Putting Best Practices to Work

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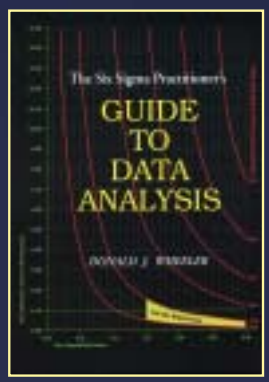

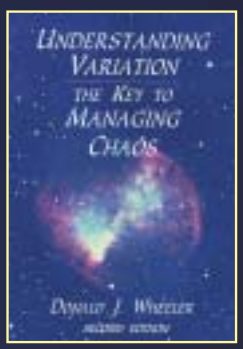

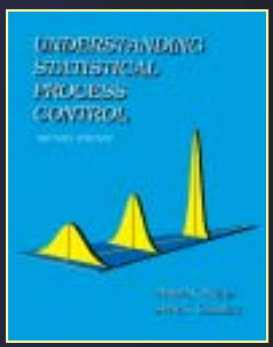

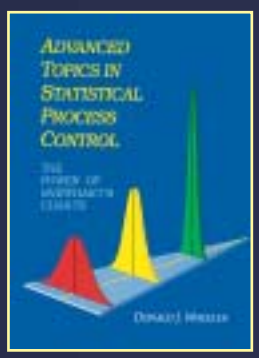

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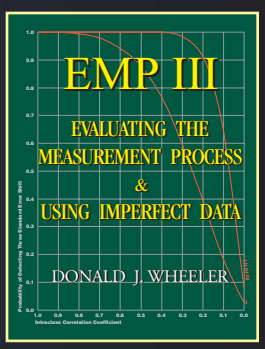

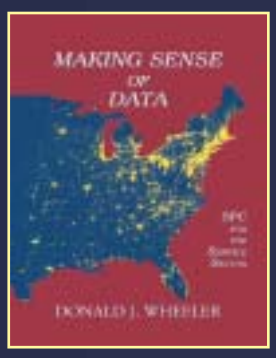

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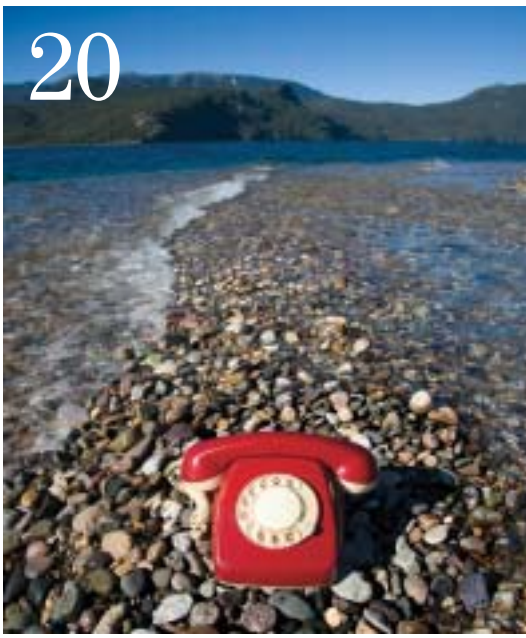

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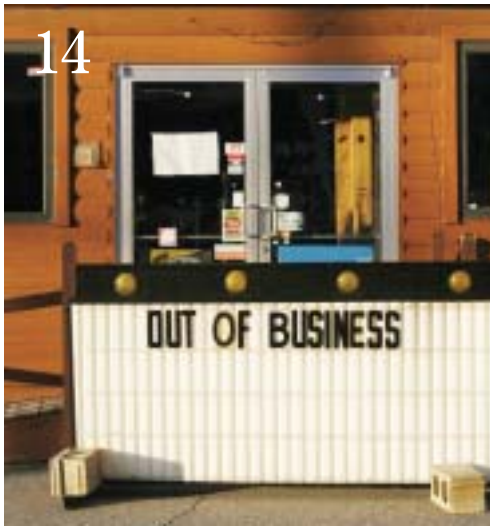

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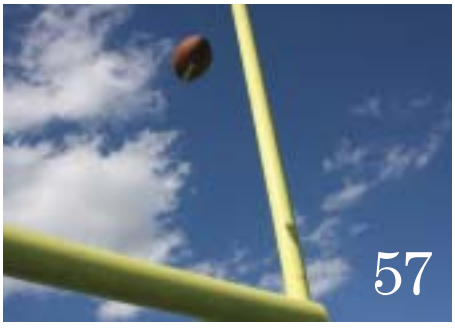

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- FMEA MINUS THE PAIN
A new twist on the traditional approach.

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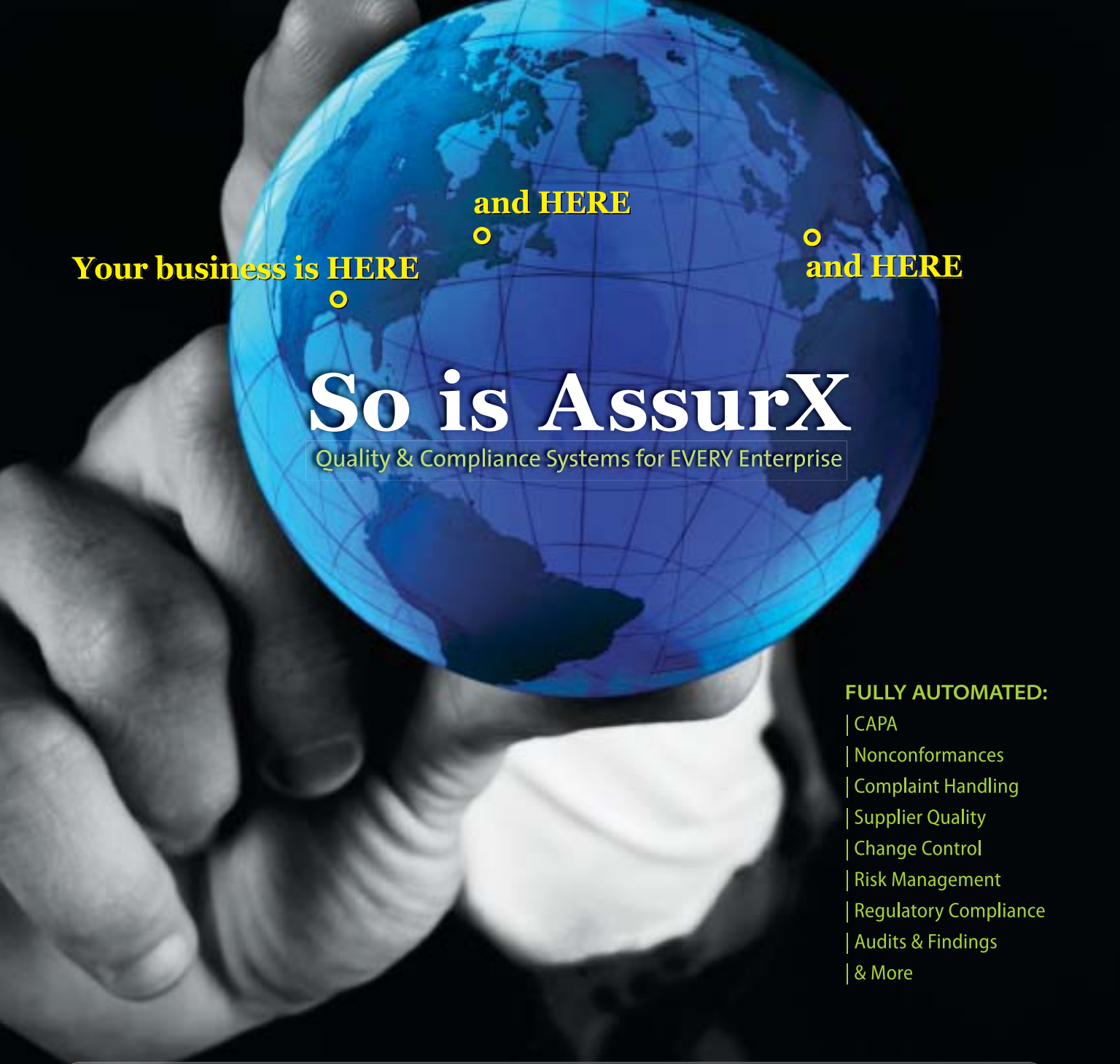

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Don't Panic!

Knee-jerk reactions limit long-term viability

IN TODAY'S SICKLY ECONOMY, consumers are attempting to stretch their dollars further than a candy-craving kid looking to spend a nickel at a dime store.

But, as businesses scrimp, cut, trim and scale back, it simply cannot be at the cost of quality if these organizations hope to emerge from the recession alive.

This sentiment was underscored by the results of a survey of manufacturers that served as the basis for the latest ASQ Quarterly Quality report titled "How Economic Recession is Affecting Quality Activities."

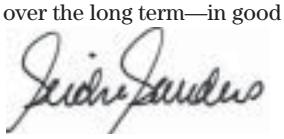
"Organizations that refuse to panic, that move ahead with new initiatives, and that don't cut too deeply will be better positioned to excel when the economy rebounds," the report says. More details are available in the Keeping Current article "Where is Quality During the Recession?" on p. 14, and the full Quarterly Quality Report is available at www.asq.org/media-room/press-releases/2009/20090109-slumping-economy.html.

"Staying the course" is often easier said than done. It might help to consider the economy from the customer's viewpoint. When customers are painfully cognizant of where their money is going, they're much more likely to take their business elsewhere if they believe customer service or product quality has suffered. By the same token, superb customer service in a down economy offers manufacturers and service providers an opportunity to shine.

Many companies are looking to outsource their customer service functions in an attempt to reduce costs. When they do, it's more important than ever to ensure that out of sight doesn't become out of mind, a point made in this month's cover story (p. 20). Author Bill Schultz uses a personal experience to illustrate some of the pitfalls that can accompany a decision to outsource customer service and provides some advice for preventing unintended outcomes or customer gaffes.

Author Kreg Kukor's article (p. 26) complements Schultz's message by describing methods for deploying a sustainable quality system for a global supply base using basic concepts, strong relationships and web-based systems. If you're looking to outsource business processes—or already are—you're bound to find some useful tips for shoring up those relationships in this article.

Quality professionals know it's not always easy to keep passion for quality alive when it seems it's all management can do to find ways to keep the lights on. Yet, the two are not mutually exclusive. Quality professionals who can help management understand that connection will find it easier to make quality a priority in achieving organizational goals over the long term—in good times and bad. QP



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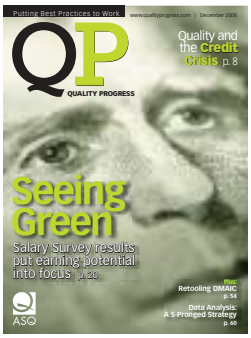
Financing quality



There is no reason the financial sector should be without quality standards, especially after this bailout ("In Crisis, Give Credit to Quality," December 2008, p. 8). It is obvious to the most casual observer that this problem was rampant and will, in fact, occur again without fail. The question is when.

The roadblock to that would be a good quality plan. These guys don't care and, like most businesses, don't want to care. They only do what they are forced to do. Now is the time to force them. But our glorious political sectors are also in opposition to anything but status quo. That is the root cause.

The public should demand a quality system be put in place, but unfortunately not enough people know what that really is. The politicians know this and are using that to just drop the cash and keep going so their bank accounts, stocks and bonds that have been primed by the offenders can prosper, while we—the taxpayers—pay the freight.

Mike Korkowski
Antioch, IL

Secret to success

I had never thought of the financial industry in the same light as manufacturing, but quality standards, reporting and assessment tools seem like a great fit. Although demanding that a quality system be put in place is not necessarily a bad thing, I'd like to suggest that one of the most effective motivations within any industry is success.

Quality systems provide a framework that ensures companies can provide predictable outputs. This is in their best interests, as well as their customers', and ultimately rewards the best practitioners. All it will take is one or two financial firms to figure out how to use this to their advantage, and the rest will follow suit.

Mark Porter
Tempe, AZ

True value

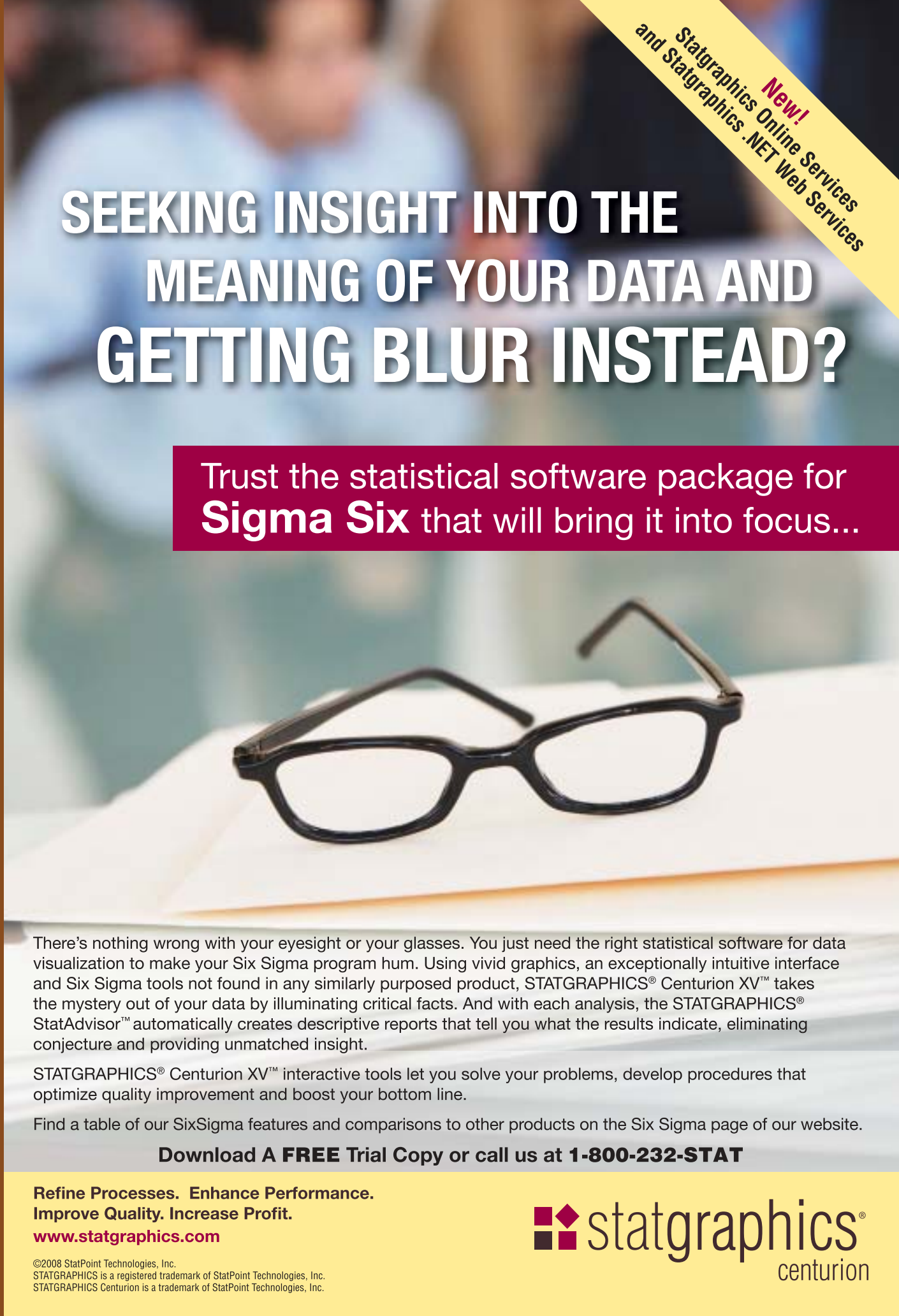
I agree with the individual who wrote the "Value in auditing?" letter (Inbox, December 2008, p. 7). I work for a company certified to ISO/TS 14001 and 18001. We have had different registrars throughout the 10 years of certification. We are a tier one and two supplier, and our customers include Detroit's Big Three, Toyota, Mercedes and Honda. Our scorecards are all green, and very seldom do we go into the red.

Auditors from each registrar are similar in auditing techniques, with low to no value added to the company. I could go as far to say the internal auditor will write something up, and the third party just rewrites the same nonconformance.

I would challenge the certification bodies to develop a management system that takes into consideration the scorecards and the number of audit days a company is in "green" status, putting them into a category that would require third-party audits once every three years.

I also challenge the registrars to employ persons who have been active in the work force in recent years and who understand the applicable processes. It would almost behoove organizations in a particular area to develop their own registrars or qualified auditors, and exchange auditors (audit each other's sites) without this third-party cost.

Name withheld



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Convincing argument

Q: I just accepted my first quality control manager position, and I seem to be running into a few problems. The biggest issue is that my co-managers are set in their old ways of penny pinching. I am trying to implement new and more productive methods and procedures, and I'm getting red-flagged by my one and only superior.

I have so many ideas for improvement but have no way of making others see my point of view. Slowly, I try to convince them of the pros of implementing these ideas. How do you negotiate with people who are afraid of improvement?

Robert Walkinshaw
Cranston, RI

A: The best way to get someone to change is to answer this question for them: What is in it for me? To the extent that one can answer this question, getting them to change is that much easier.

You may want to try to translate "new and more productive methods and procedures" into financial terms. In other words, how much money will implementing new and more productive methods and procedures save? How much additional money will they generate, and in what time frame?

After being shown this in a clear manner, any reasonable person will want to make these changes. Try to explain pros and cons in terms of what benefits the persons being asked to change will get out of the proposed changes.

Some time ago, I conducted a quality-systems audit at a large, upscale, children's-wear manufacturer in the United States. In the beginning, the director of quality mentioned to me he had a difficult

time getting the necessary resources to manage quality effectively in this multiplant company. After a careful study, however, he showed senior management how much money was being lost due to poor quality and what effective quality management could save. Soon after, he got all the money and cooperation he needed.

Pradip Mehta
Principal, Mehta Consulting LLC
Coppell, TX

Survey says …

Q: Are customer satisfaction surveys the only way to identify customer requirements and perceptions?

Omar Dawood
Dubai, United Arab Emirates

A: A formal customer survey, if done properly, can be useful in identifying customer requirements and perceptions. Its strong point is, theoretically at least, it can gather unbiased information, whereas relying on customer-initiated contacts will often generate a disproportionate number of upset or extremely happy customers.

Survey cards from restaurants and hotels also may get responses weighted toward the extremes. For example, I rarely fill out survey cards when I am generally satisfied with things, but if something really bothers me, I will be more likely to turn in a card. Yet survey cards are still useful, because they call attention to problems that otherwise could be overlooked. If the same problem continues to show up on the cards, it should be addressed immediately.

Many organizations monitor customer requirements and perceptions through product returns or complaints. It is important to make full use of these sources of information, regardless of whether formal surveys are also done. Some regulations require that all complaints generate corrective-action investigations unless a valid reason for not doing so is documented. Complaint data, coupled with surveys, can provide especially strong insights.

The usefulness of the survey is somewhat dependent on the product or service being considered. If a company makes large numbers of the same item or delivers the same service over and over, the survey can be a good source of data. If the company makes custom devices or very expensive products, however, it will want to nail down the customer requirements well before the product or service is delivered. A post-delivery survey may still be helpful, but it should uncover few surprises, if any.

Requirements need to be defined through specifications, drawings or contracts that are approved by the customer. Close contact between the provider and the customer throughout the design and

delivery phases is far more important than the post-delivery survey. A post-delivery survey can still be useful in gaining insights into customer perceptions but should uncover very few, if any, surprises.

Even for a high-volume consumer product, where the customer may not be involved in the design, you should not rely entirely on surveys. A company should consider other tools, such as focus groups, analysis of data from previous designs and studies of competitors' offerings.

Surveys can be useful in understanding customer requirements and perceptions but should only be a part of a customer data collection strategy.

Joe Tunner
Consultant, quality improvement and statistical methods
Fort Collins, CO

Pushing the envelope

Q: Does rule No. 1 (of ASME Y14.5M-1994) apply to injection molded plastic parts given the free-state exemption?

Joel Kangas
Alexandria, MN

A: Rule No. 1, in one sentence, says "when only a tolerance of size is specified, that tolerance controls both size and form." You seem to be concerned with the form end of things.

The first question is whether it applies to injection molded parts. Yes, rule No. 1 applies to injection molded plastic parts, but it applies to all parts, whether they're injection molded or not. You say, "given the free-state exemption." Here's the bottom line. The exemption deals with two things: rigid parts and nonrigid parts. Whether it's a rigid part or a nonrigid part has nothing to do with injection molding. You can have a rigid part in injection molding just as easily as a nonrigid part. The exemption applies to nonrigid parts.

The first thing you do is go back to the print. The drawing should specify the drawing standard the print is drawn to. If it's a geographic dimension and tolerancing (GD&T) print, then it should be ANSI Y14.5M-1982, reaffirmed in 1988 (what I call the old standard) or the revision to it, ASME Y14.5M-1994, reaffirmed in 1999. Those two standards, depending on what the age of the print is, will help you determine which way to go.

I don't see huge differences between the 1982 standard and the 1994 standard. In many areas, they don't conflict with each other. If you're dealing with something like symmetry, you need to know which standard you're working with. But with a situation like this, I don't think it really matters.

The whole key is whether the part is rigid or nonrigid. If you're doing injection molded parts and the parts are rigid, then you need to check them in the free state. If the part is injection molded and nonrigid, it's specified in the print what the tolerance is for the amount of free-state variation allowed.

The design engineer can put a callout on the print by GD&T that has a circle with an "F" in it. This means you're allowed free-state variation. If there's no "F" on the print, you need to check it within the free state, and free-state variation isn't allowed. Here's the rub: Design engineers aren't going to waste their time putting a free-state variation on something like O-rings, because everyone knows they're a nonrigid part.

Because the design engineers sometimes just assume you know what you're doing, if it's a flexible part, you would be allowed to take the part and move it to the specified data of the part, clamp the part in place according to those data and then check it. Basically, what you're doing is taking the free-state variation out of the part, moving it to what its rigid envelope would be and checking it in place.

In some cases, it may be required for the part to meet its tolerance requirements while in the free state. In other situations, it may be necessary to simulate the actual-use conditions of the part, warp it back into where it should be, hold it in place and then check it. This is done by restraining the appropriate features, such as the data-reference features.

The restraining forces are those that would be exerted in the assembly or in the function of the part. Let's say it takes 400 pounds of pressure to put a part back into shape and check it. The spot weld isn't going to hold 400 pounds. But if I take four pounds of pressure to bring it back into shape, a spot weld can hold that. Nobody's going to care about me doing that. You can't use excessive force. That's why, in ASME Y14.5M:1994, it says the acceptable forces are those that would be exerted in the assembly or functioning of the part.

Gregory S. Gay
ASQ Fellow
Mendon, MI

ASKED AND ANSWERED

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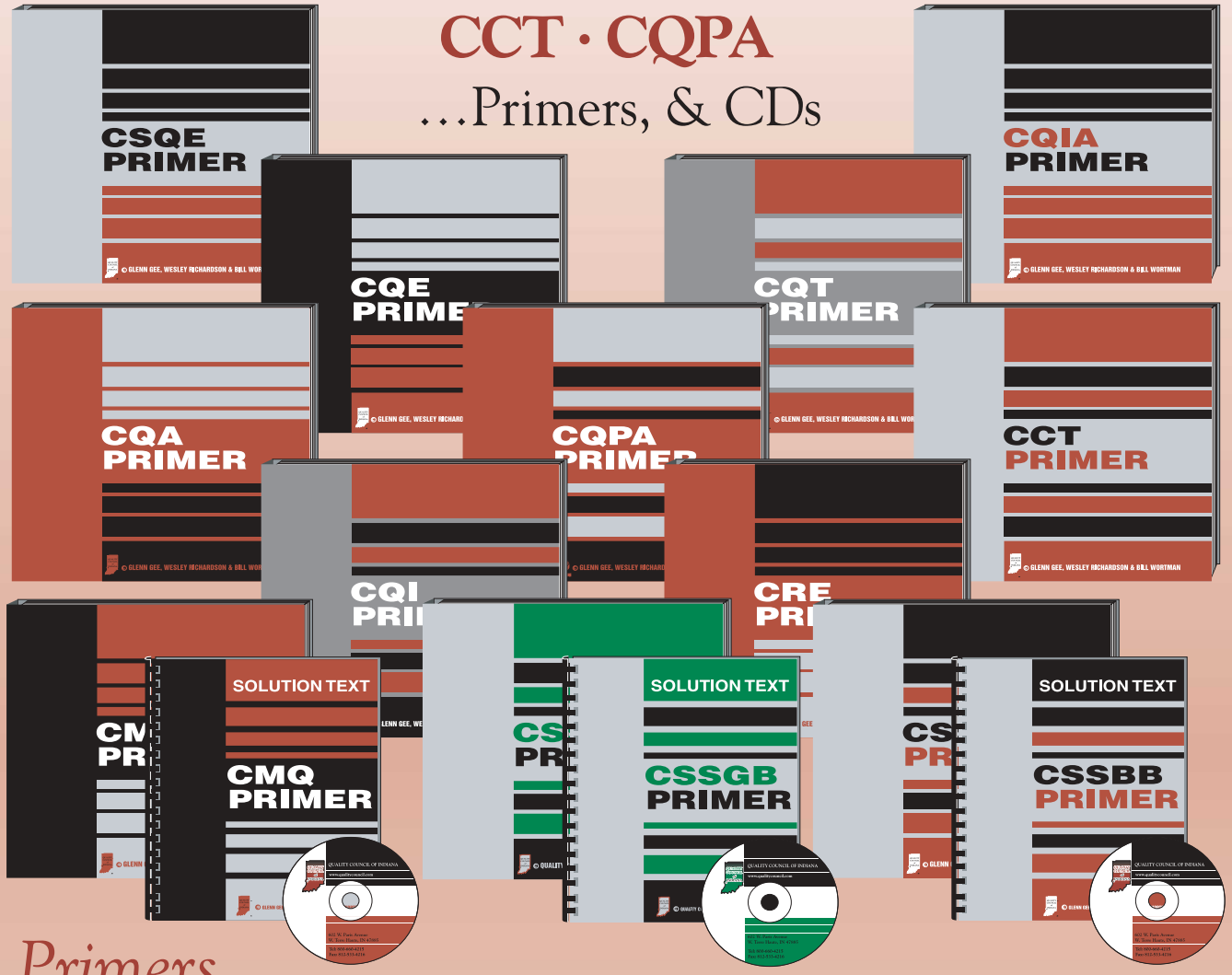

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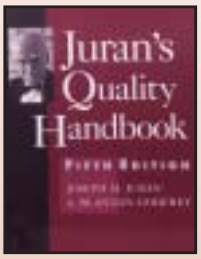

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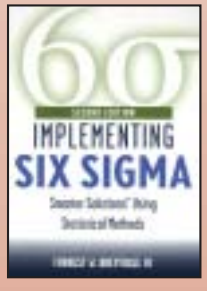

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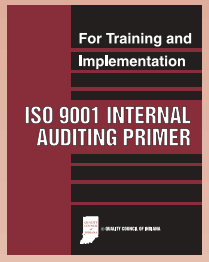

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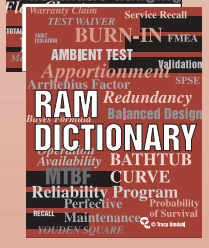

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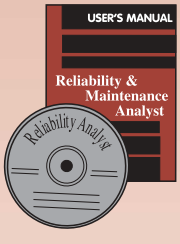

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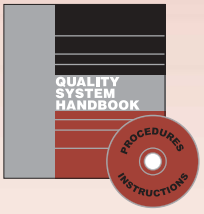


PRODUCT TESTING

Safe ... and Sorry

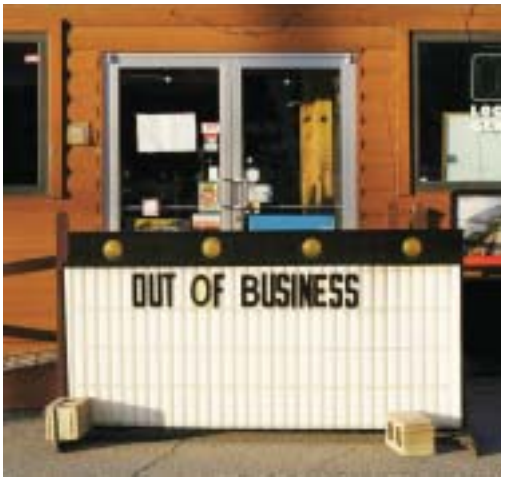
New product-testing laws set up some small businesses for failure

After more than a year of being inundated with product recalls, the U.S. government responded this past summer with the Consumer Product Safety Improvement Act (CPSIA).

Among other things, the legislation mandates that products targeted for children age 12 and younger, including clothing and toys, be tested by a third party for lead and six banned plastics. In addition, companies must affix labels on those products to show when and where they were manufactured.[1]

But, in the government's rush to prove it had the American people's best interests at heart, some believe the government may have issued a death sentence for small businesses across the country.

Dan Marshall, who co-owns Peapods Natural Toys and Baby Care in St. Paul, MN, told the *Santa Rosa Press Democrat*: "The law has no sense of scale. The same regulations apply to a toymaker making toys by the dozens as Mattel making toys by the hundreds of thousands. The testing costs more than what people make in selling these products in the first place."[2]



Marshall estimated that the testing costs for the small companies who stock his store's shelves range from $500 to $3,800 per product.[3] But that cost is a pittance compared with what noncompliant organizations face: a civil penalty of $100,000 for each violation—with each violation tagged as a separate offense that could push the overall fine to as much as $15 million—as well as criminal charges.[4]

But it's not just manufacturers who should fear the wrath of the federal government. Under the CPSIA's original terms, the nation's resale shops had two options: test all of their merchandise or toss it in the Dumpster. On Jan. 8, the Consumer Product Safety Commission (CPSC) announced its intention to relax that requirement.[5]

But that doesn't mean second-hand stores are off the hook entirely. While no longer required to meet the CPSIA's more stringent testing standards, "those resellers that do sell products in violation of the new limits could face civil and/or criminal penalties."[6]

So, in an attempt to ease the troubled minds of store owners, the CPSC lifted the

(CONTINUED ON P. 18)

ASQ

STUDY: WHERE IS QUALITY DURING THE RECESSION?

Despite the worldwide economic downturn, many companies continue to invest in quality and innovation—even doubling certain quality efforts—to keep up with or stay ahead of the competition.

In addition, some quality professionals say they are seeing more opportunities to become involved in business development activities, according to the latest ASQ Quarterly Quality Report, "How Economic Recession is Affecting Quality Activities."

Other companies, however, are trying to survive the slumping economy by cutting workers, training and budgets for quality activities. Many companies have backed away from quality initiatives that organizations typically use to cut costs, said those who took the survey.

"The really good news, if there is a silver lining in these times, is that while some companies are shrinking back into their shells, other organizations are moving decidedly in a forward-looking direction and keeping quality practices at the top of the list," said Ken Case, ASQ past president and professor emeritus at Oklahoma State University.

The report recommends a middle ground for organizations trying to balance efficiency with innovation and growth. Those who took the survey—47 people from mostly manufacturing companies—said waste reduction and increased efficiency are hot topics at their companies, as well as ways to generate inspiration and new ideas.

To view the full report, visit www.asq.org/quality-report/reports/200901.html.

FEDERAL GOVERNMENT

OBAMA CREATES POSITION TO POLICE FEDERAL SPENDING, PORK POLITICS

In an effort to control federal spending, reform massive government entitlement programs and curb pork-barrel spending, President Obama has created a new position in his administration: chief performance officer.

He has named Nancy Killefer to the position. She comes from McKinsey & Co.'s public-sector practice, where she developed strategies for improving organizational effectiveness for government clients. She had been assistant secretary of the Treasury Department in the Clinton Administration. There, she led a major modernization of the Internal Revenue Service. Clinton later appointed her to the IRS Oversight Board.

Roberto Saco, ASQ's president, said he looks forward to connecting with Killefer and discussing ways quality management can be used to improve government.

"This is a strong message that the new administration is serious about managing the enterprise of government," Saco said. "One hopes that the new position will have purview of topics and issues way beyond budgeting, however, and in areas with significant potential: procurement, general services and transaction processing, among others."

News articles from the *Chicago Tribune* were used to compile this report.

EDUCATION SURVEY

EDUCATORS TO OBAMA: STUDENTS NEED 21ST CENTURY SKILLS TODAY

Students must have 21st century skills to be productive members of tomorrow's workforce. That's what educators ranked as President Barack Obama's No. 1 education priority in a recent survey conducted by ASQ.

More than half of the 500 teachers and administrators who participated in the survey called for the Obama administration to focus on innovation, technology, and life and career skills for students to succeed.

Forty-two percent of those surveyed said retaining qualified teachers and helping all students meet achievement goals should be the top priorities for the administration. Other priorities ranked in the survey include:

- Transforming No Child Left Behind to improve measurements (29%).
- Closing the achievement gap between whites and minorities (17%).
- Eliminating budget waste and inefficiency in K-12 schools (22%).

ASQ planned to deliver the results of the survey to Obama and Secretary of Education Arne Duncan shortly after the inauguration last month.

CAPITOL Q

A request by ASQ's Measurement Quality Division and other organizations to include metrology job descriptions in the standard occupational classification has been denied by the Office of Management and Budget. The addition of these job descriptions for metrology practitioners to the U.S. Department of Labor's standard occupation classification system was considered one way to educate people about the metrology field and bring more into the profession. ASQ is seeking to have the matter reconsidered … Members of the Education Division, the K-12 Education Advisory Committee and ASQ staff are brainstorming with Washington, D.C., contacts to determine how to make the successes of school districts that have saved money and raised student achievement more visible. This education group thinks the increased visibility will help promote quality and the Malcolm Baldrige National Quality Award.

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

Mr. Pareto Head

BY MIKE CROSSEN

QP

ONLINE ONPAPER

QUICK POLL RESULTS

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

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

- Pareto analysis 33.3%
- Cause and effect diagrams 27%
- Control charts 23%
- Check sheets 6.3%
- Histograms 5.8%
- Scatter plots 2.2%
- Stratification 2.2%

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

"In light of the economy's downturn, is your organization outsourcing:"

More? Less? The same?

Correction

In January's Quality in the First Person column, author Rip Stauffer's rank was incorrect. Stauffer retired as a senior chief petty officer in the Navy, not a lieutenant.

STANDARDS

SURVEY: MANAGEMENT SYSTEM CERTIFICATIONS USED MORE

The recently released ISO Survey of Certifications–2007 reveals 175 countries are using one or more certifications from the International Organization for Standardization's (ISO) management system standards, up from 170 countries in 2006.

The principal findings of the survey are:

- ISO 9001:2000 (quality management): At least 951,486 certificates were issued in 175 countries and economies. The 2007 total represents an increase of 54,557, or more than 6% over 2006. The service sectors accounted for 32% of all certificates issued.
- ISO 14001:2004 (environmental management): At least 154,572 certificates were issued in 148 countries and economies. The 2007 total represents an increase of 26,361 (more than 21%) over 2006. The service sectors accounted for 29% of certificates issued, up from 27% in 2006.
- ISO/TS 16949:2002 (quality management for automotive suppliers): At least 35,198 certificates were issued in 81 countries and economies. The 2007 total represents an increase of 7,199 (more than 26%) over 2006.
- ISO 13485:2003 (quality management for medical devices): At least 12,985 certificates were issued in 84 countries and economies. The 2007 total represents an increase of 4,959 (more than 62%) over 2006.
- ISO/IEC 27001:2005 (information security management): At least 7,732 certificates were issued in 70 countries and economies. The 2007 total represents an increase of 1,935 (more than 33%) over 2006. Service sector organizations accounted for 90% of the certificates issued.

The survey results illustrate the evolution of the global economy, with newly emerging economies such as China, India, Brazil and the Russian Federation among the leading countries in terms of total certificates issued. Bulgaria, the Czech Republic, the Republic of Korea, Mexico, Poland, Romania, Thailand and Turkey also showed intensive certification activity.

STANDARDS

INPUT SOUGHT FOR SR STANDARD

A special working group established by the International Organization for Standardization (ISO) has issued for review and comment a new draft standard on social responsibility (SR), ISO 26000. The proposed standard is assigned to complement existing public and private sector SR initiatives.

The first round of national consensus position and comment development at ISO is known as the committee draft (CD) stage of voting and commenting. During this stage, the national standards bodies of those countries registered as members of the activity will organize their national mirror committees to review the draft and to decide on the national position and any comments to be submitted to ISO. The choice at the CD stage is whether there is sufficient support for the draft standard to advance to the draft international standard stage.

As the U.S. member of ISO, the American National Standards Institute (ANSI) has accredited ASQ as administrator of the U.S. technical advisory group (TAG) for the ISO SR activity. In this capacity, ASQ staff provides administrative facilitation for all aspects of the TAG's work.

TAG members and other interested U.S. parties are encouraged to obtain and review the draft standard and to develop their input for consideration by the full TAG. ASQ is offering access to the CD text, submittal of comment and access to U.S. TAG membership information and applications via its website, www.asq.org/standards/index.html.

National body votes and comments on the ISO 26000 CD are due by March 12. For further information, contact Steven Cornish of ANSI (scornish@ansi.org).

DATEINQUALITYHISTORY

QP looks back on an event or person that made a difference in the history of quality.

Feb. 23, 1947

The International Organization for Standardization (ISO), the world's leading developer of international industry standards, was founded in Geneva.

ISO was born from the union of two organizations—the International Federation of the National Standardizing Associations, established in 1926, and the United Nations Standards Coordinating Committee, established in 1944.

In October 1946, delegates from 25 countries, meeting at the Institute of Civil Engineers in London, decided to create a new international organization. The objective of the meeting was to "facilitate the international coordination and unification of industrial standards." The new organization, ISO, officially began operations four months later.

Today, ISO is a network of the national standards institutes of 157 countries, one member per country, with a central secretariat in Geneva that coordinates the system. Each country is represented by its own national body. The American National Standards Institute represents the United States.

SOURCE:
ISO, www.iso.org/iso/about.htm.

Who's Who in Q

NAME: Denise Robitaille.

RESIDENCE: Kingston, MA.

EDUCATION: Bachelor of arts degree from the University of Massachusetts at Amherst.

INTRODUCTION TO QUALITY: Document writing for an organization going through an ISO 9001 implementation.

CURRENT JOB: Robitaille owns her own company and divides time between consulting, training, auditing and writing.

ASQ ACTIVITIES: Robitaille has been on the leadership teams of the Boston Section and the Olde Colony Section for more than 12 years. She also serves on the U.S. technical advisory group to ISO/TC 176. She calls this work "immensely fulfilling" and treasures the "extraordinary colleagues from around the world" with whom she works.

OTHER ACTIVITIES/ACHIEVEMENTS: Raising her three children.

PUBLISHED WORKS: Robitaille has authored seven books and co-authored two others, all published by Paton Press. She's also a regular columnist for *Quality Digest* and *The Auditor,* and she's written articles for many publications, including QP.

RECENT HONOR: Recently elected ASQ fellow.

FAVORITE WAYS TO RELAX: Reading and camping (when she can get away).

QUALITY QUOTE: Quality is the common denominator. It's the thread woven into the fabric of any organization or enterprise that defines our commitment to ourselves and to those we serve.

Product testing law

(CONTINUED FROM P. 14)

testing requirement while reminding those owners of their liability if they sell tainted products, which they can avoid by identifying those products … by testing them.

With confusion reigning and the deadline looming, a CPSC spokesman tried to allay some of the fears by saying the agency doesn't have the means or the inclination to target small businesses.[7] The CPSC went a step further in January when it gave preliminary approval to rule changes to the CPSIA that would exempt:

- Items with lead parts that are inaccessible to children.
- Products made of natural materials, such as cotton and wood.
- Electronics that cannot be made without lead.[8]

"The CPSC came under fire for supposedly not doing their job, which I feel was untrue, and in response to the attack, the CPSC might have gone overboard in trying to absolutely ensure product safety and now needs to find some middle ground," said liability prevention expert Randall Goodden.

If they don't before the deadline, it might force some small businesses to shutter their windows—possibly for good.

—Brett Krzykowski, assistant editor

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1. "Consumer Products Safety Improvement Act of 2008," Consumer Product Safety Commission, www.cpsc.gov/cpsia.pdf.
2. Michael Coit, "Safety law costly for small toy makers," *Santa Rosa Press Democrat*, Dec. 31, 2008.
3. Ibid.
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5. "CPSC Clarifies Requirements of New Children's Product Safety Laws Taking Effect in February," CPSC, www.cpsc.gov/cpscpub/prerel/prhtml09/09086.html.
6. Ibid.
7. Nancy Cambria, "Resale items may get trashed with new federal law," *St. Louis Post-Dispatch*, Jan. 8, 2008.
8. A. Semuels, "Regulators rethink rules on testing children's clothing and toys for lead," *Los Angeles Times*, Jan. 7, 2009.

ASQNEWS

COOKIE FOUNDER FEATURED Wally Amos, the founder of the Famous Amos Cookie Co., has been added as a keynote speaker for this year's ASQ World Conference on Quality and Improvement in Minneapolis. Amos joins a lineup of speakers that includes Jerry Greenfield, the co-founder of Ben & Jerry's ice cream, and Howard Behar, the former chairman and president of Starbucks Coffee. Amos is known for his infectious enthusiasm and tireless promotion of his business, which became a $10 million cookie empire in its first 10 years of operation. Visit http://wcqi.asq.org for more updates on the conference, which takes place May 18-20.

APPLYING FOR OTT Applications for the 2009-2010 Ellis R. Ott Scholarship are now available through ASQ's Statistics Division. The $5,000 scholarships are for students in master's degree or higher programs with a concentration in applied statistics or quality management. Over the last 11 years, 32 students have received $165,000 worth of scholarships. Last year's scholarship winners were: Michelle Quinlan, University of Nebraska-Lincoln, and Irina Kukuyeva, University of California, Los Angeles. For more information and an application form, visit www.asqstatdiv.org. Applications are due April 1. Contact Lynne B. Hare at lynne.hare@comcast.net with questions about the scholarship.

SHORTRUNS

THE COORDINATE METROLOGY SOCIETY has announced a call for papers for its annual conference July 20-24 in Louisville, KY. Abstracts for white papers illustrating application of 3-D coordinate measurement systems should be submitted by April 10. For guidelines or more information, visit www.cmsc.org or e-mail presentations@cmsc.org.

THE AMERICAN NATIONAL STANDARDS INSTITUTE (ANSI)-ASQ National Accreditation Board/ACLASS can now accredit reference material producers (RMPs) after signing a mutual recognition arrangement with the Asia-Pacific Laboratory Accreditation Cooperation late last year.

THE INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO) and the International Electrotechnical Commission (IEC) have revised a standard that addresses RFID for item management. ISO/IEC 18000-1, Information Technology—Radio Frequency Identification for Item Management—Reference Architecture and Definition of Parameters to be Standardized revises the 2004 version of the document. For more information on ISO/IEC 18000-1, visit www.iec.ch/news_centre/release/nr2008/nr3908.htm.

THE AUTOMOTIVE INDUSTRY ACTION GROUP (AIAG) has published the Consumer-Centric Warranty Management Guideline, which is designed to promote advances in consumer satisfaction and continuous warranty improvement. For information on the e-document, visit www.aiag.org.

A COMPREHENSIVE WELLNESS accreditation program has been launched by the Utilization Review Accreditation Commission. The new program will help evaluate a worksite's wellness organization that focuses on health promotion, chronic disease prevention and health risk reduction. For more information on the program, visit www.urac.org/press/cmsDocument.aspx?id=617.

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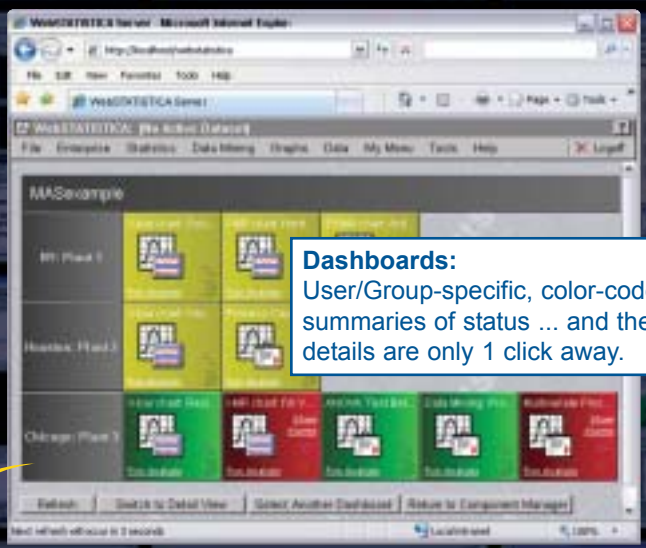

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Out of SIGHT...

When outsourcing, make sure quality **isn't left behind**

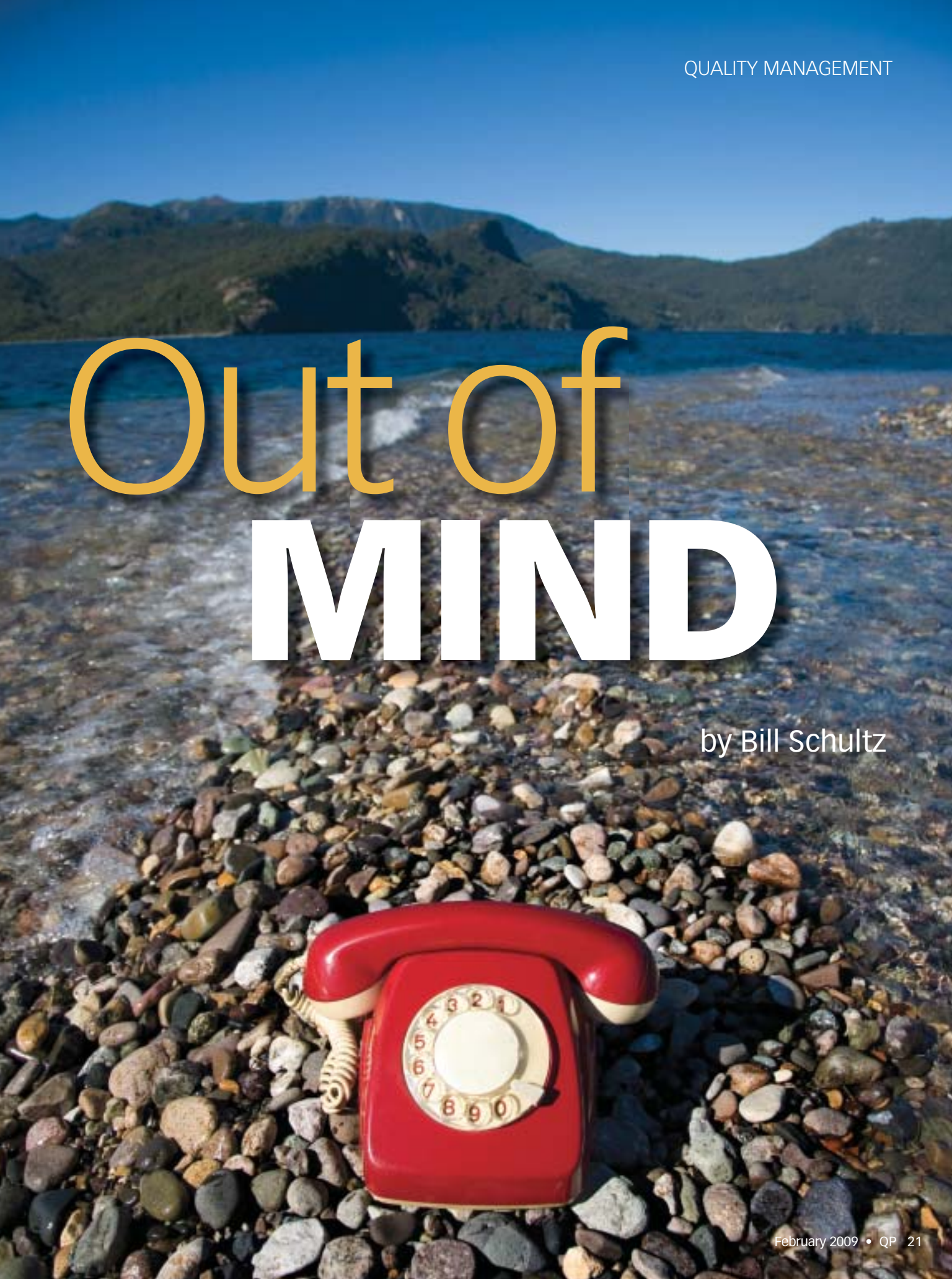
In 50 Words Or Less

- Quality often takes a hit when a company outsources any process with direct customer impact.
- Those changes can leave customers feeling alienated from a company they previously had confidence in.
- Holding the outside vendor to a standard of performance can ensure effective oversight and improved customer satisfaction.

A FEW MONTHS AGO, I had an experience that made me wonder about a common feature in today's business reality. The purpose in sharing this story is to publicize a growing gap in quality-system coverage caused by outsourcing and to share some of the challenges of fixing it. To paraphrase a popular old police drama: The story is true. The names have been changed to protect the innocent.

Out of MIND

by Bill Schultz



First, some background. One of my longest and most enjoyable professional relationships has been as the customer of a particular national organization. For the sake of this article, I'll call it United Good & Helpful (UGH).

UGH trumpets its mission to prioritize quality in all its activities, with a goal of making the company the very embodiment of the latest in quality technology, concepts and tool usage. Unlike other companies saying this, I believe UGH truly has achieved its goal and, as a result, is justly recognized as a national quality leader.

One area in which UGH has always been my benchmark is customer service. No confusing mechanical answering systems to navigate. No lengthy waits for human contact, only to encounter partially trained staff with borderline English language skills who really don't care about resolving your problem. Not at UGH.

Calls were answered on the first ring or two by friendly, knowledgeable staff. They stayed with the problem until it was fixed, involving a more expert resource if necessary. They did this to make sure customers' needs were being effectively handled without repetition or risk of miscommunication. In this realm, UGH has been a pure delight, which is a major part of why I have enjoyed being a customer.

Wake-up call

Recently, I needed to use a web database UGH first set up for its customers some time ago. I had used it before, so I already had my ID and password. I entered them at the appropriate link. This time, however, I was returned to the original login page, with my entries eliminated. No error messages or indications I had tried to log on, just a blank page.

After spending 20 minutes re-entering everything (in case I had mistyped) and looking up my account information, I confidently placed a call to UGH's reliable customer service staff. As always, a friendly voice quickly answered and carefully listened to my problem.

This time around, however, my UGH customer service representative had a different kind of message: He could no longer resolve problems with this database directly because UGH had outsourced it in the past year. He gave me a phone number to call, and what followed was my first ever quality cold shower experience with UGH.

When I made the call to UGH's outsource vendor, I found myself waiting because "all support personnel were busy helping other customers." Then, I was connected with a relatively uninterested person who poked around my system description (a Dell PC running Windows XP with standard protection software) a little bit and decided, "There must be something wrong with your internet service provider." He was sorry, but he couldn't do anything to help me. He hung up. I was on my own if I wanted to use the UGH database this time around.

To make the ensuing story short, after days of wandering in a customer service desert, I discovered the problem was invasive features of the new database provider's code, which my protection software did not like. It seems the new database was checking out its users to maintain security of its information. When it tried to check out my PC, my system refused. This feature was likely protecting other information this database merchandiser was handling for non-UGH clients using the same software.

I had fixed my problem, but the big customer service change I felt from a top company like UGH made me wonder if customer service support always falls off when activities were outsourced. Thinking about it, I had seen this happen often. Why not investigate?

Management concerns

I asked UGH management about my experience, and my contact reacted well, referring it to his peers immediately. The next morning, I got a call from Lynn, who said she was the person with direct responsibility over the database vendor. I don't know if Lynn ever actually saw a copy of my original e-mail, but she was a pleasant person who had been tasked to resolve whatever my concerns were.

Lynn began by letting me know her database vendor "had always provided excellent customer service up until now." Because I was pretty sure the fellow who answered my call hadn't always been providing excellent customer service for others, I asked her a little about what she knew of the vendor's customer service process. After some conversation, it turned out she didn't know much about it. She just "hadn't heard anything up to now."

This was my second quality cold shower with UGH. Lynn seemed to have little feel for quality systems or process quality but had been put in charge of this outsourced piece of UGH operations. I had already fixed the symptom (my unresolved customer service prob-

Does outsourcing mean **customers get stuck** with the **vendor's quality system?**

lem) on my own, but my root concern was the outsourced customer service.

As Lynn and I talked further, she asked for some suggestions on how her vendor's customer service efforts could be checked out. I volunteered a few ideas, which will be familiar to readers who have experience running ISO 9001-style systems:

1. Inquire if the vendor has a defined procedure for handling customer calls and for training its customer service representatives. Ask to see it or have it explained in detail.
2. Ask your contact to sit in with you on a live call or two and see if the process from step one is running OK.
3. Request to see the vendor's records or data on customer complaints. Are there any?
4. Ask how your vendor handles complaints, particularly from a management review perspective. Does management look at customer concerns?

My guess is that Lynn was humoring me a bit with this process discussion. I think she hoped to limit her work to a quick fix, rather than opening any interactions with the outsource vendor. If I audited this database vendor today, I doubt they would have heard of any of my suggested activities. The root cause of my problem seemed to be a customer service process gap between UGH and its vendor created by the outsourcing, and it still isn't fixed.

My original concern as a customer and quality professional had been the absence of the tremendous quality I had counted on from UGH, which always seemed to be looking out for my interests. Lynn seemed to need my suggestions on basic quality measures, so now a further worry arose about quality system management at UGH: If this outsourced operation was being allowed to run without UGH quality system support, what else was?

From a broader perspective, we could ask: If a quality pacesetter like UGH had a purchasing administrator handling a customer interface without quality input, what are average companies doing? Does outsourcing mean customers get stuck with the vendor's quality system?

Closing the gap

The four suggestions I offered to the UGH purchasing agent are appropriate if ISO 9001:2000 or similar system standards apply. ISO 9001:2000, section 7.4 requires an organization to evaluate suppliers based on their ability to supply product that meets the organization's requirements.[1] As far as I was concerned, the database tool UGH had chosen to buy from a vendor in this example was a product of UGH.

Section 7.5 of the standard requires planning and carrying out of services to be done under controlled conditions, including validation of processes and training or qualification of personnel.[2] You would expect this to include some investigation of key processes, such as customer service, and whether customer impact operations and interfaces are done directly by company employees or are outsourced to another company.

What if the vendor is not ISO 9001-certified, as many IT or service outsource operations are not? What is the requirement for the outsourcing purchasing organization? Standards such as AS9100B include additional provisions requiring flow down of parent organization requirements to suppliers, assuring customers that outsourcing isn't an excuse for not offering the same quality support.

A key point is whether the ISO 9000:2000 definition of product is applied when outsourcing support efforts are planned. The most commonly consulted standard for quality planning, ISO 10005:2005, requires consideration of all elements that impact customers in project planning (section 4.3). At a minimum, this should include a process for customer service monitoring when operations that help customers are outsourced.

Many quality professionals know from experience how inspection levels or process controls that are carefully set in-house often are forgotten when operations are outsourced. There needs to be a person with knowledge of quality systems in the room at contract time.

The main control when determining whether ISO or other standards are followed after operations are outsourced is the thoroughness of a third-party auditor. When your registrar last visited, did he or she ask

Audits that **covered outsourced areas** would certainly **help focus needed attention** for client companies.

about outsourced processes when checking your customer satisfaction or other processes?

In the past few years, I have seen accreditation checklists used by major U.S. registrars that made no mention of checking for outsourced processes or services. Hopefully, individual auditors were savvy or lucky enough to discover outsourced efforts on their own. Audits that covered outsourced areas would certainly help focus needed attention for client companies.

What just happened?

The major objective in outsourcing is cost reduction. Often, this leads to partnering with suppliers that validate the phrase "you get what you pay for." Strained quality departments are hard pressed to stay in touch with an outsourcing project team led by a champion whose sole focus is getting the operation done on schedule. In those cases, quality departments are viewed as a risk that could ruin or delay a needed cost reduction.

It is hard enough when the in-house outsourcing team has the expertise and management backing in applying company standards. It is next to impossible when dealing with support areas in which the vendor may be the expert (for example, when software applications are written by outside programmers) or when tangible company assets—besides customer goodwill—are not clearly involved.

Ultimately, the impact to a company is not damaged feelings in the quality department or fooled auditors, but a disappointed customer and lower company customer image. Nobody wants to be on the next MSN.com list of worst customer service providers or bring up the rear on a J.D. Power and Associates survey. Customers are too valuable to disappoint.

Pay attention

Careful readers will notice that no new systemic certainty has been proposed for undersupported outsourcing. Instead, quality system management attention must be directed to maintain company standards in key areas such as inspection levels, process controls and customer service.

It is difficult, but we can find the processes our customers expect in our own quality manuals. ISO registrars who police outsourced operations can remind us, but avoiding subsequent customer disappointment is a competitive opportunity that must be its own incentive.

As time passes, out-of-sight outsourcing impacts are starting to accumulate. The quality bandwagon providers have begun the typical array of webcasts and personal services offerings. Before I wrote this article, I read an online ad for a webcast that featured a principle instructor who hails from a company that does not extend its own touted quality system to numerous outsourced projects. Perhaps this instructor first needs to sweep in front of his own door a bit, but at least he is thinking about the outsourcing quality system coverage gap.

Maybe you have something that really works. The challenge is to be sure we continue to meet our own customer expectations as we move operations from our own quality systems out of sight to others. QP

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A Simple Plan

by Kreg Kukor

10 tips for **deploying a sustainable quality system** with overseas partners

In 50 Words Or Less

- Partnerships between companies and global suppliers can sour when communication and feedback are overlooked.
- Companies must give suppliers the right amount of data at the right time and provide training to ensure processes are followed.
- It's easy for companies and suppliers to look past the human element when building partnerships.

FOR MORE THAN 100 years, North American companies have advanced equipment and manufacturing technologies to constantly monitor progress and drive process improvement. Correspondingly, manufacturing engineers and quality engineers have been hired in droves to implement lean manufacturing techniques and Six Sigma processes.

Immediate and instant corrective action and process improvements have become the norm for most North American manufacturers. Or have they? Has globalization exposed a weakness in processes, systems and infrastructure? In the quest to automate and refine processes, have we overcomplicated matters and overlooked the human factor?

With today's technology and the speed of globalization, many of us may be missing simple steps in transforming a process, which in turn could be weakening our global supply base and affecting overall productivity.

We can improve our global supply base by deploying simple tools to ensure effective and efficient communication. We can make sure we use the right data, take photographs of processes being performed if needed, and integrate feedback processes critical for sustainable improvements.

These initiatives can occur in each of the four phases of a company-supplier relationship: prelaunch, prototype, production and ongoing performance.

Systems and suppliers

Most suppliers fall into one of two categories: expensive suppliers with sophisticated systems and cheap suppliers with very few systems.

Most North American organizations that source globally take cost into consideration more than systems. Some organizations think they can mold a supplier into whatever they want. When this happens, both sides usually become frustrated.

For instance, suppliers and companies must treat each other with respect. This point doesn't seem worth mentioning, but it is. Employees of a supplier or company don't start their day planning how to make defects. Most of the time, defects and failures on the supplier's side can be traced to poor or insufficient data provided by the company or a lack of communication on an issue, change or process. In these cases, culpability lies equally on both sides.

For many companies, suppliers are seen as the enemy and not a true partner. This is compounded when the supplier is located thousands of miles away. Companies sometimes don't consider the efforts of a supplier or even acknowledge internally that there's an art in communicating with overseas partners.

These obstacles are compounded if you're not working in a metadata environment and are working without web-based quality/business collaborative software. You will increase the time you spend identifying conflicts or issues with your supplier, which ultimately increases your risk of doing business.

You must remember that you can be a teacher to suppliers and act as a mentor to global partners. You can also be a student and learn about new ideas, tools and techniques from your global partners.

Prelaunch phase

There are some straightforward ways to deploy a solid, sustainable quality system for your global supply base: use basic concepts, interact with fellow human beings and become familiar with web-based systems. It begins in the prelaunch phase of a company-supplier partnership:

1. Develop human relationships: Developing relationships is the single most important way to gain mutual trust. In Asia, for instance, without that trust, business can move very slowly. Positive relationships start, of course, with effective communication. Take time to study and understand the culture of the country where the supplier is located. Learn some of the language.

Also, be aware that a simple hand gesture or an innocent comment in one culture may be considered derogatory in another culture.

Don't assume anything, either. In China, when someone says "yes, yes, yes" repeatedly, it means he or she has heard you. It does not mean he or she understands you. In India, "I understand" means "I heard you," but it does not mean the person understands you.

It is your responsibility to communicate in a way the listener will understand and to understand the cultural communication methods. Read about the city where the supplier is located. Twenty or 30 minutes of study will gain you hours of open dialogue.

Another way to begin breaking down cultural or language barriers and put others at ease is to share information about yourself and your background. In my experiences working around the globe, for instance, I have struck up conversations with people I would be working with by showing a family photo or a photo of where I live. I want the other people to feel at ease with me. Maybe this forms a connection with them: I could have the same goals as they do, such as raising a happy, healthy family or living in a nice home. I have found this simple gesture helps break down cultural and language barriers and immediately puts people at ease.

It may seem like a given, but be aware of overseas time differences. Picking up the phone at 2 p.m. Eastern Standard Time to relay data or information to a supplier contact in China is like someone calling your office in North America in the middle of the night. If you show some sensitivity with the supplier about the time difference, you will get a great amount of respect.

2. Transferring data: This must encompass all data the supplier will need to be successful. Data include corrective actions, tooling records, nonconformances,

Be aware that a **simple hand gesture or an innocent comment** in one culture **may be considered derogatory** in another culture.

process audits, preventative maintenance records, gage and calibration records, customer complaints, engineering changes, computer-aided design data and blueprints. The more information you can give to your suppliers, the better they can understand the past process and be able to work diligently at not repeating any problems. A solid, advanced product quality planning checklist should be developed to ensure that all items are coordinated and transferred accordingly.

For example, to save immense amounts of time and energy in collecting data from disparate systems and reduce opportunities for error, work in a metadata environment or with a web-based system, such as Integrated Quality Systems.

It's not just the numbers and systems that hold valuable insight and information about your processes. Those people at your company with long-term knowledge of processes must be a part of starting up or transferring operations overseas. The sooner you engage the right people with the knowledge that needs to be transferred, the better. Make sure those people are educated or trained about the language and culture of the country where the product will be manufactured, too.

Prototype phase

3. Training operators in data transfer: Operator instructions, including gage instructions, can take many forms. Would you prefer to communicate with the supplier in the supplier's native language, or take photographs or videos of the process? Or a combination of these? Unless you are fluent in the native language, the supplier probably will understand photographs and videos more easily.

I was global director of quality systems at Cequent Performance Products when a staff member developed video training for gage use. Later, the staff member videotaped activities to show the supplier how to identify nonconformance and corrective action items, as well as how to deal with shipping issues. The system was wonderfully successful in addressing issues in a manner all could understand.

Remember, when relaying information and instructions to suppliers, put yourself in the position of the person 6,000 miles away who speaks another language. The more time you spend creating a good information flow and communication process, the less time you will spend fighting fires later.

4. Transferring process data: Metadata environments and web-based quality systems modeled around the ISO 9001:2000 process model are essential to create a single source of data transfer and transition. Quality 2.0 systems will allow the supplier a direct line to predefined inspection plans, control plans and failure mode effects analyses, and any other type of instructions on control methods that will allow the supplier to integrate into the system and make your work environment's operations fully collaborative.

There are many products that provide specialized tools for this purpose. A fully integrated metadata solution, however, will provide an out-of-the-box collaborative work environment that will save substantial time, money and resources. The environment should not be based on e-mail, but on tasks. E-mail can slow down process because it is not easily searchable and cannot be tabulated into meaningful charts and graphics. The environment must be data driven and available 24/7 with instant data and reporting functions. Using the system in conjunction with simple online tools such as Voice Over Internet Protocol, WebEx and Skype can keep costs low and provide effective measures for communicating.

Production

5. Accessing data 24/7: The need for immediate data and feedback when dealing with partners who are 6,000 miles away is imperative in today's marketplace. It confuses me to see organizations demand daily financial results, but settle on waiting days or weeks for process data, customer data or supplier data that may impact the daily financial health of the company. The emphasis remains on daily order intake or sales

results. With this knowledge available, how can you translate process data, supplier data and customer data into daily financial line items?

Consider translating every quality transaction into an actionable dollar item. Translate parts per million into a dollar item. Translate the number of nonconformances into a dollar value. Prepare your own financial report for quality. Keep tabs on four key areas: prevention, appraisal, internal failures and external failures.

6. Acquiring in-process data: If you want data from your suppliers and don't have a collaborative work environment, set up a process with your suppliers to obtain data. Companies sometimes get stuck in this trap: They ask suppliers to send data, and they don't. Companies don't like the format the suppliers use, or the suppliers may miss sending some key data. Companies make repeated requests, hoping that with each request they get what they have asked for. The problem with this approach is twofold: Suppliers will feel the company is insulting them and nit-picking, and the company gets frustrated and loses faith in the suppliers.

Consider **translating every quality transaction** into an **actionable dollar item.**

Create an example of the format you would prefer the suppliers to follow when delivering data. If production gages, tools or fixtures are involved, create a video on how to acquire data—from actual measurement to recording data on the form. This process is highly effective for inspection plans. Create predetermined inspection sheets that allow the supplier to follow a sequence of events. The most effective method is to create the process in a web-based environment.

7. Transferring a less than 1.67 C_{pk} process: Many companies I encounter look to reduce labor cost by sourcing to Asia. As a quality professional, when I see "reduced labor cost," I also see the word "variation." When outsourcing, not only do you lose the tribal knowledge of your workforce, but you also add variation to a process by introducing new equipment, new employees and new materials, for example.

Often, I look at process performance prior to an outsourcing move and discover a process that contained high labor and very low process stability or control. If the process was operating with a 1 C_{pk} or 1.33 C_{pk} level, how can you expect to move this process to an outside supplier and obtain a 1.67 C_{pk} defect-free process? In fact, many of the companies I have worked with do not know their process capability. They can only tell you how many defects were found at the end of the line or by their customers.

Metadata acquisition is key to process improvement. Help your suppliers set up a data acquisition process to meet your requirements. Do not expect your supplier to exceed your internal capabilities right away. Use the internal capabilities as a starting point to teach the suppliers and benchmark them against your process.

Ongoing performance

8. Scorecards: Most organizations send reports to their suppliers only when they have issues or if they publish monthly scorecards. For most companies, data is generally 30 to 45 days old, which doesn't allow for immediate improvement and can frustrate everyone involved. It's like social networking or Web 2.0 or 3.0. If data is older than two hours, it is already stale because something has already changed.

Give your suppliers access to your systems so they can monitor their own performance. They want to know how they are performing daily in every aspect of your scoring system and they want to resolve issues immediately.

Ask a tech-savvy member of your team to review your data process, and have a goal of providing instant data to suppliers. Offer alternative solutions such as web-based software. Metadata solutions can let customers, internal workers or tech-savvy colleagues help guide the functionality and acquisition of instant data.

9. Maintaining alliances: Earlier, we discussed relationships in terms of global suppliers. When communicating the ongoing performance of the supplier, an accusatory tone, derogatory remarks or disrespect can and will eliminate all the work you've done to develop a meaningful partnership with the supplier.

I have sat through many meetings with suppliers, both on site and off site. If there is any sarcasm or demeaning behavior toward any member of the supplier team, especially in Asia, where pride and position mean respect, the supplier may not act out, but you will lose trust and respect quickly.

Stick to the facts. If there is a language barrier, speak

softly and slowly in short words and sentences. If possible, preface the discussion with a video or use photographs. Know that translating e-mails may affect the messages. Without knowing it, you could insult someone who does not entirely understand the language.

To avoid such missteps, engage the suppliers in small talk, and exchange friendly words. Find a common interest and open with light discussion. Don't just dump data and overwhelm the supplier. If you sense one or more of your team members is getting frustrated, end the meeting and reconvene when the emotion is gone.

If you sense frustration, try to smile and laugh about it. Make it funny and break the ice. Many times, I have sensed people getting angry at a meeting. To cut the tension and eliminate emotion, I've gone to a white board and simply drawn a smile. That's often gotten a chuckle and quelled any friction that may have been surfacing.

10. Marking improvements: Improvements—big or small—must be celebrated. Let people know you believe in them and you trust them. This may sound hokey, but it works. Suppliers want the same recognition companies want. The improvement process does not have to be limited to simply the product. Processes, relationships and data transactions can be improved.

Learning and growing together

Each of us—suppliers and customers—must take the evolutionary approach to all aspects of our business. Most important is building relationships and managing a data-driven improvement process that takes emotion out of decision making.

Always remember that your suppliers and their employees are real people. They must be treated with respect and dignity, just as you want to be treated. Develop lifelong relationships and friendships. You'll be amazed to discover how small the world really is.

Take some time to learn a foreign language and understand the new culture you've encountered in the overseas supplier relationship. Seek to learn and develop a thirst to grow individually. Make a difference at work, but most importantly, make a difference in today's global environment. QP

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THE POWER of Balance

Studying **trade-off relationships** to calculate **cost of quality**

In 50 Words Or Less

- A case study at an auto parts maker demonstrates a new way of calculating the cost of quality (COQ).
- The study focuses on the trade-off relationships among various quality cost categories.
- The authors calculated the point of balance, or the lowest COQ value, by comparing related total quality costs.

MANY ORGANIZATIONS face tremendous challenges calculating trade-off relationships and the point of balance when determining their cost of quality (COQ). Experts don't always agree, compounding the difficulty.

Nowadays, under an unprecedented pressure to lower costs in a fiercely competitive global marketplace, more and more practitioners and scholars are acknowledging the importance of accounting for COQ.

Using the case of a Chinese manufacturer, we researched the trade-off relationships among the various categories of quality costs and the point of balance.

by Qiang Su,
Jing-hua Shi and
Sheng-jie Lai

Lack of COQ traction

Joseph M. Juran defined COQ as "the sum of all costs that would disappear if there were no quality problems."[1] This definition implies that COQ represents the difference between the actual cost of a product or service and what the cost would have been if everyone satisfied requirements 100% of the time.[2] From this viewpoint, quality costs could be regarded as the loss of profit.

In 1943, Armand V. Feigenbaum suggested quality costs could be separated into four categories: prevention cost (PC), appraisal cost (AC), internal failure cost (IFC) and external failure cost (EFC).[3,4] Industrial practices demonstrate that the four kinds of quality costs are not independent of one another.

A trade-off relationship exists among the categories of quality costs.[5-9] For instance, an increase in PC and AC would result in the decrease of the IFC and EFC. As a result, along with the enhancement of the level of quality, the sum of the four quality costs will first go down and then go up. The COQ will reach its lowest value at a certain quality level, which is called the point of balance.

In daily operations, however, most firms do not know exactly what proportion of the four quality costs is right for them and which point is the point of balance. Therefore, many firms simply concentrate on reducing IFC, considering it the dominant category.

Because of ignorance of the interrelationship among quality costs, however, this approach most likely won't achieve the expected benefit. There is still a long way to go in helping organizations that perceive their quality costs as being too high.

Although the quality movement has used the term COQ for decades, few organizations have actually adopted a reliable and repeatable method for measuring and reporting COQ and applied it to improve operations.[10]

An investigation of the economic value provided by Six Sigma programs concluded that COQ analysis ignores an important component in the level of quality.[11] This has led to suggestions that the standard COQ model be expanded.

Prevention cost and internal failure cost relationship / TABLE 1

	Model summary	
Equation	**R square**	**Sigma**
Linear	0.004	0.853
Logarithmic	0.003	0.857
Inverse	0.003	0.858
Quadratic	0.006	0.975
Cubic	0.008	0.964
Compound	0.004	0.854
Power	0.004	0.840
S	0.005	0.828
Growth	0.004	0.854
Exponential	0.004	0.854
Logistic	0.004	0.854

Note: The independent variable is prevention cost. The dependent variable is internal failure cost.

Relationship with time delays / TABLE 2

	Model summary							
	One-quarter time delay		Two-quarter time delay		Three-quarter time delay		Four-quarter time delay	
Equation	**R square**	**Sigma**	**R square**	**Sigma**	**R square**	**Sigma**	**R square**	**Sigma**
Linear	0.001	0.942	0.436	0.038	0.140	0.320	0.051	0.591
Logarithmic	0.000	0.962	0.452	0.033	0.128	0.345	0.051	0.590
Inverse	0.000	0.981	0.466	0.030	0.112	0.378	0.052	0.587
Quadratic	0.022	0.914	0.477	0.103	0.193	0.527	0.052	0.875
Cubic	0.025	0.905	0.477	0.103	0.181	0.549	0.055	0.867
Compound	0.001	0.911	0.442	0.036	0.148	0.307	0.177	0.299
Power	0.001	0.918	0.448	0.034	0.135	0.330	0.177	0.299
S	0.001	0.925	0.451	0.034	0.119	0.362	0.178	0.298
Growth	0.001	0.911	0.442	0.036	0.148	0.307	0.177	0.299
Exponential	0.001	0.911	0.442	0.036	0.148	0.307	0.177	0.299
Logistic	0.001	0.911	0.442	0.036	0.148	0.307	0.177	0.299

Note: The dependent variable is internal failure cost. The independent variable is prevention cost.

Feigenbaum's assertion that the discipline of quality-cost economics is one of the key drivers for the new quality of the 21st century challenges the kind of business strategy and planning in which companies still don't know what things really cost, even after 75 years of cost accounting.[12]

This ambiguous method has been a primary reason for the kind of slash-and-burn cost reduction that simply moved quality problems from one department to another without solving them. It has changed some blue-chip companies to buffalo-chip companies.

In addition, there are few research works about the quantitative calculation of the trade-off relationship and the point of balance, with researchers merely suggesting some so-called correct proportions through investigations or surveys.

For example, Juran and Frank Gryna proposed the optimal proportion should be 0.5 to 5% for PC, 10 to 50% for AC, 25 to 40% for IFC and 20 to 40% for EFC.[13] Feigenbaum, however, took the optimal proportion as 5 to 10% for PC, 20 to 25% for AC, and 65 to 70% for IFC and EFC.[14]

Which estimate is more correct or suitable for a specific company? This question is troubling to managers who focus on COQ.

In this situation, our research focuses on exploring the trade-off relationship and calculating the point of balance based on a case study. The study can provide general practical guidance for organizations that want to learn their own trade-off relationships and calculate a point of balance to facilitate quality improvement.

Initial analysis

The firm in this case study manufactures automobile parts in Shanghai, China. In total, 36 sets of monthly quality costs from 2004 through 2006 were provided. To maintain confidentiality, the real data were changed, but relative magnitudes were maintained.

Given the case data, the relationship between the PC and the IFC was first detected with 11 different types of regression functions using SPSS 12.0 software. As shown in Table 1, no relationship was significant. This finding conflicts with the commonly accepted trade-off principle that the increase (decrease) of the PC will result in the decrease (increase) of the IFC.

Thorough evaluation and discussion with the firm's engineers led us to conclude that the statistical finding implied only that a real-time relationship between the PC and IFC does not exist. In other words, the PC did not affect IFC immediately in the case study firm.

For example, the effect of the PC spent on a design failure mode effects analysis will not appear until mass production starts. From this point of view, perhaps a time delay would be necessary to unveil the trade-off relationships within quality costs.

Trade-off relationships / TABLE 3

ID	Independent variable	Dependent variable	Relationship	Time delay
1	Prevention cost	Internal failure cost	Inverse	6 months
2	Prevention cost	External failure cost	N/A	
3	Appraisal cost	Internal failure cost	Inverse	0 months
4	Appraisal cost	External failure cost	Inverse	0 months

Related total quality cost / TABLE 4

T	PC (t)	AC (t + 6)	IFC (t + 6)	EFC (t + 6)	RTQC (t)
1	3,413.491	31,482.01	45,307.07	17,334.09	97,536.67
2	4,568.175	35,020.09	33,560.34	22,336.36	95,484.96
3	5,750.914	32,049.36	39,480.92	6,963.772	84,244.96
4	5,816.08	27,055.23	56,393.57	4,207.914	9,3472.8
5	4,459.53	33,482.07	57,042.78	26,864.53	121,848.9
6*	***2,099.299***	33,007.29	***38,3047.8***	58,395.9	476,550.3
7	5,385.482	31,193.51	29,527.06	6,461.838	72,567.89
8	4,621.92	31,492.06	28,151.77	74,239.49	138,505.2
9	5,300.932	29,346.18	6,509.67	10,722.08	51,878.86
10*	5,071.206	29,879.53	19,013.63	***31.45667***	53,995.83
11	4,982.432	31,754.19	24,191.69	39,710.98	100,639.3
12	5,311.798	31,213.91	34,887.8	15,992.96	87,406.47
13	5,426.234	31,330.72	89,322.01	29,440.58	155,519.5
14	6,132.962	27,608.21	52,332.96	6,571.584	92,645.71
15	6,118.888	27,863.31	9,670.098	9,330.582	52,982.88
16	5,867.445	28,259.57	46,042.53	27,337.65	107,507.2
17	6,536.591	33,402.79	13,333.15	42,640.25	95,912.78
18	6,592.281	31,758.79	14,349.31	24,286.08	76,986.46
19	5,390.68	31,260.03	26,860.4	36,152.88	99,663.99
20	4,271.972	30,754.87	74,941.26	23,300.56	133,268.7
21	4,476.391	30,597.69	91,733.78	9,369.607	136,177.5
22	5,339.317	30,323.22	67,192.26	6,092.957	108,947.7
23	4,403.507	17,644.14	79,311.22	26,618.16	127,977
24	5,608.468	31,500.75	62,611.97	6,781.61	106,502.8
25	4,663.076	18,116.36	13,7666.1	85,625.08	246,070.6
26	4,838.664	18,797.22	58,636.16	18,403.87	100,675.9
27*	4,897.665	19,652.72	***343,281.3***	***234,307.5***	602,139.2
28	5,001.556	18,842.79	61,304.34	75,323.47	160,472.1

(*) signifies the records that were removed from the data set.
The figures in black italic type were the extremes of the quality costs.
PC = prevention cost; AC = appraisal cost; IFC = internal failure cost; EFC = external failure cost; RTQC = related total quality cost.

Suggested and real proportions / TABLE 5

	PC	AC	IFC	EFC	Total QC
Suggested percentage	8.4	48.2	29.1	14.2	100
Real average percentage	4.8	26.5	44.4	24.3	100
Suggested costs	5,703.284	32,661.46	19,758.45	12,700.15	70,823.34
Real average costs	5,262.747	29,013.13	48,705.62	26,685.37	109667
Differences in costs	440.537	3,648.33	-28,947.2	-13985.2	-38843.5
Percentage change	8.37%	12.57%	-59.43%	-52.41%	-35.42%

PC = prevention cost; AC = appraisal cost; IFC = internal failure cost; EFC = external failure cost; Total QC = total quality cost.

Relationship analysis with time delay

According to the characteristics of the product and manufacturing system in the firm, four time-delay options (one quarter, two quarters, three quarters and four quarters) were chosen to detect the trade-off relationship between the PC and IFC.

Table 2 (p. 34) shows that a perfect inverse functional relationship appears with a confidence level of 97% when the time delay is two quarters. Similarly, the time delay and relationship among other costs can be derived (see Table 3, p. 35). According to the table, the PCs will affect the IFCs in six months for the firm. The ACs will affect the IFCs and EFCs within the same time period. Due to these delays, we propose a concept called the related total quality cost (RTQC) as:

$$RTQC(t) = PC(t) + AC(t+6) + IFC(t+6) + EFC(t+6)$$

in which:

- RTQC (t) is the related total quality cost in month t.
- PC (t) is the prevention cost in month t.
- AC ($t + 6$) is the appraisal cost in month $t + 6$.
- IFC ($t + 6$) is the internal failure cost in month $t + 6$.
- EFC ($t + 6$) is the external failure cost in month $t + 6$.

The equation represents the fact that the RTQC of the t month equals the sum of the PC in the t month, the AC in month $t + 6$, the IFC in month $t + 6$ and the EFC in month $t + 6$.

Calculating the point of balance

As shown in Table 4 (p. 35), the RTQC of the case firm can be calculated by using the earlier equation. Due to the six-month time delay, the original 36 sets of monthly records were reduced to 30 records. Two records with negative values also were removed, leaving 28.

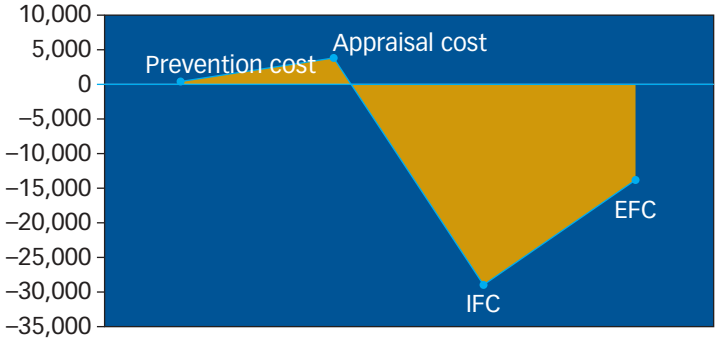
With the assistance of the managers and engineers in the case firm, the extremes of the quality costs (the figures in black italic type in Table 4) were identified, and three corresponding records (marked with *) were removed from the data set.

Among the 25 remaining records, seven with the smallest RTQC(t) and seven with the largest RTQC(t) were selected and compared statistically. T-test analysis verified that, in these two groups, the proportion and mean of all four types of quality costs were significantly different. Therefore, we could safely say the records in the smallest group represented the best performance and could be employed to calculate the point of balance for the case firm.

Table 5 shows that the suggested percentages correspond to the point of balance for the case firm. Compared with the real average percentages, the percentage of the PC should increase from 4.8 to 8.4%, and the percentage of the AC should increase from 26.5 to 48.2% for the case firm. Consequently, the percentage of IFC will be decreased from 44.4 to 29.1%, and the percentage of the EFC will be reduced from 24.3 to 14.2%.

Measuring in cost values in the terms of the absolute values, if the PC and AC are increased by 440.537 (8.37%) and 3,648.33 (12.57%), respectively, the IFC

Leverage effect between quality costs / FIGURE 1



Companies **still don't know** what things really cost, even **after 75 years of cost accounting.**

and EFC will be decreased by 28,947.2 (59.43%) and 13,985.2 (52.41%), respectively. Consequently, the total quality cost can be reduced by 38,843.5 (35.42%).

This leverage effect is clearly illustrated in Figure 1, which demonstrates the trade-off relationship between the control costs (PC and AC) and failure costs (IFC and EFC).

The area below the horizontal line in Figure 1 is much larger than the area above the horizontal line. That pattern implies that a little investment in PC and AC will result in significant savings in IFC and EFC. Accordingly, other than simply cutting IFC, the firm could improve its COQ performance by strengthening its quality prevention and appraisal approaches and systems.

Each organization is unique

We have discovered and analyzed the characteristics of time delay among quality costs for the first time. Obviously, however, the products, processes, manufacturing systems and employees of each firm are unique.

We therefore should try to find a firm's unique point of balance from its own historical records instead of simply referring to some given proportions. The suggested proportion derived in this work is applicable because it is directly derived from the firm's historical records.

More importantly, along with changes in environment, the proposed approach can be reused to take any new situations into consideration. This property can help a firm respond to changes and adjust its quality cost control strategies.

We also tried to use this approach to explore the trade-off relationships in other firms. We learned that this approach works better for firms that possess a rational quality cost accounting system and more complete and accurate records. QP

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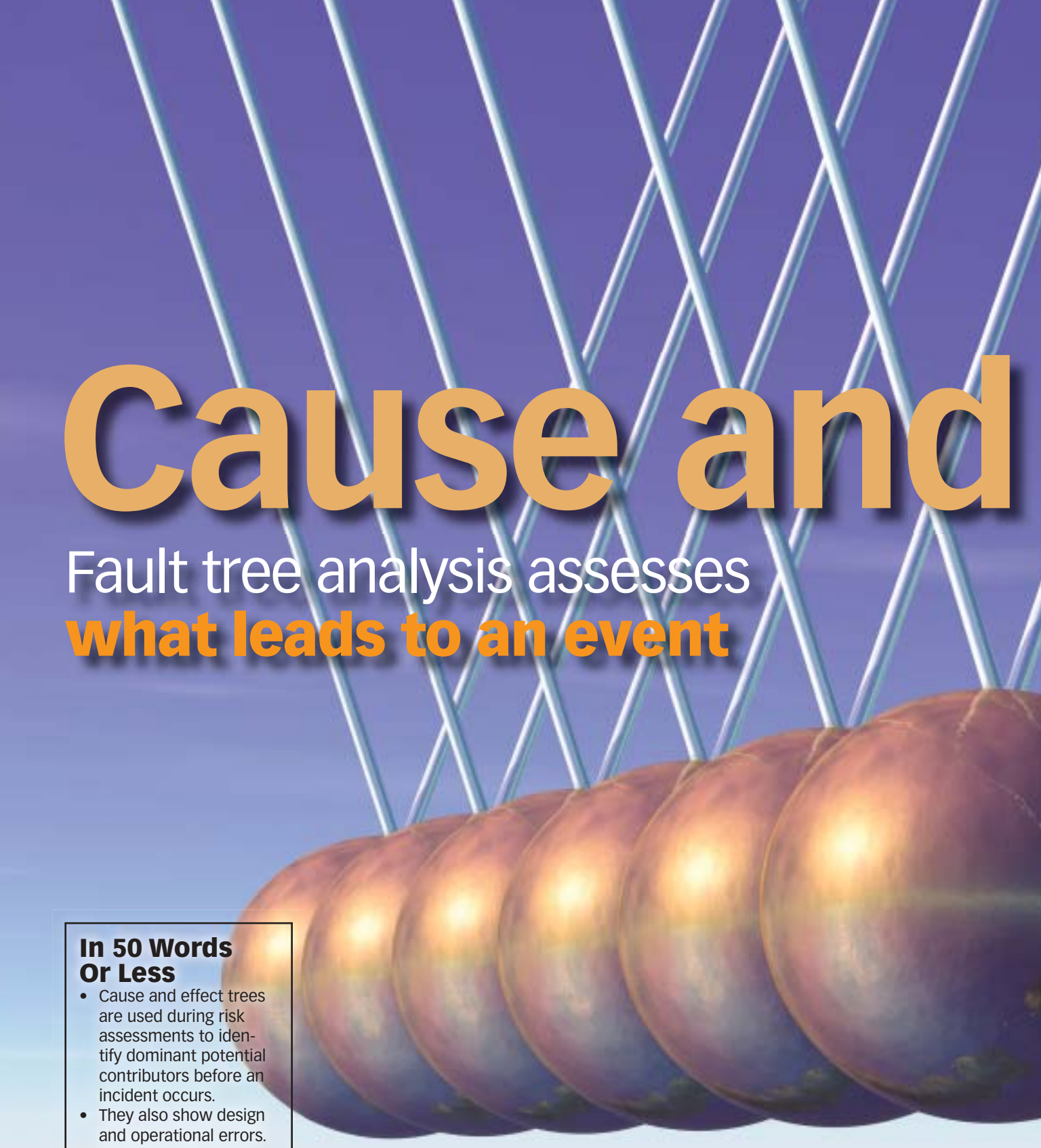
Cause and

Fault tree analysis assesses **what leads to an event**

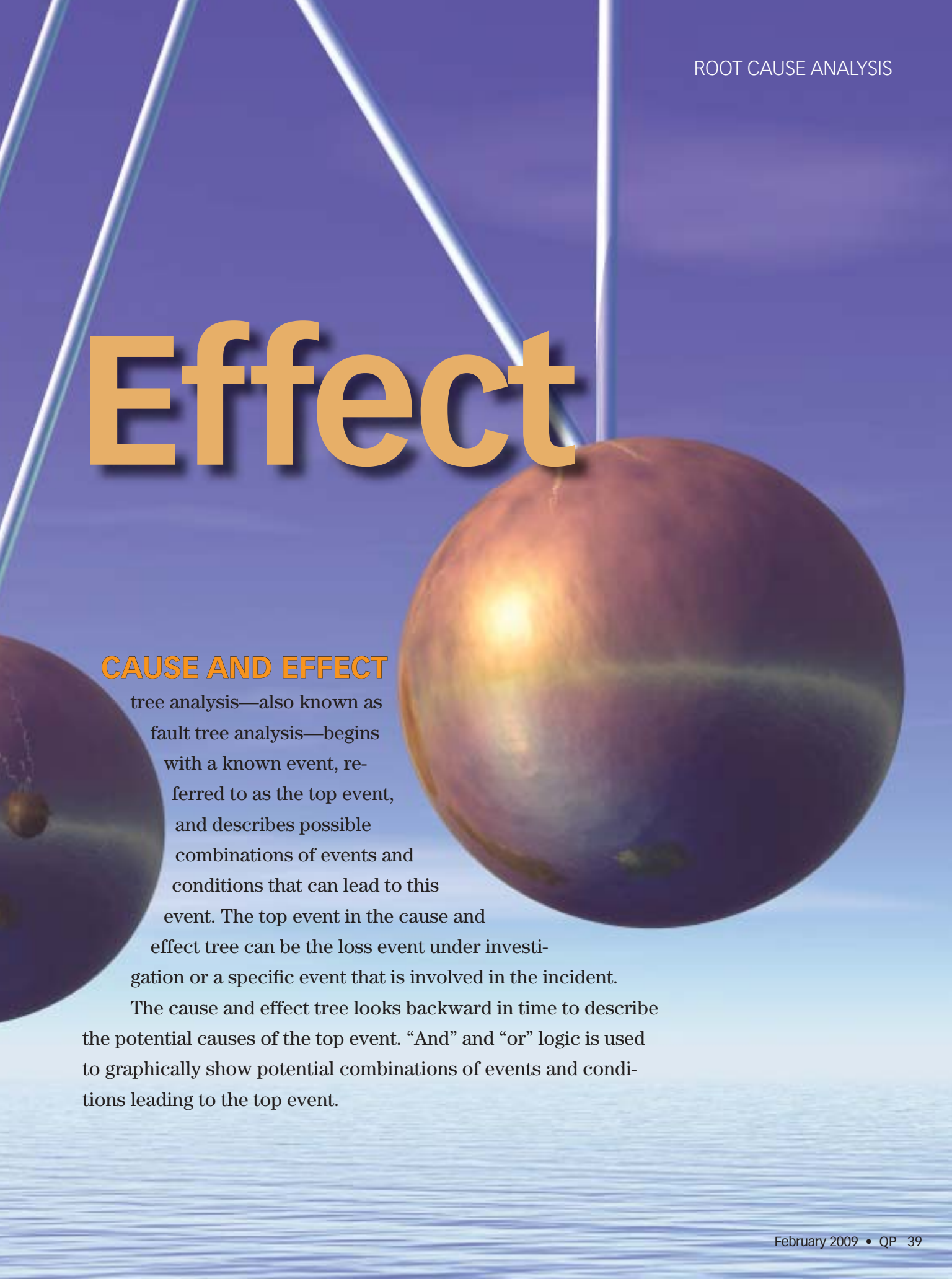


In 50 Words Or Less

- Cause and effect trees are used during risk assessments to identify dominant potential contributors before an incident occurs.
- They also show design and operational errors.
- "And" and "or" gates connect the sets of causes and effects, and a single item can be both a cause and effect.

by James J. Rooney, Lee N. Vanden Heuvel, Donald K. Lorenzo and Laura O. Jackson

Effect



CAUSE AND EFFECT tree analysis—also known as fault tree analysis—begins with a known event, referred to as the top event, and describes possible combinations of events and conditions that can lead to this event. The top event in the cause and effect tree can be the loss event under investigation or a specific event that is involved in the incident.

The cause and effect tree looks backward in time to describe the potential causes of the top event. "And" and "or" logic is used to graphically show potential combinations of events and conditions leading to the top event.

Cause and effect trees were first developed by Bell Laboratories in the 1960s, and the technique remains relevant today. Quality professionals should have a firm grasp of this important problem solving method.

The technique is commonly used during risk assessments to identify dominant potential contributors before an incident occurs. For incident investigation applications, however, the smallest possible tree is developed. As soon as a branch is shown not to be credible (proven false), development of that branch is stopped.

Most proactive and reactive analysis techniques identify only failures caused by a single event. One significant advantage of the cause and effect tree technique is that it can help identify multiple-event failures, which require more than one event for a failure to occur.

For example, for fire to form, three conditions must exist simultaneously: fuel, oxygen and an ignition source. Most incidents involve multiple-event failures. The ability to model multiple-event failures is therefore an essential element for any incident modeling method.

A cause and effect tree can also show design and operational errors. In some cases, equipment performs to its capabilities, but these capabilities are insufficient for the task. For example, a generator failed when it was overloaded, or a pump was designed to deliver 100 gallons per minute (gpm), but 150 gpm was required.

Basic structure

Cause and effect trees are constructed with sets of causes and effects that are connected by gates. Figures 1 and 2 show the basic elements of a cause and effect tree.

There are two types of gates: "and" gates and "or" gates. When referring to them generically, they are simply called gates. The effect is above the gate, and the causes are below. Note that a single item on the tree can be a cause and an effect, depending on which gate you are examining. For example, in Figure 3, Item 4 is a cause of Item 1. Item 4 is the effect of Cause 5 or Cause 6. For any gate on the tree, the event above the gate is the effect, and the events below the gate are the causes.

Three examples

Example 1—spill from a tank: Figure 4 shows a portion of a cause and effect tree for a spill from a tank. In this case, three possible causes of the spill were identified by the investigator:

1. Misdirected flow.
2. Excessive flow.
3. Failed tank or piping.

Each of these causes is sufficient to cause the spill from the tank, so an "or" gate is used. Next, each of these three items is examined to determine its causes.

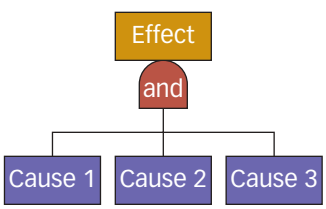
For the misdirected flow event, two events must be present at the same time: Valve 1 must be closed, and Valve 2 must be open. Closing Valve 1 is not enough to cause the misdirected flow. If Valve 2 is also closed, the flow will not go through Valve 1 or Valve 2. Because the line with Valve 1 is so much larger than the line with Valve 2, Valve 1 must be closed to force flow through Valve 2. Therefore, both conditions must be present for the misdirected flow to occur, so an "and" gate is used.

To cause the other two events, excessive flow and failed tank or piping, two possibilities are identified for each. Either item is sufficient to cause the event above it, so "or" gates are used. In this example, there are five combinations of events that can cause the top event:

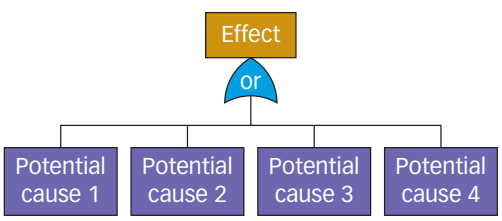
1. Valve 1 closed and Valve 2 open.
2. Normal flow not stopped in time.
3. Tank full before fill started.
4. Failed tank.
5. Failed piping.

In an actual root cause analysis, efforts are made to cut off the branches as soon as possible by collecting

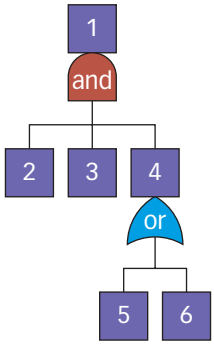
"And" gate structure / FIGURE 1



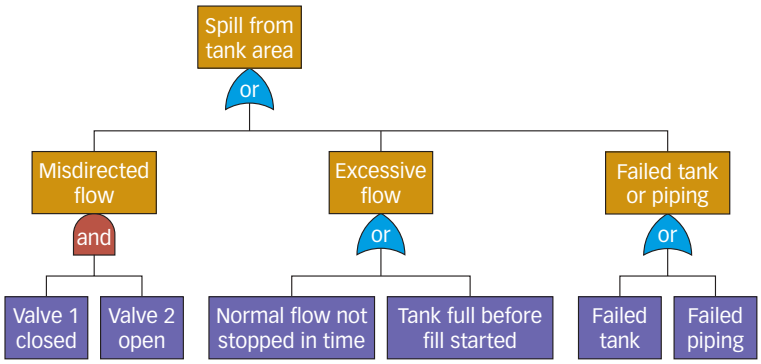
"Or" gate structure / FIGURE 2



Example tree with multiple levels / FIGURE 3



Cause and effect tree for a tank spill / FIGURE 4



data to determine the validity of a branch (whether the branch is true or false). This will be discussed in the next example.

Example 2—lighting failure: Work in a portion of a facility has been halted because the overhead lighting has gone out. The emergency lighting has illuminated, but it is not sufficient to continue normal operations. Quick troubleshooting is needed to determine the source of the problem and restore regular lighting. Figure 5 shows a circuit diagram.

Construction of the cause and effect tree in Figure 6 (p. 42) was based on the assumption the switch and relay were closed before the lighting was lost. The tree starts with very general concepts and works down to specifics. The primary reason for doing this is to minimize effort. In an actual investigation, it is possible that only a small portion of the tree would be needed.

For example, Figure 7 (p. 43) shows just the top of the tree. This is what the tree would look like after the first level was developed. Some effort will be saved if it can be determined which of the branches are correct (true) and which of the branches are incorrect (false). If this can be determined, it may not be necessary to pursue all the branches.

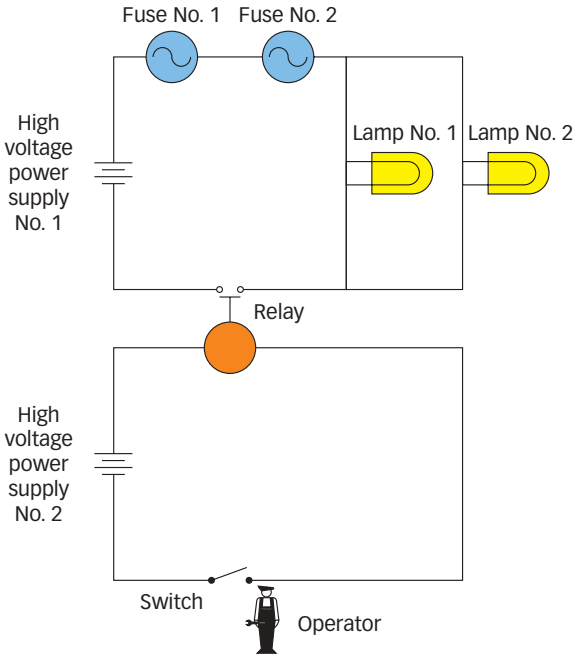
To figure this out, data are needed. A question to ask at this point is, "What data can we collect to determine whether the problem is with the lights, the power or both?" This will help determine what information is needed and how much of the tree to draw.

In case one, an electrician using a multimeter determines there is power to the light sockets. Having this information can save a lot of effort because it is now known that none of the events below Event C are causing a problem with the lights. As a result, no time needs to be spent developing the tree below Event C. Any events below Event C would lead to loss of power to the light socket, and this has just been proven to be false.

To represent this, an X can be put through Event C, and attention can then shift to examining the lights (Event B). Because this is the only other cause identified, replacing the lights should make them operational again.

Case two uses the same test as case one. It is performed by an electrician, but this time the electrician

Circuit diagram / FIGURE 5



says there is no power to the light sockets. Now, more work has to be done to develop the tree below Event C.

While individual components could be tested, it would be better to test on a more global scale, testing many components at the same time. As a result, the next level of the cause and effect tree is developed (see Figure 6) with a general item, "No continuity in high-voltage circuit" (Event D), along with "power supply No. 1 fails off" (event 3).

By testing the continuity in the high-voltage circuit (Event D), a number of components can be checked with a single test. The electrician determines there is no continuity in the circuit. That means the cause and effect tree needs to be developed below Event D.

The next level, with Events E and F, is outlined. First, "relay opened" is investigated. The electrician tests the relay and finds it is closed. An X can now be placed over Event E, and the development of the tree below Event E can be stopped. Finally, it needs to be determined which fuses have failed. Through testing, it is found that both fuses have failed. Events 5 and 6 are circled, and the fuses are replaced. If these are the only failures, the lights will come back on.

For case three, suppose the lights and power to the sockets are tested, and neither is the cause of the failure. To represent this on the tree, an X is put through Events B and C. Now we have a dilemma: The top event is true, but all the causes we have identified (Events B and C) have been eliminated. Now what?

There are two other possible causes of this situation. The first is that there is a cause of the top event that has not been identified. For example, maybe the lights were installed incorrectly or have vibrated loose. Neither of these causes is captured by "both lights have burned out" or "no power to the light sockets."

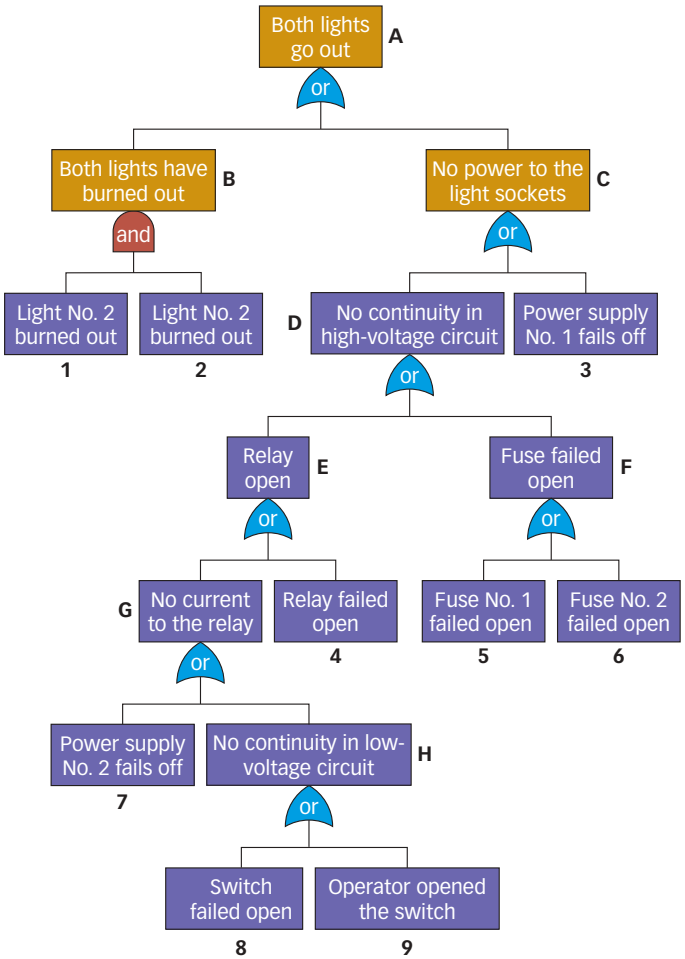
Under Event A, another event needs to be added: "Lights installed incorrectly." Now, the tree reflects the new potential cause that was identified. The second possibility is that one of the tests used to eliminate Events A and B was faulty or incomplete. For example, to test the lights, two new lights were obtained from stores. When these were installed, they did not work. It had already been established there was power to the light sockets, so it was concluded it could not be the bulbs (Events 1 and 2 were crossed out) because they were new. It is unlikely, but both bulbs could be faulty due to damage during shipment, manufacturing errors or damage during storage.

"Light No. 1 burned out" and "light No. 2 burned out" were eliminated (crossed out) as possibilities based on using new bulbs, not necessarily good bulbs. A better test would be to take two lights that are working in another fixture and install them in the problem circuit. If they do not work, take them back to the original system and reinstall them to make sure they are still functional. This is a better, more robust test of the lights.

Example 3—hand injury during sandblasting: The first two examples primarily involve equipment; this example primarily involves people. The cause and effect tree in Figure 8 was based on this incident.

The incident description says the event occurred when the operators were sandblasting metal tanks in preparation for repainting. Each sandblasting machine was staffed with the normal two-person crew (a nozzle

Cause and effect tree for a lighting failure / FIGURE 6



operator and a blast-pot operator). When the nozzle operator observed that abrasive material was no longer flowing through the nozzle of his machine, he suspected a clog in the blast hose. He responded by releasing (disengaging) the dead man's switch, a switch automatically operated in case the human operator becomes incapacitated. The nozzle operator then signals to his co-worker, the blast-pot operator.

Assuming the system was depressurized, the blast-pot operator attempted to disconnect the blast hose from the equipment so he could clean away the suspected clog. The blast-pot operator was unable to rotate the quick-disconnect coupling the one-quarter turn required to remove the blast hose. Assuming the fitting was stuck because of dirt or contamination, he asked another blast-pot operator working nearby to assist him.

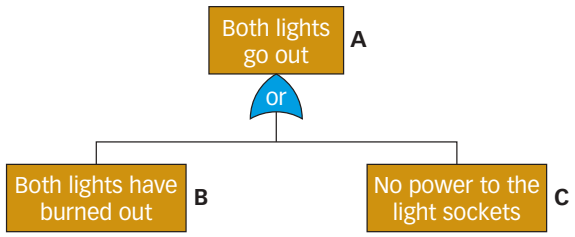
Acting together, the two blast-pot operators were able to twist the hose fitting to the point where it could be forcibly disconnected. The system rapidly depressurized through the opened coupling, spraying abrasive material through the coupling and onto the hands of the worker nearest the outlet, the first blast-pot operator. This worker sustained relatively minor, but painful, skin abrasions to both hands.

All workers were fortunate their eyes and faces were not injured, and the injured blast-pot operator was lucky his wounds did not become infected from the embedded sand.

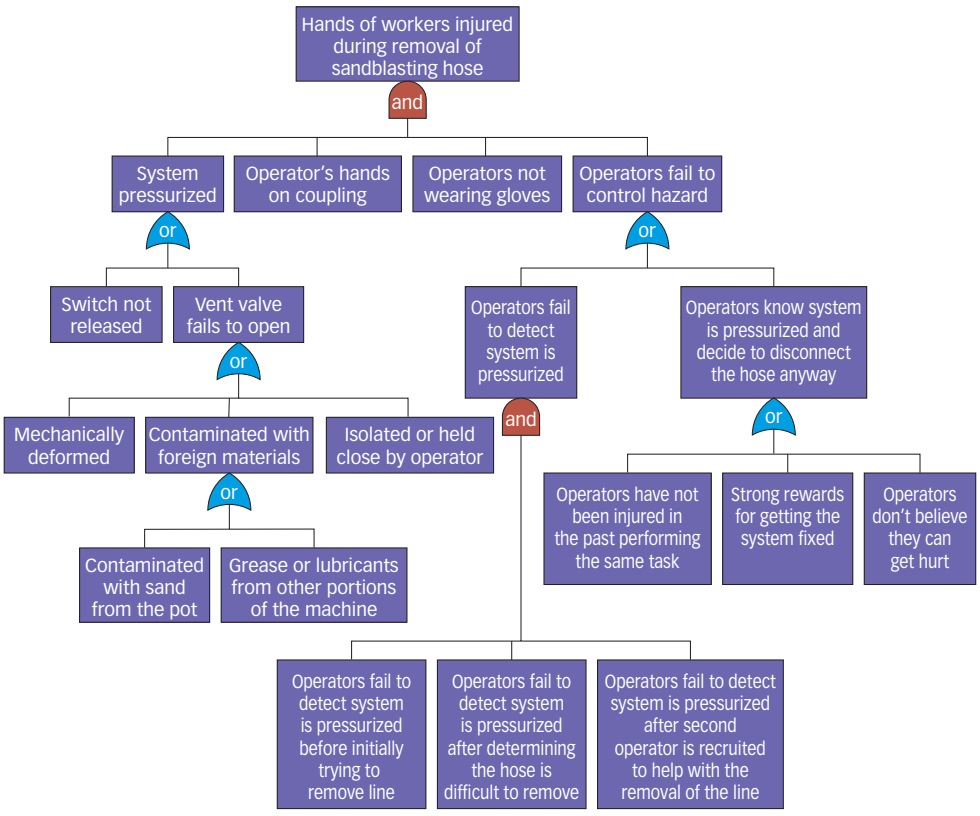
The equipment description is that the sandblasting machine involved in this incident is a relatively common piece of equipment. The machine consists primarily of a pot to hold abrasive material (similar to sand) and a flexible, 1-inch (2.5-centimeter) diameter blast hose to carry and direct abrasive material to the surface being cleaned. The machine is designed to be connected to a compressor and to operate at a pressure of 100 pounds per square inch (6.89 bars).

The pot can be pressurized and depressurized by the blast-hose nozzle operator using a pneumatic dead man's switch, which controls and synchronizes the opening and closing of the air inlet and outlet valves

Cause and effect tree with Events A, B and C / FIGURE 7



Cause and effect tree for hand injury during sandblasting / FIGURE 8



located on the pot. When someone engages the dead man's switch to start the sandblasting process, the air inlet valve opens, the outlet valve and the pop-up valve close to seal the pot, and the pressure in the pot forces sand through the blast hose.

When the dead man's switch is disengaged, the air inlet valve closes and the air outlet valve opens. This allows the pot to depressurize through the air outlet valve. When the pressure in the pot nears atmospheric pressure, the pop-up valve opens to allow more abrasive to be added to the pot.

The top event in Figure 8 is "Hands of worker injured during removal of sandblasting hose." For this to happen, four general events need to occur:

1. The system must be pressurized.
2. The workers detach the hose with the system still pressurized.
3. The operator's hands are on the coupling.
4. The operator is not wearing gloves.

All four events need to occur, so an "and" gate is used. If the system fails to depressurize but the users never take the hose off, they will not be injured in the way the top event describes. If the system is depressurized when they take the hose off, they also will not be injured. Finally, if the operators are wearing gloves, they will not be injured.

So why would they disconnect the hose with the system still pressurized? The cause and effect tree identifies two possibilities:

1. They did not detect that the system was pressurized.
2. They knew there was a hazard but decided they could disconnect the hose anyway.

Data are gathered to determine which branches are true and which are not. Interviews are performed and the equipment examined to determine which branches should be eliminated.

In this case, multiple causes may exist. Although it may end up being necessary to train personnel on how to determine whether the system is still pressurized, the employees may still not know that a pressurized system poses a hazard. Therefore, it might be necessary to address both of these potential causes, not just one.

In the second case, personnel knew there was a hazard but decided they could disconnect the hose anyway. Why would they decide to do this? The cause and effect tree shows three possible reasons:

1. The operators have disconnected the hose with the system pressurized in the past and have not been injured.
2. The operators are highly motivated to fix the system because of expected job rewards or penalities.
3. The operators don't believe they can get hurt in this situation.

If the first case is true, we need to ask why the improper behavior has not been corrected in the past. In the second case, we need to ask why an unsafe behavior has been encouraged. In the third case, we need to change the operators' perceptions of the risk. Of course, this incident will help change the injured operator's perception of the risk, but we also need to change other personnel's perception of the risk.

Visit www.qualityprogress.com for a continuation of this article, which covers the construction and drawing of a cause and effect tree. The online material includes examples of symbols and structures and a nine-step procedure, along with 21 additional figures. QP

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THE TREE GROWS

The online continuation of this article explains how to construct a cause and effect tree using a nine-step procedure. This additional material, along with 21 more figures, can be found at www.qualityprogress.com.

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Driven

A driver education tool can be used to develop company strategy

by Kimball Bullington

In 50 Words Or Less

- Scan, interpret, predict, decide and execute, a driver education model, can simplify strategic planning.
- Driving and strategic planning involve scanning the external and internal environments, interpreting the data collected from the scans, deciding which data to react to, deciding between alternative courses of action and executing the actions—a strategy.

STRATEGIC PLANNING IS an important element in quality management, as evidenced by the Malcolm Baldrige National Quality Award criteria. A strategic plan that helps reduce variation related to possible strategic outcomes should be the aim of any organization.

Strategy is a plan for improvement. It assumes you know your current state and have a vision of the future state. The strategy becomes a path from your current state to the future state. But the development of strategy can be a frustrating process. How can that frustration be avoided?

to Succeed

A group I led several years ago was tasked with developing a strategy for our organization's supply base. To complete that task, we enlisted the assistance of a university known for its research in supply chain management. The result was confusion. The suggested process was complex and seemingly random. To those of us who had to implement the strategy, it seemed to be merely a list of suggestions with no obvious source or structure.

Road test

Sticking with the idea that strategy follows a path or road, the answer to this dilemma may be found in a process widely used in driver education in the United States. This process, known as the SIPDE model, includes the following steps:

- Scan (or sweep or search).
- Interpret (or identify).
- Predict.
- Decide.
- Execute.

In driver education, SIPDE is used to train a driver to think proactively. The driver scans the environment, looking at the road ahead, the side of the road, other vehicles, signs and, using the mirrors, the traffic behind. The driver also scans the internal environment, looking at dashboard indicators, such as warning lights and those for fuel level, speed and engine temperature.

For example, while traveling down a city street, a driver may notice a stop sign, parked cars on the side of the street and children playing in a yard. A motion interrupts the scan, and the driver interprets the motion as a ball that has escaped the children and is rolling across the street. The driver predicts a child will follow. Children may not actually enter the street, but this is the only safe assumption.

What should the driver do? The driver could:

- Maintain speed while watching for the appearance of a child.
- Slow down and be prepared to stop suddenly.
- Begin braking immediately.

The driver decides to begin braking immediately. Having made this decision, the driver executes it by taking his or her foot off the accelerator and pressing the brake pedal.

So what does a driver education process have in common with developing company strategy? The SIPDE process and the creation of strategy both involve planning, although the SIPDE process addresses extremely short-range planning. SIPDE involves scanning the external and internal environments, interpreting data collected from the scans, predicting which data to react to, deciding between alternative courses of action and executing the actions. The same is true for strategy creation.

A benefit of using a model such as SIPDE is that it is simple, easy to remember and communicate, and is already a part of the common culture to some extent. But how can the process be used to create strategy?

Yes, we scan

Scanning is a typical component of classic strategy development. It includes internal scans of strengths and weaknesses, and external scans of opportunities or threats as identified in strengths, weaknesses, opportunities and threats (SWOT) analyses. Scanning includes objective and subjective evaluations, but the better the data captured for the scan, the higher the confidence in evaluations and subsequent strategic direction.

Internal scanning examines organizational performance as indicated by key performance measures of whatever the company views as strategic. These measures can look at performance for product measures (such as cost, quality and delivery) and process measures (such as lead time, rate of innovation and employee turnover).

Internal scanning also looks at past strategy, performance to plan, mission and vision, as well as human issues, such as organizational structure and current and planned personnel.

For example, an organization that provides training for social workers is focused on training hours delivered per trainer (productivity) and throughput time for the process of developing new curricula. At this point, data are not available for the quality of the actual training delivered. The strategic scan has identified quality data as an area to be addressed.

BALDRIGE AND STRATEGY

To learn more about strategic planning, which is one of the seven Malcolm Baldrige National Quality Award criteria for performance excellence, go to www.qualityprogress.com.

The **strategic process** may even lead to decisions regarding **mission and vision.**

Production performance, process performance and organizational health should be evaluated in the scan. The word "scan" implies you are looking from measure to measure to find clues about what is important. Most of the data may contain little information. We are looking for something that will spur action.

Let's go back to the driving example. It is common for one out-of-the-ordinary occurrence in the environment to attract our complete attention. This is a danger. We should note the unusual and pay proper attention to it but not let it consume our focus.

Recently, I was driving near my home when I noticed a lady waving at me as she ran across the four-lane street. I slowed and watched her approach, wondering what the problem was. As she approached I realized she wasn't waving at me at all. I looked away just in time to avoid striking an elderly couple who had wandered onto the street. My focus on the lady running across the street was natural, but continuing to scan would have been safer.

It is natural for a strategy session to focus on the urgent or difficult issues, but it is better to continue to scan after noting a significant measure. Failure to continue scanning may result in a plan that is short-sighted—perhaps catastrophically so.

A recent strategy session with the training organization mentioned earlier focused on the upcoming refunding of its primary grant. This is understandable, but a strategy must also look beyond this crucial point in time.

External scans include customers, suppliers, competitors and the competitive environment (potential entrants and substitutes). Some people use the acronym PEST for scans that include political, environmental, sociocultural and technological factors. PEST scans can be external or internal, though they are more often used to assess external factors.

Scanning customers often includes warranty return, complaint and survey data. Such data are often incomplete or a lagging indicator. Supplier scans usually focus on performance data related to cost, quality, delivery and lead time, though these scans also can include number of suppliers, geographic location and supplier capabilities. Obtaining solid evidence of your own performance as a customer of your suppliers is difficult.

Competitive scans can also be challenging. Some industry data may be available. Customers may provide input relative to competitor performance. Some information, such as price and breadth of product offering, may be publicly available. Reverse engineering is often possible to provide insights into cost, design and processes used by the competition.

The training organization used as an earlier example knows some of its possible competitors well, because the competitors are also current customers. Other potential competitors include consulting organizations. It is not rare for large organizations' competitors to be their suppliers and customers.

Open to interpretation

Data are interpreted in a context. For strategy development, the context can include prior strategy: Have you been cost focused or a differentiator? Did the marketing strategy affect sales as expected?

This phase is sometimes referred to as "identify." Identify what has changed or has not changed but should have. Pareto charts may be used to interpret defect data by organizing them in descending frequency order according to cause. Hypothesis-testing tools aid in interpreting data by classifying them as belonging to the same or a different distribution.

Have these measures changed or not? Out-of-control points on a control chart indicate the presence of assignable causes and are interpreted differently from random variation. This type of change demands some action be taken, though that action may be at the operational level, not strategic.

We often think of out-of-control points as unpleasant surprises, but they can signal pleasant ones (an increase in sales or reduction in variation, for example). The training organization monitors throughput time of new curricula through its printing and graphics supplier partner. Out-of-control points representing either shorter or longer throughput times would be of interest.

The ball rolling across the street is an example of a scan that detects a change and an interpretation that could indicate the change is important. We may see unexpected changes in cost, quality, sales, customer satisfaction or any number of measures.

Sometimes, we detect no change, which is also significant. An airline pilot, flying the plane through clouds on an approach to an instrument landing, scans ahead looking for the runway or an obstacle. If he continues to see clouds, he may abort the landing. In the business world, a sales promotion should result in increased sales. No change in sales is a problem.

Predictable response

Predictions are also context dependent. A ball rolling across an interstate highway does not result in the same prediction as a ball rolling across a residential street with children nearby. On the interstate highway, we may predict our vehicle will or will not hit the ball. The consequences of that impact are significantly different from a prediction that a child will run into the street and into the path of the car.

Not all deviations from desired performance demand strategic attention. In the predict phase, the task is to evaluate the future importance of signals observed in the scan stage and, it is hoped, to place them in the correct context in the interpret phase.

Control charts enable predictions. If processes are in a state of statistical control, they are stable and predictable within limits. The current situation will not change without some intervention if the process is within statistical control. A stable control chart of throughput time indicates upper and lower limits on capacity expectations. If more capacity is needed than the system is currently capable of producing, then the process must be improved or additional capacity must be added.

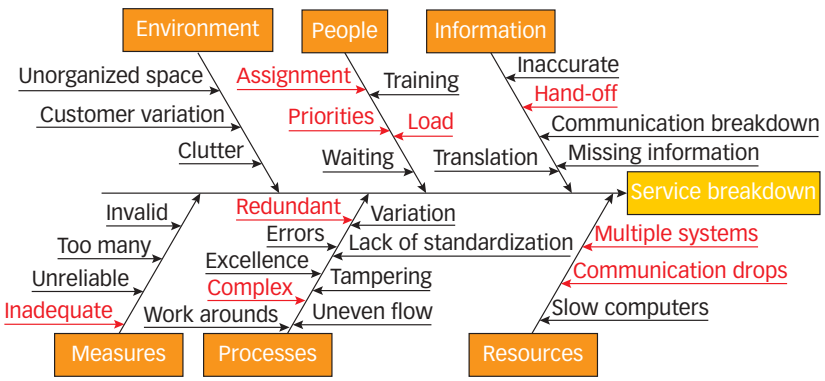
Sensitivity analysis is used to put limits on predictions, often of a financial nature. Sensitivity analyses, combined with present-value analyses, may be used to create expected values for capital investment projects.

Failure mode effects analysis (FMEA) and similar processes, such as potential failure mode effects analysis or failure mode and criticality analysis, are used to make predictions. The output from the use of these tools is a risk priority number. These are predictions of the combined severity, probability of occurrence and likelihood of detection failure of various failure modes and their outcomes.

Some companies use FMEA only as a product reliability tool. Others use it for products and processes, including super processes, such as those involving major suppliers.

Cause and effect diagrams are qualitative tools for predicting which causes create a desired or undesired effect. Selecting the appropriate causes leads to appropriate responses. Cause and effect diagrams are often used to troubleshoot, but they can also be used to organize the efforts to create positive outcomes, as shown in Figure 1. The diagram depicts the result of a structured brainstorm of possible causes of service breakdowns. The red causes are the ones believed to be most important.

Cause and effect diagram for positive outcomes / FIGURE 1



Conditions that are not predicted to be practically significant could be identified as statistically significant. Conditions that are of practical significance may not be strategic or may not be predicted to persist. Conditions that are predicted to be of practical significance, strategic and persistent must be addressed.

The final stage of the predict phase is to forecast what responses could be taken to address the significant present or future conditions.

Decision time

As you notice a motion, interpret it as a ball rolling into the street and predict a child could follow—you must decide on a course of action.

Strategy development requires you to act on some data and decide not to act on other data.

A model such as SIPDE is **simple and easy** to **remember and communicate.**

Peter Drucker noted that posteriorization is more important than prioritization. What will you put behind you? What will you choose not to do? [1]

A decision to attempt too much is fatal to strategic plans. The training organization would like to expand and offer services in other states, but the dilution of efforts focused on process improvement might prove to be disastrous to the organization at this time. The potential increased market may not be an area that can currently be addressed by the organization.

Strategic responses are driven by data and tempered by the availability of current and future resources. Responses to data not backed up by resources are dreams, not plans. Project management software includes tools to manage not only the strategic responses (projects and tasks), but also resources.

The combination of task and resource decisions results in decisions about the appropriate levels of response. The combination of tasks, resources and levels leads to the creation of timed objectives, strategies and tactics—the heart of strategy. In some cases, the strategic process may lead to decisions regarding mission and vision. But strategic decisions must be measured. What would constitute success? If measures cannot be identified, the decisions should be challenged.

Execute

Once you decide to come to a stop after predicting a child will run into your path, the execution phase is automatic. Execution is far from automatic in most organizations, but sometimes it is isolated from the actual strategic planning process, with the exception of a review of the previous year's execution. This is a mistake. The plan must include means of ensuring its execution and regular reviews.

Some annual reviews can be effective. If the review includes sufficient pain for failure or reward for success, it can then act as a motivator throughout the year. There should be planned opportunities for ensuring progress, perhaps monthly or quarterly, but more frequent than annually. These reviews may be driven further down in the organization.

SIPDE in action

The SIPDE model provides a simple and familiar framework for building a strategic planning process. The SIPDE model in action looks like this:

- **Scan**—Collect data and review external and internal factors. Tools: SWOT and PEST analyses, competitive forces analysis and key performance measures.
- **Interpret**—What is changing? What isn't changing that should be? Which factors are of statistical significance? Tools: Hypothesis testing, Pareto charts and control charts.
- **Predict**—Which factors will be of practical significance in the future? Where is the greatest risk? Where is the greatest reward? Tools: Present value analysis and control charts.
- **Decide**—Which factors will we decide not to work on? What will be the strategic response to key actionable factors? Tools: Written strategic plan and decision tree analysis.
- **Execute**—Put the plan into action, driving it throughout the organization into everyday responses. Tools: Personal objectives.

I have used the SIPDE process to create strategy on a trial basis with a small nonprofit organization. The initial response has been favorable. The participants understood the process and enthusiastically participated in the creation of strategy. QP

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 BY FORREST W. BREYFOGLE III

Control and Grow Your Enterprise

The right business measurements and controls benefit the whole company

TO ACHIEVE maximum efficiencies and financial results in turbulent business and financial markets, executives and senior managers must revisit their business models to make certain measurements lead to the right behaviors.

It's critical that a company's business model provides a structured approach for control and predictability. For this to occur, measurements, analytics, innovation and process improvements must be blended at both operational and corporate levels.

This advanced approach to managing an entire enterprise must integrate lean, Six Sigma and all the other quality-oriented methods into a pragmatic process that can result in far greater efficiencies and responsive operational units for achieving corporate financial goals.

Six Sigma's define, measure, analyze, improve and control (DMAIC) roadmap needs to be used not only for project execution, but also for full enterprise business management. In this approach, DMAIC is referenced as P-DMAIC for the project level. At the corporate or enterprise level it is E-DMAIC.

E-DMAIC will provide organizations with a basic long-lasting governance system that will provide the framework and predictability for operating a business more successfully than conventional methods.

A couple of the components in the E-DMAIC system are:

- An analyze phase that blends analytics and innovation as part of the specific organizational and strategy-building process.
- An improve phase in which P-DMAIC process improvement projects are initiated and executed in alignment with overall business improvement needs determined analytically and innovatively.

Lean and Six Sigma roles

Where lean meets Six Sigma, all projects begin with a problem statement. Because of this, lean Six Sigma deployments are a de facto method of problem solving. These deployments are not a business system. Inclusion of lean with Six Sigma expands traditional Six Sigma defect-reduction problem statements to include waste of time and resources.

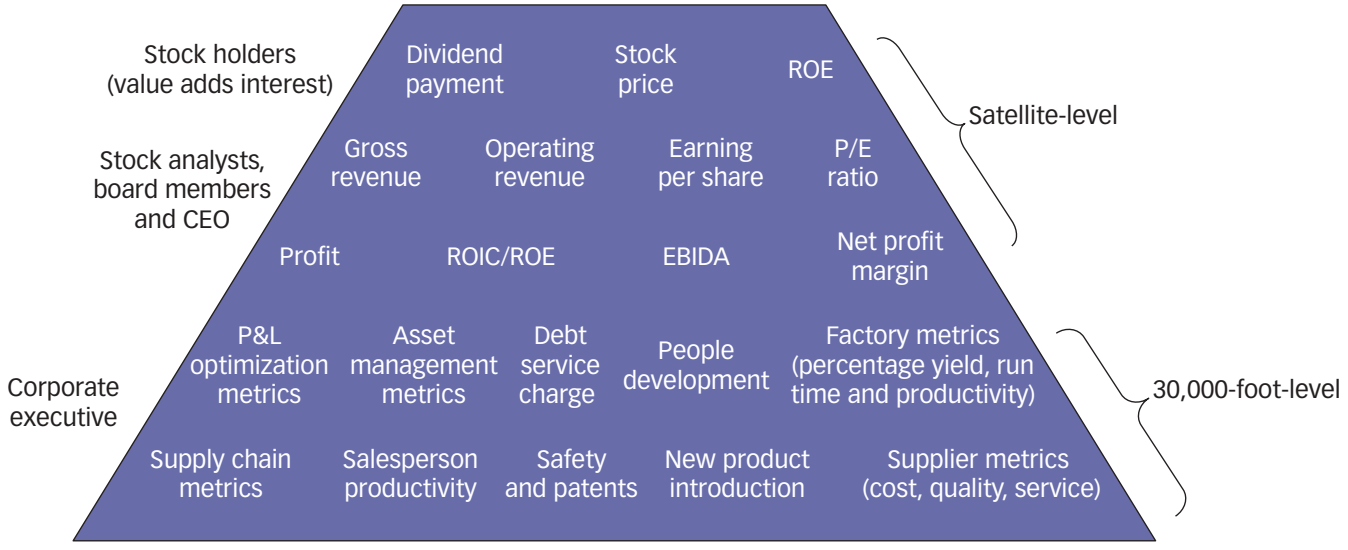
Yet, when DMAIC is used in lean Six Sigma deployments, its aims are limited. Projects are selected with two primary objectives: reporting financial benefits from all improvement projects and providing an employee with a project to use as part of his or her certification.

Lean or Six Sigma typically initiates or uses a push approach for project creation, in which management and others brainstorm projects and prioritize a list, sometimes scrambling to find a certification project for someone attending a lean Six Sigma Black Belt class.

This deployment approach can be successful initially because first-project improvement needs are obvious to everyone without any enterprise analyses. Sooner than later, it becomes difficult to find projects. Many completed project savings might sound good, but they have questionable financial benefits for the entire enterprise. There is usually no sense of urgency for completion because projects are not formally tied to management performance metrics improvement needs.

Many completed project savings **might sound good**, but they have **questionable financial benefits.**

Example of satellite-level and 30,000-foot-level metrics / FIGURE 1



ROE = return on equity; OI = operating income; P/E = price to earnings;
ROIC = return on invested capital; P&L = profit and loss;
EBIDA = earnings before interest depreciation and amortization;
VOC = voice of the customer.

In typical lean Six Sigma deployments, project selection is not the result of analytically and innovatively assessing the organization as a whole. A company might select projects without identifying overall enterprise constraint, which can lead to counterproductive behavior and suboptimization of processes. Such projects could set a company back.

This risk dramatically increases when lean Six Sigma deployments create groups to manage project selections that remain separate from operational scorecards and other business units. These units often get downsized when times get tough.

In contrast, a management system that blends analytics with innovation in the E-DMAIC analyze phase identifies improvement opportunities for the business as a whole. The system's analysis uses theory of constraints, lean, Six Sigma and other tools to develop specific, targeted strategies that will help improve an entire corporate structure and its bottom line.

In the E-DMAIC define phase, a value chain describes functional activities with their drill downs. In the measure phase, functional activities have a 30,000-foot or operational level metric reporting, shown in Figure 1.[1] The figure shows the process response from such operational or airplane level perspectives, as well as an even higher view from a satellite or corporate level to determine whether a process is predictable or has common-cause variability.

If the process output from common-cause variability is not satisfactory or what is desired, then a process-improvement effort would create a pull for project creation. This is in contrast to traditional control charts, which are created for timely identification when special causes occur so adjustments can be made to bring the process back into control. As a business metric, reporting at this operational level can lead to more efficient use of resources and less manipulation of the numbers.

Unlike many traditional management report formats, these operational level metrics have neither calendar-year restrictions nor variance-to-goal tracking (for example, red-yellow-green scorecard). In the E-DMAIC analyze phase, the business as a whole is evaluated to determine strategies and improvement goals that favorably impact the entire business. Success of the projects is determined and quantified by a statistically significant shift in the 30,000-foot-level control chart to an improved predictability level.

These strategies lead to the identification of value-chain metric improvements. This creates a stimulus that draws out or pulls projects that will be in true alignment with business needs instead of imposing or pushing the creation of projects that may be counterproductive for the overall enterprise. The result will

lead to the creation and execution of a long-lasting business measurement and improvement system for any organization. It will also generate process improvement and R&D design projects that focus on developing innovative solutions that will help an entire enterprise.

Goals for corporate or operational levels include the reporting of corporate-level financial revenue growth and profit margin metrics in a format that is not bounded by calendar year, assesses predictability, and makes a predictive statement when appropriate.

This approach puts the emphasis on creating financial benefits that will be experienced by an entire company, not just individual portions of the business, which often have a silo view of the organization. This measurement pull-for-project creation approach helps ensure that initiatives undertaken are truly aligned with overall business needs.

Lasting effects

The E-DMAIC roadmap provides an organizational governance system with a long-lasting, continuing framework that is independent of leadership changes. In contrast, a project selection process does not demand blind obedience to the creation and completion of a given number of projects in a set time period to benefit the entire system.

Instead of prioritizing projects based on presumed importance to a certain functional area on the organizational chart, managers can determine what should be done to make the enterprise stronger and more competitive as a whole. In addition, this system provides a method for how metrics are viewed and how the business is managed day to day.

When the roadmap is implemented, the enterprise system becomes more data-driven and sustainable. The capacity for better performance measurement can lead to significant reductions in waste and unproductive firefighting activities. Activity checks and balances ensure continuing improvements and timely project completions in the control phase.

DMAIC goes enterprisewide

Three of the nine steps for aligning projects with business needs (see "Nine Steps To Align Projects With Business Needs" at www.qualityprogress.com) involve establishing metrics. Balance is important. For example, you don't want to sacrifice quality when improving on-time delivery; however, you don't want to force an unnatural balance throughout the organization, such as what might be suggested by the balanced scorecard of financial, customer, internal business processes, learning and growth processes.

Operational and corporate metrics must tie into a system for monitoring the voice of the customer. Metrics at this level are created in alignment with organizational value-chain functional operations. They can include defect rates, on-time delivery, inventory, safety, and product development and production lead time.

These metrics are developed to produce a natural balance and dependency on value-chain needs rather than the company's current organizational chart, which changes over time. With this management system, a company's core value-chain metrics will not change because of a shift in leadership, strategy and the organization chart.

Achieving the right balance demands attention to the entire enterprise value chain. System performance is a function of how well constraints—such as internal resources, external markets or policies—are identified and managed.

When viewed as a whole, a system's output is determined by its weakest link. If you don't choose metrics and their goals carefully, focus may not be placed on overall performance improvement, but instead on a subsystem that would not impact overall output, even if it is significantly improved.

The E-DMAIC corporate and operational-level metrics are not bounded by calendar year. So if nothing has changed over 10 years (for example, the metric has demonstrated to be stable for this period), this metric reporting system would not only report this predictability, but also provide a predictive statement. For this to get better in time, teams need to determine improvements that will significantly improve this metric.

This view of the way a company functions can change behavior from a focus on doing whatever it takes to meet quarterly financial goals (the Enron approach) to improving performance at all levels so the overall output always reflects the maximum potential for an entire enterprise. QP

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MORE FROM BREYFOGLE

Forrest W. Breyfogle III has written about control charting at the 30,000-foot-level in 3.4 per Million columns that appeared in the month of November every year from 2003-2006. You can access these columns at www.qualityprogress.com.

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BY MARK BRAND

Be All That You Can Be

From football to the Army, one man sees quality in all he does

AT FIRST glance, my journey into the quality world may seem unusual. But when I look back, I see it wasn't about where I worked or what type of job I had; it was more about how I did those jobs and what they did for me.

I grew up in a small Ohio town that was crazy about high school football. The town was only about 30,000 strong, but we averaged 12,000 spectators per football game. For the big game at the end of the year, capacity would reach 20,000. This was the culture I grew up in—small town America, with a passion to be the best at something.

I still remember the stadium maintenance guy standing on a ladder to inspect the screws that held the team photos of years past in the locker room. He would turn every screw that was slightly off to a perfect vertical position until the slot of the screw was pointing perfectly at the sky and the ground. There were more than 60 years of team photos with four screws in each frame. Most people would probably never notice a missing screw—let alone if one was off position by a few degrees—but the maintenance guy would know, and this team deserved perfection.

This is the passion for quality I saw at an early age, but I didn't realize until much later the full impact it would have on my life.

Basic training

After graduating from high school, I enlisted in the U.S. Army and learned I would receive training on maintaining an anti-tank missile system. I joined in December, using the delayed entry system, which meant I would not have to leave for basic training until the following August. Two weeks before my departure for basic training, however, Iraqi forces invaded Kuwait. The event opened my eyes, and I realized I had better make the most of the training because I might need to use it soon to save myself or my fellow soldiers.

I went through basic training trying to learn everything I could and to become the best I could at it. I learned to shoot an M-16 and throw a hand grenade at an expert level. I gained skills at hand-to-hand combat and improved my fitness. After basic training, I went off to my specialty training in anti-tank missile systems. Great importance was placed on this training from the instructors. I was told if I failed to keep this system in operation, somebody wearing the U.S. insignia might come home covered by the U.S. flag. What more inspiration did I need to do the very best I could?

> "I learned a **valuable life lesson** about doing the best work you can because **someone's life may depend on it.**"

I graduated with distinguished honors at the top of my class. Fortunately, the battle ended before I was released from training, but I learned a valuable life lesson about doing the best work you can because somebody's life may depend on it.

After my years of service, I entered into a new challenge by working in the electrical construction business. I began as an apprentice and worked my way up to journeyman electrician. Again, I found myself in a position that if I made a mistake or crossed some wires, somebody might get hurt or a building might burn down. This great responsibility motivated me to become the finest electrician I could be.

I attended training courses, took college classes and learned from seasoned journeymen. Eventually, I tested for and obtained a state of Alaska electrical administrator license, which is closely related to many master electrician licenses in other states.

I moved up within the company and began to manage projects and small crews of journeyman and apprentice electricians. In this leadership position, I was able to inspire many others about the responsibility they had not just to the company, but to the customer and the safety of the community.

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Entering a new world

After a while, I began looking for new ways to expand my knowledge and was introduced to the world of quality management.

My first opportunity was working as a contract electrical and instrumentation quality assurance field representative for a large oil company at the fabrication shops in town. There, I was responsible for overseeing the implementation of the electrical and instrumentation portion of the fabricator's quality management systems, and for the company's overall quality plan implementation.

After a short period, I moved into the office to work as a quality assurance coordinator. I was responsible for coordinating quality assurance and supplier quality surveillance activities for entire projects, from the planning stage to closeout. Opportunity and hard work once again paid off when the oil company offered me a full-time position as its quality assurance and quality control representative, which is where I am today.

I am responsible for supervising the third-party agencies that we use to fill the roles of the quality assurance coordinators, quality assurance field representatives, auditors and supplier quality surveillance inspectors. Additionally, I am responsible for developing the audit schedules, assisting in improvement processes, maintaining record-retention protocols, providing technical and procedural support, and the development of our quality procedures.

I continue to look for new ways to grow in this field. Recently, I successfully completed ASQ's certified quality manager/organizational excellence exam.

No matter how bright the future is, however, it is always nice to look back and see how quality has been a part of my life, from seeing the maintenance guy straightening the screws, to feeling the inspiration of defending this country and its soldiers, to protecting the community where I live.

Now, I have the opportunity to impart the passion I have for quality to my coworkers and business and personal contacts. I am not sure what I will be doing down the road, but I do know quality will always be a part of it, as it always has been. QP

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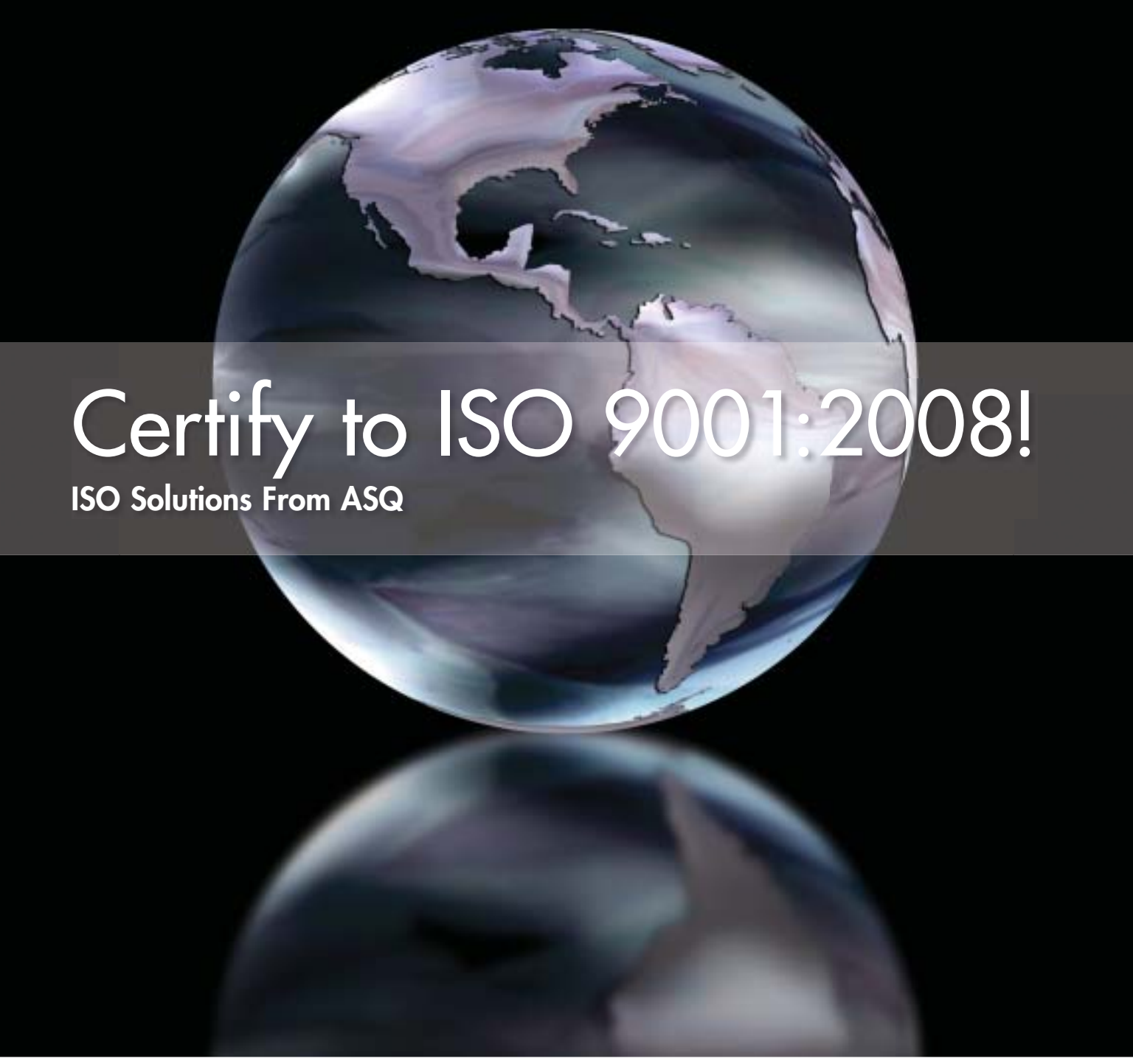

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BY I. ELAINE ALLEN
AND CHRISTOPHER A. SEAMAN

Predicting Success

Simulation can forecast probable success in clinical trials

SIMULATION IN DRUG development is becoming standard practice for pharmaceutical and biotechnology companies. Considering that a phase three efficacy clinical trial for a potential new product could cost nearly $100 million, spending time on simulation activities before fully committing to developing a new product has proven to be increasingly worthwhile for more companies.

Knowing the probability of success in specific patient populations before investing big dollars can cut costs or even stop a trial before it starts. Using mathematical or stochastic models of clinical trials, including information about drug activity, drug availability and the disease process, have been discussed in statistical and clinical literature.[1] The methods have spawned niche clinical research organizations that specialize in simulating and forecasting probable success in a clinical trial and software packages.[2-4]

Another related application of simulation to clinical trials is simulating a futility index for a trial and using it as an interim endpoint for stopping the trial during an interim analysis.[5] Using interim futility monitoring of phase three trials can substantially increase the probability of stopping trials early for futility when there is no treatment effect that can lead to meaningful reductions in study duration and patient resources in many disease settings without substantial loss of power for the primary test of efficacy.

The most complex simulations are multivariate and possibly Bayesian: They introduce patient and clinical covariates that may impact success and information derived from early clinical trials (phase one and phase two) or even preclinical results.

More recently, these simulations have been expanded to include evaluating test strategies for diagnostics[6,7] and building prediction models for the angel investment and venture capital community. All of these simulations can be considered as introducing efficiency and cost-effectiveness to the process.

We will examine two simulations that were constructed to evaluate the probability of success of ongoing trials, based on published information by biotechnology companies. These analyses were carried out for the investment community before it was recommended to commit funds to develop the product.

Antiviral compound example

Example one is a simulation of the results of an ongoing phase three trial comparing a new antiviral compound against standard treatment with a primary outcome of a difference in the percentage of patients with a viral load less than 400.

The trial includes 500 patients—250 randomized per treatment group increased from an initial 150 per group. This is a non-inferiority trial with one-sided difference of 13% determined to be an important clinical difference between the two treatments. The power of the test between groups is between 80% and 90%, and the level of significance is assumed to be alpha = 0.025 (two-sided 5% level of the test). The simulation was estimated to determine whether the trial was sufficiently sized and powered to show a significant result.

Usual non-inferiority design: The non-inferiority test setup is that the new treatment must be within the confidence bounds of ±13% of the absolute percentage of patients with viral load < 400 copies in the control group with the following null and alternate hypotheses:

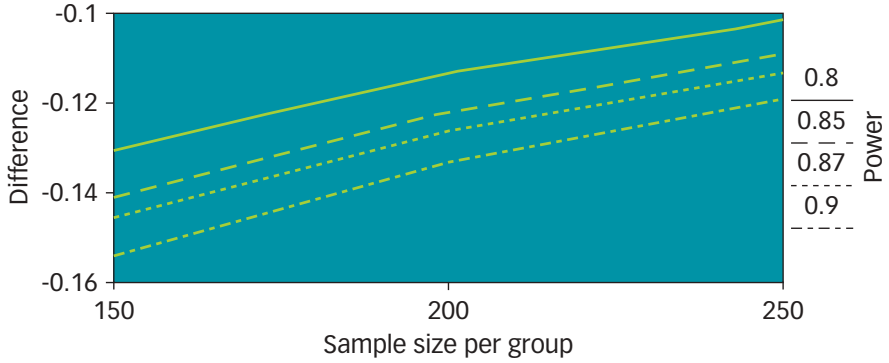
Null hypothesis:

$$|\text{Control} - \text{treatment}| \geq 13\%$$

Alternate hypothesis:

$$|\text{Control} - \text{treatment}| < 13\%$$

Sample size vs. power vs. difference between treatment control / FIGURE 1



There are two criteria based on this one-sided confidence interval: Is the treatment above the non-inferiority lower bound of -13%, which would show non-inferiority, or is it above the upper bound of ±13%, which would show superiority?[8]

Sample size requirements to show superiority: Table 1 includes required sample sizes to show a significant non-inferiority or superiority result. The simulation varied the required sample size per group (double for trial size); used rounded estimates of 80%, 85% or 90% for power; started with a control rate of 60%, 65%, 70% or 75% of the patients with viral load < 400 copies; and varied the treatment rate from 75% to 90%.

Results of the simulation: Given the non-inferiority boundary, superiority can be claimed only if the difference is greater than 13%. If we assume the difference is between 85% and 71% (or 14%), as long as there are at least 175 patients per group that are analyzable (no dropouts), there will be a statistically significant difference with power of 87%. If the number of patients is higher, power will increase. If the number per group is smaller, however, or the difference is less than 13%, superiority can't be claimed, but non-inferiority may be possible.

Another way to examine this is shown in Figure 1. Power is plotted against the sample size, and the hypothesized difference between 10% and 16% is given.

Hodges-Lehmann estimate

Example two is a simulation of the Hodges-Lehmann estimate for treatment versus placebo in a pulmonary arterial hypertension study.

This trial, already under way, compares two groups on a six-minute walk, with an estimated mean baseline distance of 350 meters, based on results from a similar clinical trial. The comparison statistic in the statistical analysis plan is the Hodges-Lehmann estimate paired with a

Required difference for treatment vs. control given assumptions on power, significance level and sample size / TABLE 1

Power = 90% significance level = 5% (two-sided test)

Control	Treatment 75	76	77	78	79	80	81	82	83	84	85	86	87	88	89	90
65					228	197	172	152								
66						223	193	168								
67							218	188	164							
68							249	213	184	160						
69								243	208	175	155					
70									237	202	174	151				
71										230	196	169	146			
72											223	190	163	141		
73												216	184	158		
74												248	208	177	152	
75													239	200	170	146

Power = 85% significance level = 5% (two-sided test)

Control	Treatment 75	76	77	78	79	80	81	82	83	84	85	86	87	88	89	90
65				230	197	171										
66					225	193	167	145								
67						220	189	163	142							
68							215	184	159							
69							248	210	180	155						
70								242	205	175	151					
71									235	199	170	146				
72										228	193	164				
73											221	187	159			
74												214	180	153		
75												249	206	174	148	

Power = 80% significance level = 5% (two-sided test)

Control	Treatment 75	76	77	78	79	80	81	82	83	84	85	86	87	88	89	90
65			239	203	174	151										
66				235	199	171	148									
67					230	195	167	144								
68						225	190	163	141							
69							219	186	159	137						
70								214	181	155						
71								250	208	176	150					
72									243	202	171	146				
73										236	196	165	141			
74											228	189	160	136		
75												221	183	154		

Sample size required for a statistically-significant difference.
Blue shaded areas = no chance at showing non-inferiority or superiority.
Green shaded areas = always superior.
Sample size numbers indicate areas where dropout rate may play a role.

rank-based test to get a significance value comparing the two groups. The simulation was intended to determine the minimum difference between groups that would be statistically significant.

Significance test criteria: The Hodges-Lehmann estimate looks at a paired comparison between treatment and a placebo patient by subtracting each treatment patient's walk distance from each placebo patient's walk distance. Its estimate is the median of those differences. To compare the groups, we look at the differences. A positive difference indicates a treatment patient walked longer than a placebo patient. Positive ranks (1, 2, 3 ...) are assigned to the positive differences and negative ranks (-1, -2, -3 ...) to the negative differences. The ranks are summed, and a large positive sum favors treatment over placebo (close to zero or no difference). The p-value is calculated from the number of positive differences, negative differences and the sum of the ranks.

Simulation techniques can be used to **examine the probability** of a clinical trial **reaching significance.**

Results of the simulation: Assuming the six-minute walk distance outcome is normally distributed for treatment and for placebo, based on previous clinical data, a Monte-Carlo simulation was performed looking at all possible differences comparing treatment and placebo groups.

Tables 2 and 3 show the median difference in walk distance and in Z-score for different mean walk distance differences with a baseline of 325 meters (standard deviation = 65 meters). Sensitivity analyses changing the 325 baseline mean did not change the conclusions.

The inputs for the model were distributions for baseline walk distance and treatment walk distance because the placebo group was not expected to change from baseline. These were normal distributions with mean 325 meters for baseline and 325-plus improvement for treatment. The standard deviation was assumed to be 65 meters for both. There was also inclusion criteria in the trial that baseline walk distances be between 200 and 450 meters, and treatment walk distance was assumed to be greater than 100 meters.

There were 1,000 trials run for each improvement value estimating the Hodges-Lehmann median difference and Mann-Whitney-Wilcoxon Z-score value for each simulation value. If the mean walk distance was longer, but the distributions remained identical, you would expect the same Hodges-Lehmann estimates and Z-score values. If the standard deviation was larger, there would be greater variation in the 1,000 Hodges-Lehmann estimates and Z-scores, but the median of the 1,000 would stay the same.

For a test between groups at the p = 0.05 level, there would need to be a minimum difference between groups of 18 meters to show statistical significance. For a test

Simulation results for the minimum mean and median difference to show significance (p = 0.05) / TABLE 2

Simulation 1 (p = 0.05, z > 1.96)							
Baseline mean	Difference	Median difference	1st quartile	3rd quartile	Z-score	1st quartile	3rd quartile
325	5	4.716	(-1.526,	10.748)	0.536	(-0.183,	1.205)
325	6	6.276	(0.699,	12.114)	0.719	(0.082,	1.382)
325	7	7.081	(1.524,	12.692)	0.779	(0.170,	1.451)
325	8	8.281	(2.437,	13.726)	0.918	(0.277,	1.562)
325	9	9.67	(3.718,	15.159)	1.117	(0.429,	1.704)
325	10	10.292	(4.354,	15.859)	1.158	(0.470,	1.792)
325	11	11.198	(5.444,	17.029)	1.275	(0.609,	1.931)
325	12	11.672	(5.849,	17.747)	1.331	(0.653,	1.994)
325	13	13.111	(6.762,	19.008)	1.499	(0.773,	2.136)
325	14	14.458	(8.033,	20.506)	1.653	(0.915,	2.285)
325	15	14.961	(8.751,	20.657)	1.698	(0.997,	2.338)
325	16	16.336	(9.873,	22.745)	1.836	(1.114,	2.540)
325	17	16.68	(11.046,	22.734)	1.884	(1.249,	2.566)
325	18	17.656	(11.690,	23.504)	1.969	(1.338,	2.657)
325	19	19.502	(13.338,	24.940)	2.187	(1.530,	2.805)
325	20	20.225	(13.700,	26.001)	2.288	(1.549,	2.919)
325	21	21.46	(16.159,	27.552)	2.405	(1.811,	3.067)
325	22	21.847	(15.958,	27.695)	2.458	(1.789,	3.093)
325	23	23.222	(17.051,	29.304)	2.607	(1.947,	3.254)
325	24	23.929	(18.168,	29.669)	2.67	(2.048,	3.269)
325	25	25.239	(18.910,	31.378)	2.865	(2.143,	3.490)

between groups at the p = 0.10 level, there needs to be a minimum difference between groups of 15 or 16 meters.

Significance in simulation

Simulation techniques can be used to examine the probability of a clinical trial reaching significance. This information is important for the sponsor of the trial, regulatory agencies and business investors.

The first example calculated the likelihood of a trial showing a significant difference between treatment and control based on a sample size, level of significance and power estimates. The difference between groups was calculated (in percentage reaching optimal viral load), and the sample sizes in which significance was guaranteed, possible and not likely given.

The second example offered the results of simulating a statistical test on ranks using the Hodges-Lehmann estimate as the overall statistic and the Mann-Whitney-Wilcoxon test. Using two levels of significance, the value of the Hodges-Lehmann estimate (in difference in meters walked between treatment and placebo) was found.

As shown in these two examples involving clinical trials, simulation can leverage a small amount of known information to reduce the range of possible outcomes of an experiment and identify where there is the most risk in drawing conclusions. It is most important to identify and understand the assumptions of the simulation at the outset and determine how confident you are in these assumptions to be able to interpret the resulting predicted outcomes with validity. QP

Simulation results for the minimum mean and median difference to show significance (p = 0.10) / TABLE 3

Simulation 2 (p = 0.10, z > 1.645)							
Baseline mean	Difference	Median difference	1st quartile	3rd quartile	Z-score	1st quartile	3rd quartile
325	6	6.276	(0.699,	12.114)	0.719	(0.082,	1.382)
325	7	7.081	(1.524,	12.692)	0.779	(0.170,	1.451)
325	8	8.281	(2.437,	13.726)	0.918	(0.277,	1.562)
325	9	9.67	(3.718,	15.159)	1.117	(0.429,	1.704)
325	10	10.292	(4.354,	15.859)	1.158	(0.470,	1.792)
325	11	11.198	(5.444,	17.029)	1.275	(0.609,	1.931)
325	12	11.672	(5.849,	17.747)	1.331	(0.653,	1.994)
325	13	13.111	(6.762,	19.008)	1.499	(0.773,	2.136)
325	14	14.458	(8.033,	20.506)	1.653	(0.915,	2.285)
325	15	14.961	(8.751,	20.657)	1.698	(0.997,	2.338)
325	16	16.336	(9.873,	22.745)	1.836	(1.114,	2.540)
325	17	16.68	(11.046,	22.734)	1.884	(1.249,	2.566)
325	18	17.656	(11.690,	23.504)	1.969	(1.338,	2.657)
325	19	19.502	(13.338,	24.940)	2.187	(1.530,	2.805)
325	20	20.225	(13.700,	26.001)	2.288	(1.549,	2.919)
325	21	21.46	(16.159,	27.552)	2.405	(1.811,	3.067)
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325	25	25.239	(18.910,	31.378)	2.865	(2.143,	3.490)

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BY LES SCHNOLL

To Launch or Not to Launch

Quality pros help streamline medical device development and eliminate last-minute conflicts

WITH THE ENACTMENT of the Quality System Regulation (QSR), 21 CFR 820, in 1996, the world of research and development changed significantly for many medical device manufacturers.

Then, in 1997, when the process of design controls came under the auspices of the Food and Drug Administration (FDA), that world changed even more. Activities such as risk assessment and management, design transfer and documentation of activities in a design history file (DHF)—once only known and implemented by relatively few progressive organizations—became regulated and thus became the basis of many FDA Form 483 findings and warning letters. The use of a product development process (PDP) in the FDA-regulated world was born.

To ensure compliance with the requirements for design controls defined in the QSR, companies should use a structured PDP with well-defined degrees of freedom that instills discipline into the complete product life cycle without sacrificing creativity.

In this scenario, actions required to take an entire product offering from conception to commercialization are structured in a hierarchy. The hierarchy arranges these actions from phases (the highest level) to steps to activities and finally to tasks (the most specific). Phases divide product development into stages, and each phase has a unique theme and set of deliverables.

Early phases emphasize concept formation, product definition and project planning; later phases focus on development, verification, rollout and maintenance of the defined product. Careful planning and flawless execution are desirable attributes of all phases. The PDP process I describe here is comprised of five phases.

Timely product launch is one **key to a company's** success.

Five-phase process

Phase 0—concept research: The concept research phase is initiated through the use of an approved concept project proposal. This starts the PDP but precedes the use of formal design controls.

The purpose of this phase is to identify new market opportunities, determine and prioritize customer needs, and conduct a high-level, rapid, assumption-based evaluation of the opportunities to assess their strategic fit.

The concept research phase concludes with management approval of an integrated business plan for the project. This document is updated at the conclusion of each phase. Once approved for phase 0, the team may begin phase 1 activities and the initiation of design control.

Phase 1—definition and planning: The definition and planning phase initiates the design control activities. The first step in this process is the establishment of a DHF. The purpose of the definition and planning phase is to define a whole product offering and complete the project plan. Key deliverables from this phase include the formalization of the customer requirements and product requirements specifications. It is in this phase that the design requirements specification is prepared.

Phase 2—design and development: The purpose of this phase is to design and develop the whole product offering and the supporting processes. The key deliverable is a complete design and development activity that delivers a product that is ready for verification and validation testing. Design changes beyond this phase are handled using the appropriate document control procedures.

Phase 3—verification and validation: The purpose of phase 3 is to verify and validate that the entire product offering and its supporting processes are robust and comply with the design requirements specifications and the customers' specifications before making the product commercially available.

All regulation, code, standards and product safety approvals must be obtained by the end of this phase. Although orders cannot be accepted and customer shipments cannot be made until phase

21 CFR 820 / TABLE 1

PDP phase	Design control element initiated
Phase 0: Concept development	None. Design control activities are initiated after management approval of phase 0. There are no regulatory requirements in this phase.
Phase 1: Definition and planning	820.30(b): Design and development planning Each manufacturer shall establish and maintain plans that describe or reference the design and development activities and define responsibility for implementation. The plans shall identify and describe the interfaces with different groups or activities that provide or result in input to the design and development process. The plans shall be reviewed, updated and approved as design and development evolves. 820.30(c): Design input Each manufacturer shall establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient. The procedures shall include a mechanism for addressing incomplete, ambiguous or conflicting requirements. The design input requirements shall be documented and shall be reviewed and approved by a designated individual(s). The approval, including the date and signature of the individual(s) approving the requirements, shall be documented. 820.30(d): Design output Each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements. Design output procedures shall contain or make reference to acceptance criteria and shall ensure that those design outputs that are essential for the proper functioning of the device are identified. Design output shall be documented, reviewed, and approved before release. The approval, including the date and signature of the individual(s) approving the output, shall be documented. 820.30(e): Design review Each manufacturer shall establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development. The procedures shall ensure that participants at each design review include representatives of all functions concerned with the design stage being reviewed and an individual(s) who does not have direct responsibility for the design stage being reviewed, as well as any specialists needed. The results of a design review, including identification of the design, the date, and the individual(s) performing the review, shall be documented in the design history file (DHF). NOTE: Design reviews are conducted throughout phases 1, 2 and 3. 820.30(g): Design validation (risk assessment) Design validation shall include software validation and risk analysis, where appropriate. 820.30(i): Design changes Each manufacturer shall establish and maintain procedures for the identification, documentation, validation or—where appropriate—verification, review and approval of design changes before their implementation. 820.30(j): DHF Each manufacturer shall establish and maintain a DHF for each type of device. The DHF shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of this part.
Phase 2: Design and development	Design control activities continue.
Phase 3: Verification and validation	820.30(f): Design verification Each manufacturer shall establish and maintain procedures for verifying the device design. Design verification shall confirm that the design output meets the design input requirements. The results of the design verification, including identification of the design, method(s), the date and the individual(s) performing the verification, shall be documented in the DHF. 820.30(g): Design validation Each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validation shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions. Design validation shall include software validation and risk analysis, where appropriate. The results of the design validation, including identification of the design, method(s), the date and the individual(s) performing the validation, shall be documented in the DHF. 820.30(h): Design transfer Each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications.
Phase 4: Commercialization	No further design control activities are initiated. This phase closes out all development activities and begins the requirements for post-market surveillance.

4, demand-building activities may be initiated in anticipation of commercial release.

Phase 4—commercialization: The purposes of phase 4 are to deliver the product to customers in a controlled manner and to gather performance feedback on products that are commercially distributed. Full-scale launch of the product, including the release of evaluation equipment, coordinated mass communication to customer and the release of final pricing information, is initiated in this phase.

A commercial release notice is developed and distributed to indicate commercial availability of the product. In support of the product launch, manufacturing operations are ramped up to support full-scale production. In addition, a postlaunch evaluation is conducted to assess the overall success of the product versus the original targets. The core team exits the project at the conclusion of this phase and transfers product ownership to the supporting organization.

Steps and activities

The levels that are below phases within the structured process are steps that consist of multiple activities and are used to manage the progress of product development. Steps are the primary planning and scheduling mechanism to ensure all aspects of the whole product are considered.

The levels below steps within the structured process are activities and define in more detail how a step is performed. These consist of a number of tasks and describe the day-to-day work individuals do to complete their activities. Tasks can be thought of as work-scheduling units at an individual level.

Collectively, the structured whole-product process provides the basis for decision-making, project scheduling, resource planning, process measurement and continuous improvement.

Certain elements of the design control requirements are initiated by phases. In general, these elements continue through the development process and are maintained through the change control process.

Table 1 (p. 65) contains the design control elements that are initiated in each phase. In general, these elements continue through the development process and are maintained through the change control process.

The PDP should be flexible and scalable; that is, it should be generic, comprehensive and applicable to all projects at each phase level. Some steps and activities may not be applicable to all projects, however, and the process should be flexible enough to allow for these differences.

At the end of each phase, the project team tailors the process for the next phase by identifying and justifying steps, activities and deliverables that will not be applicable to its project. This is documented in the design and development plan for the next phase. This process is shown in detail in Figure 1 (p. 68).

In addition to documenting and defining a logical approach to commercialization of new or modified medical devices, the PDP also reduces the potential conflicts between functional groups, such as marketing and quality.

A product **development plan reduces potential conflicts** between functional groups.

I'm certain that each of us has experienced—at least once—debates and accusations that quality is delaying the launch of a product. In today's environment of quality acting as a strategic business partner (rather than as the quality cops), the use of a PDP only enhances that relationship. Quality and regulatory personnel should be members of any project core teams, and their early input into the PDP will eliminate most of the eleventh-hour conflicts prior to launch.

The company's management team bears the responsibility for ensuring the process is implemented and followed. While there are always exceptions to the phased-gate approach shown in Figure 1, they need to be exactly that—exceptions.

Core teams should understand that their failure to meet all requirements in the applicable phases of the process will preclude their ability to move forward. This way, any delays that impact product

HIRING FREEZES. Layoffs. Cutbacks.

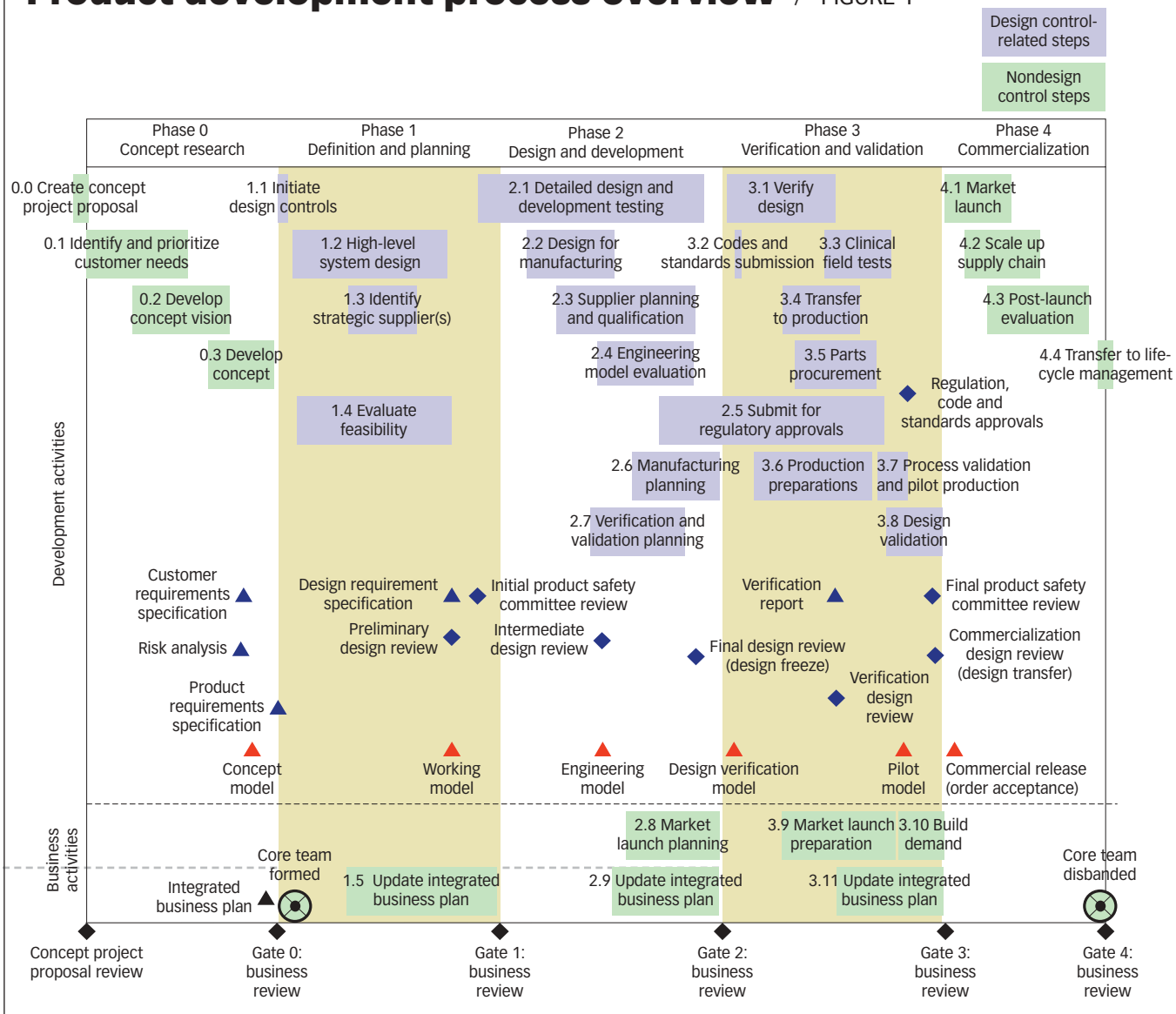
Most of you have been impacted by economic pressures. Maybe a project was put on hold—indefinitely. Or maybe your department's headcount has dwindled.

For an upcoming article, QP editors want to know: What's your story?

- How has the economy affected you, your department, your company and its quality efforts?
- How are you positioning yourself and your company's quality initiatives to keep them alive and well?
- What advice can you give others dealing with similar situations?

Send your experiences, anecdotes, advice and ideas (150 to 200 words) to editor@asq.org by March 31 and we'll consider it for inclusion in an upcoming article. Include name, title, company, phone number and e-mail address. Submissions may be edited for space and clarity.

Product development process overview / FIGURE 1



launch are the responsibility and the ultimate result of the core team's failure to follow documented procedures.

It's clear that the ability to launch a product on a timely basis is key to the success of a company. What is typically not so clear is whether the product is ready to launch. An effective PDP, tailored to the needs and products of the company, is a useful and proven method to address the second issue. A great deal of work is required to implement a PDP, but the rewards will be immediately apparent. QP

LES SCHNOLL has 30 years of experience in industries regulated by the Food and Drug Administration and is currently vice president of quality, regulatory affairs and operations for ThermoGenesis Corp. in Rancho Cordoba, CA. He is a senior member of ASQ and an ASQ certified quality engineer, auditor and manager. A member of the U.S. technical advisory group to International Organization for Standardization technical committee 176, Schnoll wrote The Regulatory Compliance Almanac *(Paton Press, 2001, 2008).*

MEDICAL DEVICE ADVICE

Past Standards Outlook articles on medical devices can be found at www.qualityprogress.com.

Looking Out for No. 1

Lay the groundwork for your next big career move

FINDING WORK during a recession is a challenge, not an impossibility. But, whether you are unemployed and seeking work, or currently employed and seeking an improved career, it is your responsibility to get results.

Many organizations have career ladders or career growth opportunities, such as training, tuition reimbursement or promotions. Keep in mind, however, these organizations exist to be profitable, not to take their employees' careers to the next level.

I am not advising disloyalty to your company or to any company with which you have been associated. You signed on with that organization for a reason, and you need to give your full attention to the job you were hired to do. But, if you are in the job market or just trying to advance your career, keep the following in mind:

- Always be audition ready.
- Stay connected.
- Get your name out there.
- Use speed networking.

Always be audition ready

No matter where you are, you are always auditioning. My family teases me because I do not like to go anywhere, even the post office or grocery store, without minimal makeup and a basic hairstyle. I firmly believe that you never know when you will meet a potential hiring manager.

I went to a large discount store one day and ran into a former coworker and his friend. Little did I know that the friend was a hiring manager at a company where I would interview months later. That same hiring manager remembered meeting me and the impression I made—even though I didn't know at the time that I was auditioning.

You may be auditioning at a public venue, a company function, a professional society meeting or during a project. Be prepared to always put your best foot forward.

Stay connected

I advise people to stay connected at all times, even when happily engaged in work they enjoy. Staying in touch has always been my philosophy, especially because it has worked for me.

A friend recently told me how he left work on a Friday, happily employed. When he returned the following Monday, a sign on the door said the company had been closed due to the current financial crisis. Two of the four investment firms that supplied the company's funding had gone out of business. Just like that, my friend was unemployed. Fortunately, he had kept in touch with his network and was able to find another position in a relatively short time.

The message here is to be current and connected. It is much easier to rely on an already-built network than it is to try to create one in a time of need.

Get your name out there

This is a slogan in the sales world. Potential clients are typically those you already know. The same is true for career opportunities. Your reputation is everything, and what people know or say about you matters. It is much easier to get a better job, or any position at all, with someone who knows you and what you can do.

Attaining career growth at your current organization or obtaining a new job is a numbers game based on probability. The more times you try, the more likely you are to succeed. Don't let past mistakes or errors in judgment during job searches stand in your way. Even if you must reinvent yourself and change careers, it is your responsibility to do so if that's what is needed.

Speed networking

The concept of speed dating has turned into speed networking. Speed networking events involve you, your business card and 30 seconds to talk about yourself. Speed networking is an opportunity to spread the word about yourself to as many people as possible while wearing your sales and marketing hat.

All you need is a brief, well-rehearsed speech describing yourself and what you can do. In turn, you get to learn about others, what they do and maybe even their companies. Real-estate agents have been successful obtaining clients through speed networking. So can quality professionals.

Taking responsibility for your career growth and finding employment may be difficult, particularly in down times. It's easy to say, "No one wants me, the boss hates me, the economy is terrible, and this company won't promote me." Remember that you have the power to control your destiny.

Creativity, positive thinking and due diligence will help you achieve your goals. Resolve to take responsibility to become whatever you wish. And remember that the only person responsible for your destiny and your own career path is you. QP

TERESA A. WHITACRE is a quality assurance professional and owner of Marketech Systems in the Pittsburgh area. She is a senior member of ASQ and holds ASQ certifications of quality auditor, quality engineer, quality manager/organizational excellence and Six Sigma Green Belt. Currently Pittsburgh section secretary, Whitacre is a long-term instructor for quality inspection certification for the section.

QP TOOLBOX

Diesel exhaust gas temperature sensor ▸

The Sensor Connection has released the diesel exhaust gas temperature (EGT) sensor which features an enclosed foul proof probe tip that permits operation in biofuel and diesel engine applications. This type K thermocouple can withstand extreme conditions, making it ideal in research and development and in various applications with the agricultural, marine and automotive industries.

The EGT diesel sensor is capable of surviving extreme vibration and heat up to 1,200° C. The foul proof sensor tip is recommended for EGT measurements of sulfuric fuels. A 90° bend to the probe accommodates tight-spaced mounting locations.

Call: 248-417-2622; visit: www.thesensorconnection.com.

Automatic switchover ▾

Concoa's Universal Medical IntelliSwitch offers continuous pressure and flow control from liquid to high pressure medical cylinders. It can be used in hospitals, clinics, healthcare facilities and medical gas pipeline systems.

This automatic switchover features proprietary software and control logic that lower annual gas costs and comply with the National Fire Protection Association 99 Economizer requirements. It is designed to eliminate liquid cylinder vent loss and excess residual return.

The Universal Medical IntelliSwitch allows users to remotely monitor status for added protection and convenience. It can serve as a single remote monitoring source or be linked to a facility alarm systems.

Call: 800-225-0473; visit: www.concoa.com.

Ductless fume hood ▾

The Purair 5 ductless fume hood from Air Science USA meet, Occupational Safety and Health Administration, American National Standards Institute and other international standards. The ductless design allows the unit to be positioned over a sink or benchtop apparatus. There are three models available.

The unit operates at low noise levels, and because it recirculates it does not exhaust conditioned or heated air into the atmosphere. The Purair 5 features an alarm that alerts the operator if airflow falls to an unacceptable level.

The unit can be placed on any benchtop,

and an optional polypropylene spillage tray can be provided if required. The rear of the unit has lighting to illuminate the work surface.

Call: 800-306-0656; e-mail: info@air-science.com.

Capacitive sensor ▲

Turck has introduced a noise immune capacity sensor for level applications. The BCF10 sensor's small size makes it flexible for mounting, and it has the ability to detect liquids with high concentrations of chlorides, such as soaps and cleaners.

In applications where a detergent high in chlorides is used, it is typically contained in a plastic container. Over time, the detergent leaves a film or etch on the inside wall of the container. If a standard capacitive sensor is used for level detection, it will detect this film even though the container is empty.

Call: 800-544-7769; visit: www.turck.us.

Laboratory capillary rheometers ▸

The Rheologic and Smart Rheo laboratory capillary rheometers from ATS RheoSystems are used to determime flow behavior in a wide range of materials. Both floor and benchtop models are available with single and dual bore capabilities.

The computer-controlled instruments offer testing abilities in measuring shear viscosity, extensional viscosity, wall slip, melt fracture and rupture with a variety of dies and accessories.

The capabillary rheometer system features two level software interface, which offers standard test control functionality and scientific evaluation capabilities for better understanding of the data.

Call: 609-298-2522; visit: www.atsrheosystems.com.

Setting blocks ▼

Pres-On has released a heavy duty line of setting blocks in commercial grade silicon, neoprene or ethylene propylene diene monomer.

The Pres-On setting blocks are installed inside a window sash to protect insulated glass from the impact of sash openings and closings. The blocks stop the glass from cracking while maintaining the integrity of the glazing bead.

Pres-On setting blocks provide stress relief when vinyl windows expand and contract due to temperature changes.

The setting blocks can be configured specifically to meet the requirements of window original equipment manufacturers.

Call: 800-323-7467; e-mail: industrial@pres-on.com.

QP REVIEWS

Innovation Generation

Peter Merrill, ASQ Quality Press, 2008, 242 pp., $45 list, $27 member (book).

In his book, *Innovation Generation*, Peter Merrill focuses on innovation's role as the missing link to achieving prosperity and how it can be woven into the fabric of an organization. The book's framework is based on three elements: process, people and implementation.

Early in the book, Merrill introduces a concept through which he categorizes people into one of four basic types: creators, connectors, developers and doers. The results of this 12-question process offer insight to team members about where they might best contribute to the innovation process.

I particularly enjoyed the premise in chapter four that "the idea of a lone genius is a common myth about innovation" and that most innovations come from a collective base of knowledge. My experience supports that.

Merrill establishes a core principle that people and knowledge sharing build the culture. He spends considerable time trying to convince managers that the people side is important and must be cultivated to build trust and a shared vision.

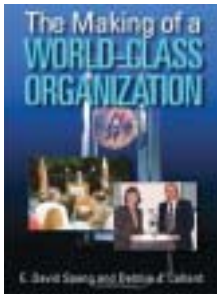
In chapter 17, he establishes a relatively simple organizational assessment that covers the six aspects of innovation: leadership and strategy; knowledge management; process and system; people involvement; culture; and results. He maintains that these six aspects are keys to establishing and maintaining an innovative organization.

This book is user friendly, doesn't get overly academic and is a valuable resource for upper management that wants to focus on innovation and knowledge sharing as core competencies.

Reviewed by Bill Baker
Speed to Excellence
Santa Fe, NM

The Making of a World-Class Organization

E. David Spong and Debbie J. Collard, ASQ Quality Press, 2008, 96 pp., $40 list, $24 member (book).



This extraordinary, albeit brief, book provides leadership and management solutions, as well as insights into creating business excellence. The authors describe how they took two divisions of Boeing—airlift and tanker, and aerospace support—from unsatisfactory and mediocre levels to excellence, achieving Malcolm Baldrige National Quality Awards for each division.

When the authors began their task in 1991, the airlift and tanker division was looking to cut 10,000 jobs. Seven years later, after implementing the Baldrige criteria, the company was recognized as a world-class organization.

Both divisions raised their Baldrige scores by 400 points during their improvement efforts. The keys to this success are first described in detail and then summarized at the end of each chapter. The book also provides tools, techniques and advice on making your organization more effective and profitable, with improved customer and employee satisfaction.

The authors do not avoid the tough questions they encountered, such as "Why should I care about Baldrige?" They discuss their experiences with supportive employees and those who felt, "I don't have the time for all this soft stuff." They show how they dealt with those who provided "lip service and malicious obedience," and delve into how to avoid "initiatives du jour" and other pitfalls.

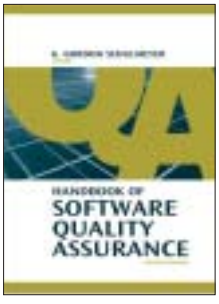
The authors reveal how they motivated leadership and employees, and built relationships with unions. Perhaps most important, they discuss how they coordinated a process improvement toolbox that included Six Sigma, lean, benchmarking, balanced scorecards and other approaches under the Baldrige framework.

Whether you are new to the Baldrige criteria, a veteran or simply want insights into effective leadership and management to create a world-class organization, this is a must read.

Reviewed by Denis Leonard
Business Excellence Consulting
Bozeman, MT

Handbook of Software Quality Assurance, fourth edition

G. Gordon Schulmeyer (editor), Artech House, 2008, 464 pp., $99 (book).



The new edition of this handbook boils down the 21 chapters found in the previous iteration to 17 chapters, reflecting a thorough revision that brings the handbook completely up to date. In a sense, condensing the material makes the book a completely new offering.

Topics covered by the 16 authors include: organizing for quality management, software quality assurance activities, Capability Maturity Model Integration and process and product quality assurance, software quality assurance (SQA) for small projects, quality management in IT, SQA metrics and software reliability engineering. Schulmeyer's excellent editorial work is evident throughout. He has crafted a unified, state-of-the-art publication, with a variety of perspectives that cover the most important aspects of modern SQA.

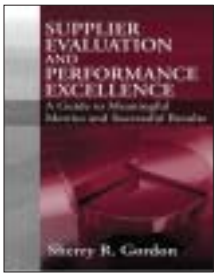
The book targets engineers interested in ASQ's software quality engineering (CSQE) certification, which has an entire chapter devoted to it, and software quality managers and engineers looking for practical and field-tested methods and tools. In addition, the examples and topics covered would provide software quality researchers and students excellent background information.

The fourth edition of the *Handbook of Software Quality Assurance* should find a ready place on bookshelves of practitioners and universities alike, regardless of whether they already have previous editions.

Reviewed by Ron S. Kenett
KPA Ltd.
Raanana, Israel

Supplier Evaluation and Performance Excellence

Sherry R. Gordon, J. Ross Publishing, 2008, 222 pp., $59.95 (book).



This book takes on supplier evaluation and performance, and, as its subtopic indicates, provides a guide to meaningful metrics and successful results. For the most part, it does what its title implies.

Gordon defines and outlines the process used to achieve supplier performance as supplier performance management (SPM). She does a superb job of taking the reader through the entire process, from development to implementation.

Gordon's approach to handling the always-confrontational nature of customer-supplier relationships is particularly interesting. She freely admits the customer is not always correct when it comes to information communicated from the customer to the supplier. This assertation alone makes the book a breath of fresh air.

This book has one of the better discussions of the metrics that are needed to measure suppliers. Gordon has experience in this realm, gleaned from founding a company that provided supply management software solutions to customers.

Another excellent feature of the book is how it links supplier measurements to an organization's business goals and objectives, which is what some standards require for metrics and continuous improvement activities in the purchasing department.

The process outlined is very detailed and is more suited to larger companies with enough resources to implement SPM as described by Gordon. That doesn't mean, however, that the ideas found in this book are not applicable to all organizations, no matter the size.

Reviewed by Wayne Sander
Dove Quality Consulting
Dousman, WI

RECENT RELEASES

The New Art of Managing People

Phil Hunsicker and Tony Alessandra, Free Press, 2008, 357 pp. $18 (book).

Business Is Hard ... Failure is Optional

Sam Khoury, For CEOs Only Inc., 2009, 89 pp., $19.95 (book).

100% Leadership

Gabriel Hevesi, Enna, 2008, 130 pp., $21.99 (book).

Advertisers Index

QP CALENDAR

To receive information or to register for ASQ Education Courses, contact Learning Offerings, ASQ, 600 N. Plankinton Ave., Milwaukee, WI 53203, call 800-248-1946 or 414-272-8575, fax 414-272-1734 or visit www.asq.org.

MARCH

2-3 ASQ Education Course. **A Baldrige-Based Approach to Organizational Learning and Development.** Milwaukee.

2-3 **ASQ Lean Six Sigma Conference.** Phoenix. Call Mark Olson at 800-248-1046 or e-mail molson@asq.org.

2-4 **Agriculture, Industrial and Construction Equipment Conference.** Call Thomas J. Seaberg at 309-765-7548 or visit www.aiceconference.com.

4-5 ASQ Education Course. **Cost of Quality: Finance for Continuous Improvement.** Phoenix.

4-5 ASQ Education Course. **Lean Enterprise.** Phoenix.

4-5 ASQ Education Course. **Lean for Service.** Phoenix.

4-5 ASQ Education Course. **Managing and Leading in a Six Sigma World.** Phoenix.

4-5 ASQ Education Course. **Baldrige Self-Assessment for Higher Education.** Phoenix.

4-5 ASQ Education Course. **Lean *Kaizen*: A Simplified Approach to Process Improvement.** Phoenix.

4-5 **5th Annual North American Summit on Food Safety.** Toronto. Call the Strategy Institute at 866-298-9343 x275 or e-mail registrations@strategyinstitute.com.

5-6 **21st Annual ASQ Quality Management Conference.** Irvine, CA. Call David Little at 717-810-3741 or e-mail dmlittle@tycoelectronics.com.

6 **Lean in the Office.** Milwaukee. Call the Association for Manufacturing Excellence at 224-232-5980 or visit www.ame.org.

11-12 **Special Conference on the Consumer Product Safety Improvement Act of 2008.** Chicago. E-mail Randall Goodden at info@RandallGoodden.com or visit http://randallgoodden.com.

16-18 ASQ Education Course. **Implementing and Auditing an ISO 9001:2008 Quality System.** Las Vegas.

16-18 ASQ Education Course. **Skills for Success for the Management Representative.** Las Vegas.

16-19 ASQ Education Course. **Guide to Process Improvement and Change.** Las Vegas.

16-20 ASQ Education Course. **Design for Six Sigma.** Las Vegas.

16-20 ASQ Education Course. **Introduction to Quality Engineering.** Las Vegas.

16-20 ASQ Education Course. **Lead Auditor Training for AS9100.** Las Vegas.

16-20 **Measurement Science Conference.** Anaheim, CA. Call the MSC offices at 866-672-6327 or visit www.msc-conf.com.

17-20 **Lean and Six Sigma and Business Improvement in Healthcare Summit.** New Orleans. Call Worldwide Conference and Business Forums at 800-959-6549 or e-mail reg@wcbf.com.

18-20 ASQ Education Course. **Design of Experiments.** Las Vegas.

18-20 ASQ Education Course. **Root Cause Analysis.** Las Vegas.

19-20 ASQ Education Course. **Using Control Charts to Interpret Healthcare Data.** Las Vegas.

19-20 ASQ Education Course. **Strategic Quality Planning.** Las Vegas.

23-26 **Software Engineering and Process Group Conference.** San Jose, CA. Call the Software Engineering Institute at 888-201-4479 or visit www.sei.cmu.edu.

24 **Quality Conference of the Carolinas.** Rock Hill, SC. Call the South Carolina Manufacturing Extension Partnership at 803-252-6976 x229 or e-mail btaylor@scmep.org.

25-27 **Black Executive Supply Management Summit.** Orlando, FL. Call the Institute for Supply Management at 800-888-6726 or visit www.ism.ws.

SAVE THE DATE

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YOURQUALITYADVISOR

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.

QP's experts will provide answers and insight to your toughest quality queries. Simply e-mail your situation, question or problem to editor@asq.org, and QP's subject matter experts will offer their sage advice in our Expert Answers department.

Chart Smart

Decipher what the customer is telling you by using control charts

MORE OFTEN than not, a company's phone number and internet address appear on its product to provide consumers an outlet for expressing their opinions and experiences. Unfortunately, customer data obtained through these outlets are typically poor measures of performance.

Factors such as the price of the product, market, type and severity of a defect or consumer preferences and idiosyncrasies result in highly variable results. A torn package for a toy may not warrant a response from the vast majority of consumers and, hence, will go unreported. Some consumers will respond negatively to a product, even though there is no reason to do so, perhaps enticed by a discount coupon for future purchases.

Even though there are many shortcomings associated with using consumer data, with proper analysis, detective work and integration of other sources of information, consumer response data can be translated into a viable story of what the consumer is truly experiencing.

One of the greatest challenges with consumer data is to make sense of it. A company may get thousands upon thousands of phone calls or e-mails each year from consumers. Some companies have complex systems that classify different consumer contacts. A manufacturer of cartons for a consumer product might have categories related to defective packaging, with several subcategories.

Typical summarization schemes usually take the form of standalone statistics, such as a percentage increase or decrease in consumer complaint levels. For instance, a report might state that consumer dissatisfaction for torn handles has increased 50% over the previous month. Such summaries are largely useless because they have no context of variability or indication of what the underlying numbers are.

Chart a course

A particularly useful way to summarize consumer call-in information is the control chart, which can transform data into a time-series graph, along with an estimate of noise. Control charts, largely used in manufacturing, increasingly are finding their way into nontraditional areas as a way to make sense of data. When shown in relation to other pieces of solid information, control charts provide a formidable analysis tool for gauging consumer satisfaction.

A control chart used to summarize consumer complaint data for a packaging company can be found in Online Figure 1 at www.qualityprogress.com. A chart can be easily created in Minitab or Excel using simple control chart formulas found in many statistical textbooks.

In some businesses in which seasonality is a concern or monthly production numbers vary, indexing consumer response helps minimize the effect of seasonal variation. In the packaging company example, the index is the number of complaints per 100,000 packages for a consumer product. Because consumer data is count data, indexing is helpful in creating a more symmetrical data set, which is essential to an individual control chart, especially if accurate inferences are to be made.

In the example, data is plotted for 36 months. Looking at information in the context of history negates the effect of short-term analysis and thinking. Comparing this month's number to last month's number without the context of noise will lead to knee-jerk reactions, finger pointing and wasted effort.

The packaging company notices a drop in consumer complaints in the middle of the chart. Standard control chart analysis reveals this pattern as a process shift. Because correlation does not always imply causality, performing additional detective work and integrating additional pieces of information create a reliable story of what the consumer is experiencing.

An investigation of the shift reveals that it coincided with the introduction of a new supplier that provides paper cartons with enhanced performance characteristics. The company also notices the process shift hasn't been sustained, which would require further analysis to determine the cause. A similar chart can be created for rare-event occurrences, such as safety incidents, based on time between events.

Consumer data can be an effective component in a continuous improvement process when properly applied. By integrating that data and other sources of evidence, a control chart can deliver instant benefits, form a credible picture of what the consumer is experiencing and help untangle many of the complexities associated with field data. QP

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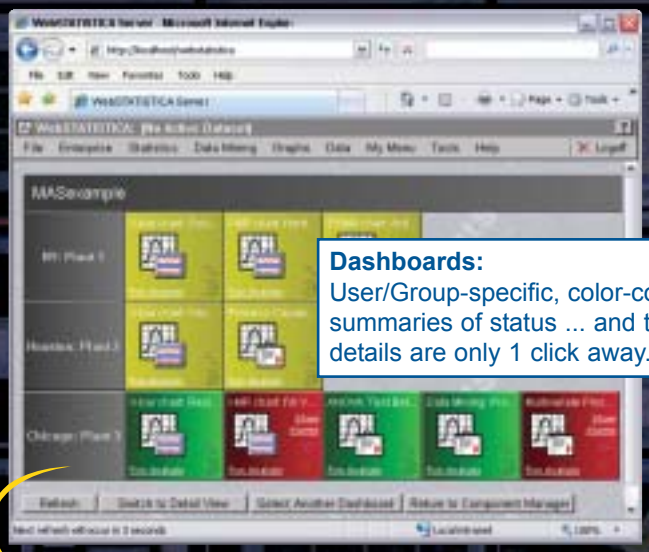

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