a significant aspect of the text, but the primary focus is on marketing and how to inspire loyalty.

Champy wants organizations to take the viewpoint of the customer and reconsider how they operate and engage customers by focusing on convenience with economy, trust, simplification and honesty. Case studies are used throughout the book to illustrate how this has

been achieved by organizations that have shown growth of 15% or better during a period of at least three years. At the end of each chapter, rules of engagement are provided to help the reader focus and take action to spur innovation and out-of-thebox thinking.

In our current economic situation, anything that shows how organizations can focus on and better engage the customer is a valuable resource. While this book will be of particular interest to those in marketing, it will also be of interest to executives, those involved in strategic planning and business owners.

> Reviewed by Denis Leonard Business Excellence Consulting Bozeman, MT

RECENT RELEASES

Do It Right the Second Time Peter Merrill, ASQ Quality Press, 360 pp., \$42 list, \$25 member (second edition, book). Journey to Excellence

Kathleen J. Goonan, Joseph A. Muzikowski and Patricia K. Stoltz, ASQ Quality Press, 226 pp., \$50 list, \$30 member (book). Lean for the Process Industries

Peter King, CRC Press, 333 pp., \$49.95 (book).

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SEPTEMBER

9-10 ASQ Education Course. Lean for Service—Virtual Course.

16-18 Lean, Six Sigma and Business Process Improvement for Supply Chain Conference. Chicago. Call Worldwide Conventions and Business Forums at 800-959-6549 or visit www.wcbf.com/quality/5098.

17 ASQ Education Course. Process Validation for Medical Devices—Virtual Course.

21-22 ASQ Education Course. Cost of Quality: Finance for Continuous Improvement. Phoenix.

21-23 Ninth Annual ENBIS Conference. Goteborg, Sweden. Visit the European Network for Business and Industrial Statistics' website at www.enbis.org.

21-25 Achieving Results in Uncertain Times: The 2009 Fall Conference. St. Louis. Call the International Society for Performance Improvement at 301-587-8570 or e-mail info@ispi.org.

23-24 The Annual Washington Conference on Product Safety. Arlington, VA. Visit http://randallgoodden.com or e-mail info@randallgoodden.com. 23-24 Demonstrating Reliability with Accerlerated Testing. San Jose, CA. Visit Hobbs Engineering's website at www. hobbsengr.com or call 303-465-5988.

24 ASQ Education Course. ISO 14000 Lead Auditor Training (RABQSA International). Phoenix.

24 calibration Demystified: Separating Truth from Myth (live webinar). Call Pilgrim Software at 813-915-1663 or visit www.pilgrimsoftware.com.

25 ASQ Education Course. Black Belt/ Quality Engineering Statistics. Phoenix.

28-30 Lean to Green Manufacturing. Austin, TX. Visit the Society of Manufacturing Engineers' website at www.sme.org.

29 ASQ Education Course. Lean Six Sigma Black Belt for Healthcare. Milwaukee.

30 How to Perform a 5S. Webinar. Visit 5S Supply's website at www.5Ssupply.com or e-mail webinar@5Ssupply.com.

OCTOBER

5-6 ASQ Conference. **18th Annual** Service Quality Conference. Long Beach, CA. Register at www.asq.org/sqd. 7 ASQ Education Course. Corrective Action—Virtual Course.

13-14 ASQ Conference. Lean Six Sigma. Buffalo, NY. Visit the Buffalo Section's website at www.asqbuffalo.org.

17 ASQ Education Course. ISO 22000:2005 Food Safety Management System Requirements: An Overview— Virtual Course.

15-16 ASQ Conference. 18th Annual Audit Conference. Tucson, AZ. Visit the Audit Division's website at www.asq.org/ audit/interaction/conferences-audit.html.

23 ASQ Conference. Silicon Valley Quality Conference. Santa Clara, CA. Visit www.asq-silicon-valley.org.

25-27 ASQ Conference. National Quality Education Conference. Jacksonville, FL. Visit http://nqec.asq.org.

20-21 **SCOR Framework**. New York. Call the Supply Chain Council at 202-962-0440 or e-mail info@supply-chain.org.

21-23 15th International Symposium on Quality Function Deployment. Monterrey, Mexico. Visit Latin American Quality Function Deployment's website at www.qfdlat.com/isqfd09.

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Gimme Five

Count on the 5S improvement method in the lab

ANYONE WHO has worked for an innovative company in the last 15 years has likely encountered a 5S program. It is sometimes described as good housekeeping, but 5S is much more than a cleaning program. It is a system of creating and sustaining an organized workplace for the purpose of improving efficiency, productivity and employee morale.

Typically, a manufacturing organization applies this method to its production environment as part of a continuous improvement initiative. But, like the manufacturing floor, quality and test labs are susceptible to accumulations of clutter and inefficiencies that 5S is designed to eliminate.

By integrating 5S into the culture of your lab, you will see landmark improvements in the performance of those who work there, while setting an example of excellence for your entire organization to follow.

Sort

A thorough sorting of every item into two categories—keep or discard—is essential to starting an effective 5S program.

Labs notoriously hoard obsolete check gages, documents, mating parts and prototypes. Closets and cabinets house broken gizmos and binders full of dead quality standards. Throw that junk out. Clutter is the enemy of organization and clear thinking. If any item is not essential to the day-to-day quality function, remove it from your lab.

Straighten

The articles that remain after completing the first phase need to be arranged in a logical and accessible manner. For the serious adherents to the 5S principles, this process starts with a floor plan. After removing the nonessentials from the lab area, many practitioners find they no longer need many of the racks and cabinets that were used to store these items. This step offers the ideal opportunity to rearrange the lab furniture and optimize the flow of people and information.

Once the foundation of an effective layout is in place, add the tools and visual aids to organize your lab's contents. Group the tools and procedures near where they are most commonly used. Clearly label drawers, cabinet doors and binders. Unknot the nest of cables behind your desk. Design a bulletin board for displaying current and relevant information. Apply the old adage: A place for everything, and everything in its place.

Shine

This step is as simple as it sounds. In practice, straighten and shine largely overlap.

While emptying filing cabinets and rearranging furniture, it's a convenient time to wash and wax under and behind them. Clean the shelves and countertops. Repaint the walls. Replace the stained and broken ceiling tiles. Strip and wax the floors. Repair the broken handles and hinges. Make your lab and test area look professional and well groomed.

This phase isn't just a one-time event; it's an ongoing pattern of cleanliness. Each person who works in the lab should be assigned an area to keep neat and organized. As inspectors and technicians maintain their areas, they will develop a sense of ownership and satisfaction. As company executives and prospective clients tour your facility, they will see the same precision and consistency employed in the quality lab built into every product.

Standardize

The first three steps are corrective in nature, while the last two are preventive. The step of standardization moves the cleanliness effort upstream by preventing the disorder from occurring in the first place. There are several situations in which this could prove useful:

- By establishing and following procedures for retrieving and returning hand tools and production documents, the items get misplaced far less often.
- By standardizing best practices for conducting product tests and issuing first-piece approvals, your tools and equipment are used in a consistent manner that prevents damage and minimizes loss.
- By implementing calibration and preventive maintenance programs, your measurement systems remain in a state of readiness. Standardization builds order into your quality-related processes.

Sustain

This final "S" comes from the Japanese shitsuke, which means "a commitment that flows naturally from within." Sustaining isn't just the last step of 5S. It's the true goal of continuous improvement, in which efficiency, integrity and diligence are integral to the people who are part of your team.

As people committed to these virtues develop quality systems, inspect material and build measurement tools, the natural outcome of their work is excellence. *QP*



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