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QP
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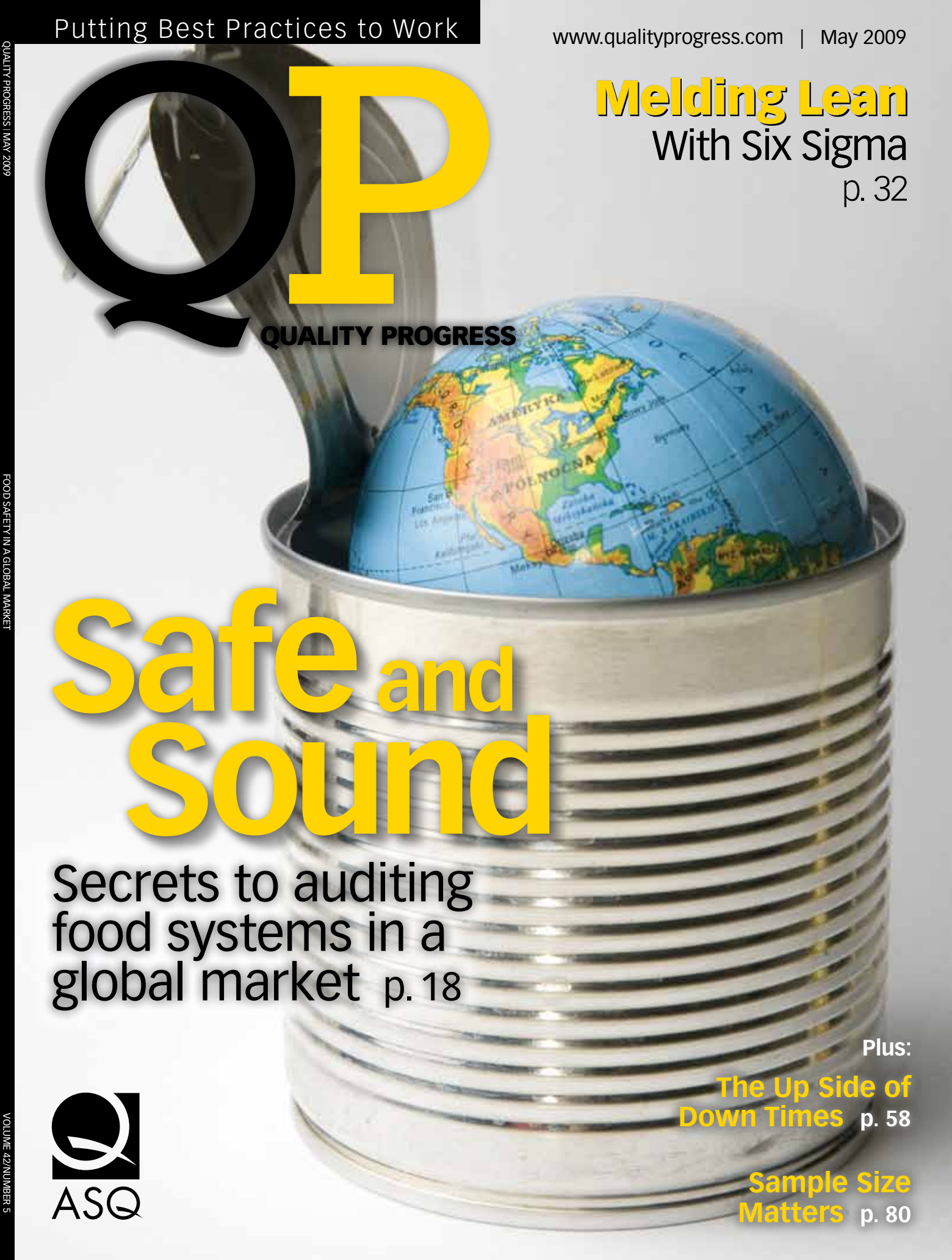

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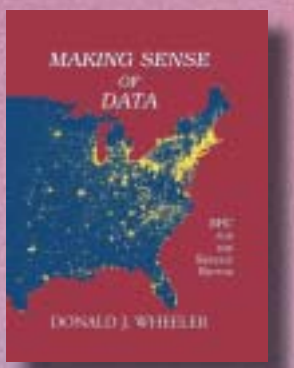

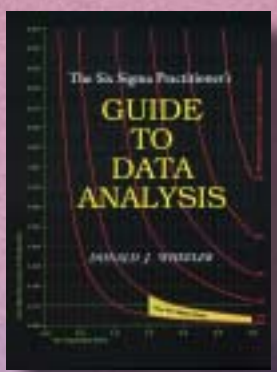

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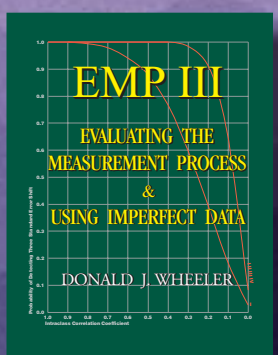

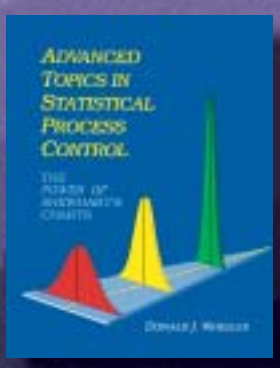

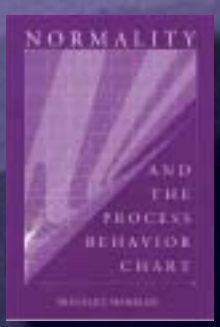

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Brave the New World

Navigating today's social networks

I'VE ATTENDED SOME dud presentations in my day—the kind where you later say to yourself: "I wish there had been more solid ideas I could implement now," or even worse, "That was a serious waste of my time!"

Last month, I got lucky. I attended a session on social networking sponsored by the Society of National Association Publications. I'd been dabbling in it for some time, but I was looking for more ways to leverage QP content in a sea of social network options.

The presenter offered some really good tips, ideas and advice for engaging members in this brave new world of pages, portals and platforms.

As QP (and ASQ) ramps up its virtual presence, I invite you to join me in the various cyber-hotspots.

LinkedIn: Join the *Quality Progress* group to network with other quality professionals, get the latest Quality News Today headlines and interact with editors about hot topics.

Facebook: Become a fan of *Quality Progress* on Facebook. While you're at it, send me a friend request if you'd like (Seiche R Sanders).

Twitter: Follow me on Twitter: ASQ_Seiche.

What's in it for you? That is the million-dollar question when it comes to social media. In short, you get what you put in. Yes, I'm plugging QP on the web, but these networks offer benefits far beyond your favorite magazine.

Not only can you connect to QP, but also to thousands of other quality professionals. These sites offer quick, easy and free methods of connecting with peers and discussing today's hot topics, and they eliminate geographic communication barriers.

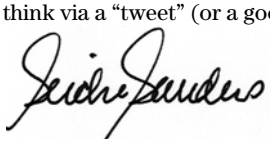
My personal intent in the social media realm is to comment and report on topics and articles making news in the quality world—and spark conversation. Beyond that, I hope you will find these options to be easy ways to communicate your opinions, thoughts and ideas on quality.

I know, based on QP research and general publishing trends, that print media will be around for a long time to come. The web, for now, is a complementary method for connecting with readers and serving their information needs. For you, it provides another convenient option for procuring information and engaging with peers.

QP followers, friends and networks aren't huge—yet—but social media use is growing exponentially (Facebook alone just cracked the 200-million user mark).

The way people communicate is changing. QP is changing, too. As always, please tell me what we could be doing better.

This issue's focus is food safety—a topic on everyone's minds. Let me know what you think via a "tweet" (or a good old-fashioned e-mail will work, too: editor@asq.org). QP



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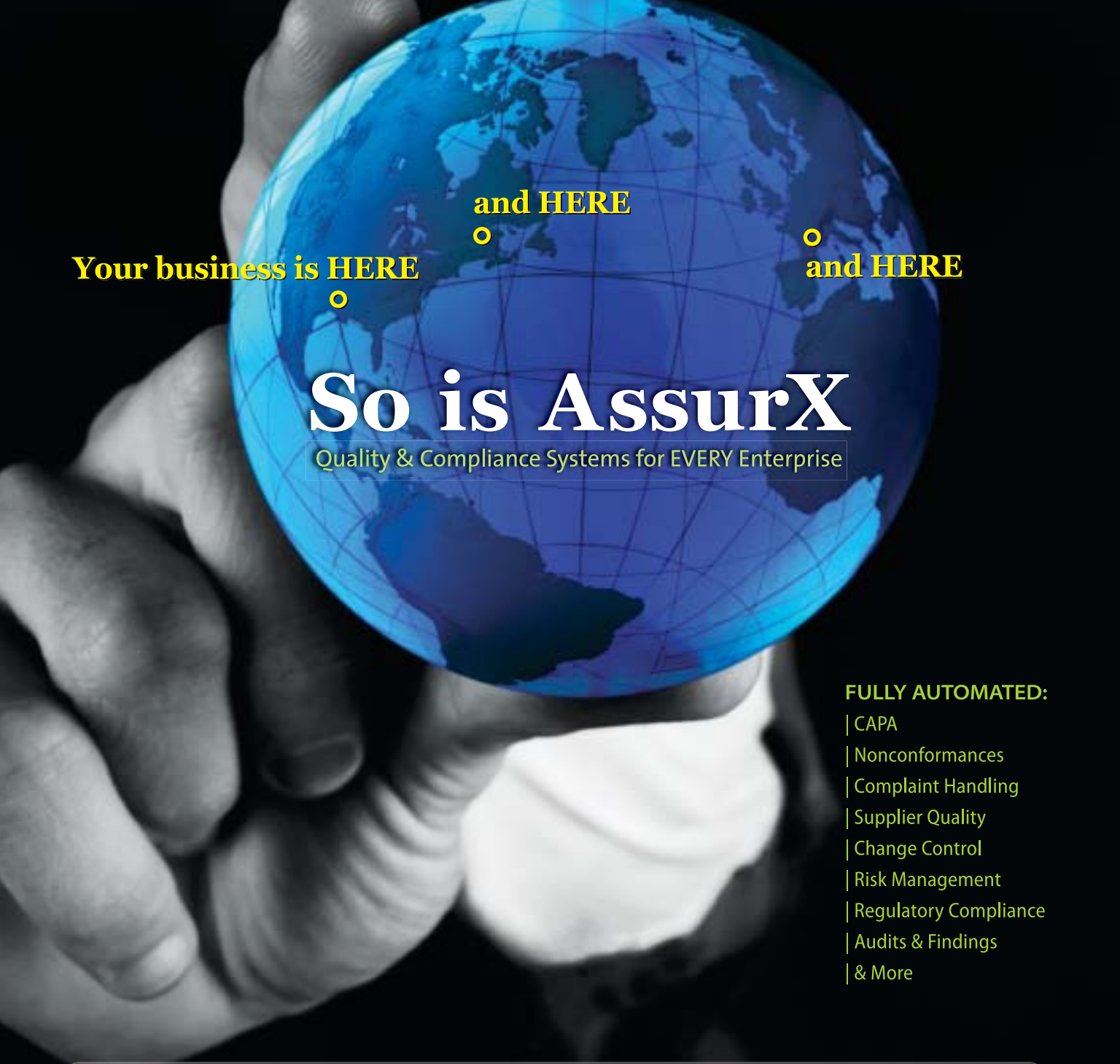

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INBOX

Editor's note: The state of the U.S. economy is on everyone's mind, and QP readers are no exception. Many wrote to us regarding the U.S. government's attempts to right the ship and offered their own ideas for how to keep the economy afloat. A few of those letters are reprinted here, and you can find more at www.qualityprogress.com.

Logical solutions

Rather than making a list of reasons for or against the U.S. stimulus package—now passed and signed into law—time might be better spent on addressing the main issue: What should be done by the federal government regarding the economy?

Is a logical problem-solving process relevant to this main issue somehow? I think it should be discussed. The logic of a problem-solving process, as we in ASQ so often advocate, would at least point out opportunities and pitfalls.

The answer to the question is related to many others our companies face today:

- Should we expand? If so, how can we grow our company?
- Should we expand our offerings of products and services?
- Should we acquire another company to expand?
- Should we go global to reach new markets?

How a company approaches these questions is rooted in the context of company history, company culture, company ethics and values, internal resources, external constraints and many other factors. Some firms are successful, while others are not.

Federal stimulus packages have been tried before, and they have a poor track record. The money for stimulus packages must be taxed out of the economy, borrowed from future taxpayers through government bonds or paid back with inflated dollars caused by expansion of the money supply. All are poor choices. The academic basis for stimulus packages from the federal government is based on Keynesian economics, which is problematic.

Any discussion of potential approaches should ask: What has been tried before in similar circumstances, what has worked before and what has failed before?

There lies the rub. Apparently, the current thinking in Washington, D.C. is that history is irrelevant, this is a new era, and new approaches must be tried without an examination of the lessons of the past. So, the idea of the application of logic to problem solving is, at the moment, politically unfashionable.

Without the application of logic, we are in an environment of experimentation. Unfortunately, history has shown that ill-conceived experiments within a large economy have negative consequences.

Larry G. DeVries
ASQ senior member
Eden Prairie, MN

Spending spree

Although I have been a quality technician for more than three years now, my bachelor's degree is in economics. I have followed President Obama's proposed plan, and I have not been very impressed with it.

When you increase government spending (which the economy doesn't need right now), someone has to pay for it. In this case, the U.S. Treasury Department

can make more money to cover the costs, yet in time the dollar will deflate in value with all this new currency floating around. Plus, I'm sure taxpayers will have to spring for most of this bill, and it does not take a quality assurance tech to realize that raising people's taxes in times like this is not the smartest idea.

The simplest way to get out of this hole is for the U.S. government to decrease government spending and to lower taxes so people can keep more of their money. In the short term, some areas of the economy may not get the money they need, but in time the overall economy will get better.

It has been argued that if President Roosevelt had not offered his own stimulus plan when he did, the Great Depression would not have lasted as long. It makes you think the government should apply some basic quality process control to its decisions.

The best we can do to get out of this mess is to keep our heads up and work hard. In the end, the health of the economy traces its source to the home. This may hurt for a while, but this situation is nothing the United States has not seen before. It's time to suck it up and sacrifice a little bit.

J.D. Horton
Quality technician, GAF
Mt. Vernon, IN

Find the cause

Regarding the stimulus plan, to use quality vernacular, it is only a containment action. Until the root causes of what is clearly a systemic failure are remedied, I question the sustainability of any recovery.

If you think of three well-known entities—AIG, Chrysler and Bank of America—as products (outputs) of the economic system, then you have evidence of three very different—albeit related—products serving different markets or different industries. Yet all are in a failed state.

What does this mean? When products that are outputs of different processes fail, often the causes are systemic in origin. There is ample evidence of a system breakdown in this case, and until the root causes are corrected, countermeasures such as a stimulus plan will be suboptimal at best and will fail outright at worst.

Congress and the Obama administration would be well served to perform some old-fashioned root cause analysis (RCA) and build plans based on those findings. I suspect if they did, they would realize there are ways to broker deals between ailing entities and stronger firms. That way, critical services could continue through the stronger firm, while at the same time the operations of the mismanaged companies could gradually come to an end. This would create a softer landing than just letting them die on the vine and would also leave the companies in the hands of the private sector.

But getting to that point is going to take a lot of intensive RCA, corrective action plans and project management—the likes of which have rarely been seen.

The company I work for—Mid Continent Controls—is a supplier of electrical distribution and controls and cabin management systems for general aviation companies. The stimulus plan will have little bearing on our future. What is more damaging is the characterization of private aviation as a symbol of excess.

General aviation provides good wages and is one of the few remaining industries with a strong U.S. manufacturing base. Admittedly, my opinion is biased, but this industry is an asset, not a liability. Unless we want the same thing to happen to aviation that is currently happening to the automobile industry, it would seem to me that building it up, fostering growth and encouraging innovation would be in everybody's best interest over the long term.

Mike Alumbaugh
Director of operations
Mid Continent Controls
Derby, KS

Ideological differences

The stimulus plan is not a stimulus. It is pork (8,000 earmarks) and payoffs to Obama's contributors and supporters. It is designed to enlarge government and convert our republic to socialism as fast as possible.

The change we got in Washington is ruining this country, and all of my clients are feeling the impact. Many have already laid off at least 20% of their workforce. With Obama's attack against free enterprise, ASQ as an industry group could—and should—make its mark by vocalizing and mobilizing against this attack. We could take a positive, proactive position for free enterprise.

We, as quality-systems experts, understand data, root cause, cause and effect, and corrective and preventive action. We should expose the lack of knowledge of these principles in Washington, D.C.

Debra Mervyn
D.A. Mervyn and Associates
Portland, OR

WE HEAR YOU

Share your thoughts about the U.S. economy, the federal government's efforts to revive it or anything else that might be on your mind by e-mailing editor@asq.org.

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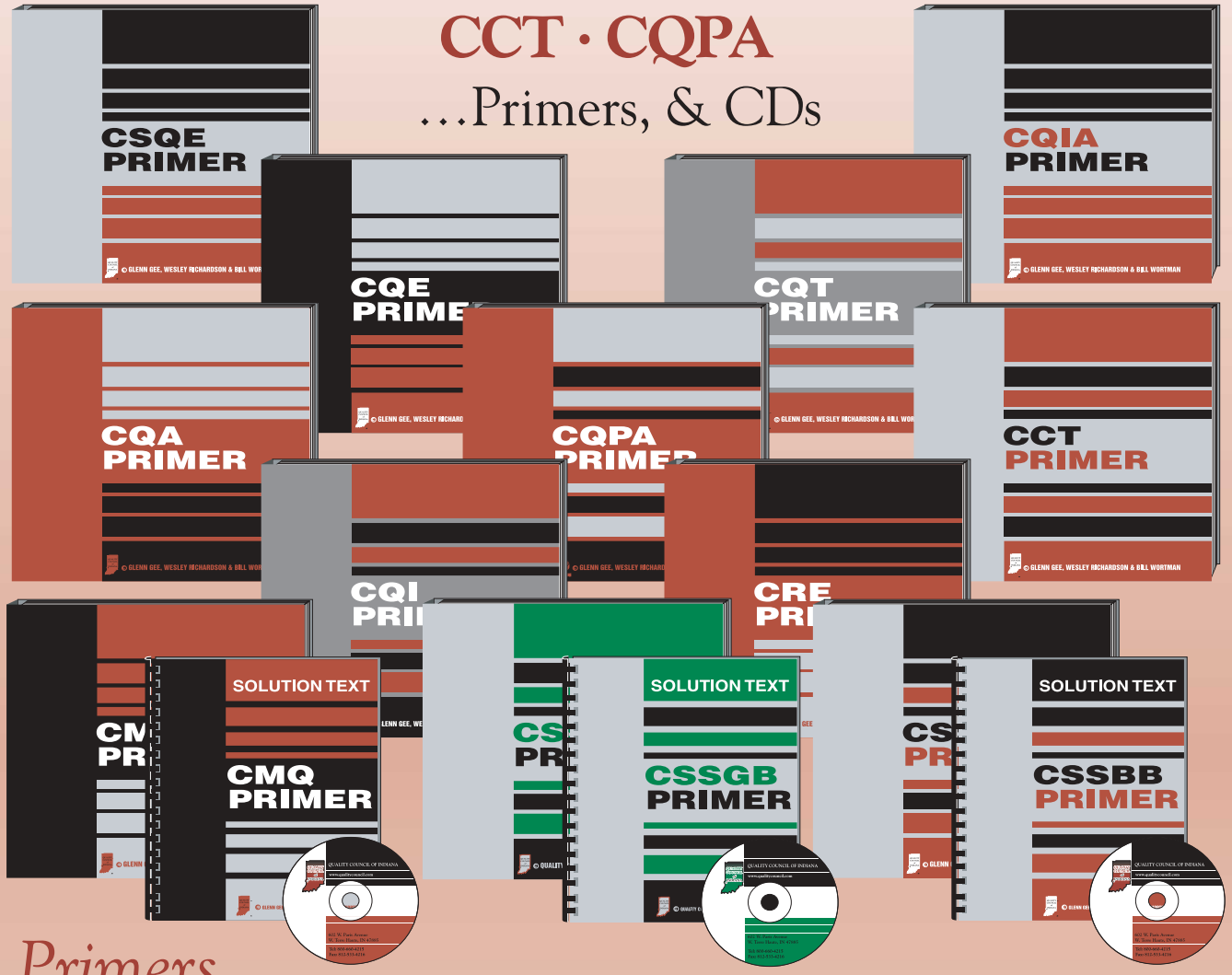

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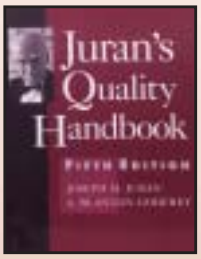

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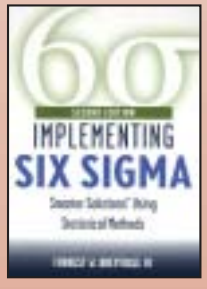

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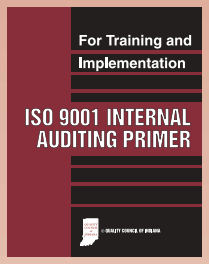

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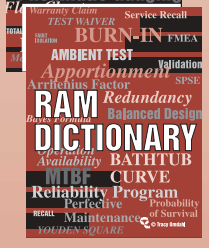

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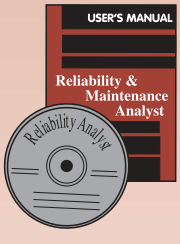

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EXPERTANSWE

Dealing with deviation

Q: We have two sites manufacturing the same product. There is concern, however, that the new site has deviated from the original design intent. What is the best tool or strategy to use to perform a gap assessment of the new site's process to determine whether there is any gap from a design transfer perspective?

John Surfus
San Mateo, CA

A: You have every right to be concerned. Any deviation from the original design intent introduces risk and uncertainty. The original manufacturing site has experience with the process, and it knows how well the product performs in the field.

Will changes to the proven process make the product better, or will they produce unintended consequences? It is very important to proceed with caution, because it is much easier and cheaper to prevent problems than it is to fix them once they are in the field.

The first question to consider is whether the change is with respect to the product design intent or the process design intent. Let's consider the process intent first. The process intent specifies the sequence of operations, the selection of equipment and tooling, the machine settings (such as temperatures and speeds), and procedures for measuring and controlling the process.

Deviations from the approved process (such as faster feed rates) may actually improve productivity and quality. For example, some machining operations can be improved by increasing the speed of the equipment, which reduces tool chatter and results in a smoother finish and less tool wear. If this is the case, the new site should provide detailed evidence showing that the change improves the process. Management can review the evidence and decide whether the expected benefits justify taking a risk.

If possible, the risk should be quantified through a formal risk assessment. One common method of quantifying risk is to create a process failure mode effects analysis (FMEA), which lists potential failure modes. Each failure mode has associated numerical estimates for severity, occurrence and detection. These three numbers are multiplied to create a risk priority number (RPN).

Failure modes with high RPN values should be avoided if possible. If the RPN is low, then the benefit of the proposed change may be worth the risk. The proof is in the results. The new site must provide documented evidence that the output of the revised process meets all of the product requirements. The product requirements always include visual and dimensional specifications but may also include performance criteria, such as corrosion resistance and durability tests.

If the deviation is with respect to the product design intent, then the risk is considerably greater. A product FMEA works the same way as a process FMEA, except that a failure now indicates a design flaw because the product no longer meets the design intent. These flaws can include a feature that does not work or the product wearing out too soon.

Suppose the new site has conducted studies that show its equipment is not capable of meeting the specifications. Management does not want to perform 100% inspection and carry the burden of scrap or rework, so it requests a deviation to widen a particular tolerance. Although this type of request is common and usually harmless, we have all suffered at some point from unintended consequences.

In this case, a formal cross-functional review is needed. Involve personnel from design engineering, quality, reliability and maybe even marketing. Will this change affect performance? Durability? Customer satisfaction? A formal risk assessment is crucial to answering those questions.

Andy Barnett
Consultant/Master Black Belt
Houston

FOR MORE INFORMATION

Borror, Connie M., ed., *The Certified Quality Engineer Handbook*, third edition, ASQ Quality Press, 2009.
Ramu, Govind, "FMEA Minus the Pain," *Quality Progress*, March 2009, pp. 36-42.

Capable approach?

Q: I am an avid reader of QP but was never moved to contact you until I read the article "Calculated Decision" in the January issue (p. 30). The article was very well written—thorough, yet presented in a format that was easy to follow

I have two follow-up questions. The first relates to the choice of using a statistical process control (SPC) chart, which indicated three out-of-control points. These points were convincingly demonstrated by the authors to be false triggers, which were caused by the non-normal process data.

I was thinking an X-bar chart would have been a more robust chart to determine whether the process was in control, because the central limit theorem would apply and would thus provide a robust workaround to handling the non-normal data. Would you agree? If so, what would be an appropriate rule of thumb for an appropriate subgroup size with non-normal data?

My second question is a personal sore point. It relates to the 1.5-sigma shift assumption for short-term versus long-term capability studies. My understanding of the logic behind this assumption is as follows:

RS

It is much easier and cheaper **to prevent problems** than it is to fix them **once they are in the field.**

If you perform a short-term capability study, you can assume the process will be less capable if studied over a longer period, which makes sense. The assumption goes that a 1.5-sigma shift can be assumed.

I can live with that, but my personal issue comes with the application of this 1.5-sigma shift assumption. It appears to me that the application goes the opposite way. For example, a Six Sigma table or calculator might report 3.14 as the sigma value, but I understand that proper application of the 1.5-sigma shift should result in 0.14 being reported as the sigma value.

I favor reporting 1.64 as the sigma value (and therefore reporting no shifting), whether we're talking about a short-term or a long-term study. Can you help provide me with a sanity check?

Andrew McDermott
Lansdale, PA

A: You have some interesting questions. Let's take them one at a time:

First, for the data scenario in the article—and many others—I would not agree with taking subgroups and counting on the central limit theorem to assure the normality of the averages, which would allow the use of a standard X-bar chart.

The reason I disagree is because the samples that constitute a subgroup are assumed to contain only common-cause variation. As a result, the pooled standard deviation from all the subgroups can be assumed to be an estimate of the short-term variability or common-cause variability in the response. These are commonly referred to as rational subgroups.

This is an important assumption about subgroups that allows you to use the pooled standard deviation to estimate the control limits for an effective X-bar chart. These data points are individual readings, with a relatively long time between readings. As a result, we could not assume that five or more samples contained only common-cause variation.

Combining individual data points into subgroups to generate an X-bar chart risks inflating the estimate of the within-subgroup standard deviation, resulting in wide control limits and an ineffective control chart. In a different data scenario in which a sufficient amount of measurements are taken during a relatively short timeframe, simulations have shown that for a subgroup size of five or more, the high rate of false alarms caused by assuming normality for non-normal data decreases to a negligible rate when using the standard X-bar chart calculations. So I would guess that five is the number for which you are looking.

I should warn you, however, about using subgroups of auto-correlated data that are very similar when taken in subgroups over short periods. The variation within the subgroup will be very small, causing tight control limits that result in an X-bar chart with many data points appearing to be out of control.

As for your second question, this is a highly debated topic with several lines of thinking. Here is mine: The logic behind the 1.5-sigma shift is not wrong; it is just confusing in its application.

In your example, I believe the assumption is that the original calculation of defects per million opportunities is from data calculated over the long term. Thus, 1.64 is a long-term capability estimate. Because empirical evidence estimates an additional shift of the mean of approximately 1.5 standard deviations over the long term, and because sigma is supposed to be an estimate of short-term or potential capability, sigma should be 1.64 + 1.5 = 3.14.

So, 3.14 is correct only if you assume the original estimate was arrived at using data taken over the long term, if you agree with the 1.5-sigma shift estimate, and if you understand sigma to be a short-term process capability index. How to incorporate the 1.5-sigma shift in your calculation is confusing, but it does not lack a logical backing.

Louis Johnson
Senior technical trainer, Minitab
State College, PA

FOR MORE INFORMATION

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ASKED AND ANSWERED

Sooner or later, everyone runs into a problem they can't solve alone. Let us help. Submit your question at www.qualityprogress.com, or send it to editor@asq.org, and our subject matter experts will help you find a solution.

CUSTOMER SATISFACTION

Satisfaction Scores Take Off

Airlines, retailers improve performance ratings

After plummeting to all-time low scores in 2007, the nation's largest airlines improved their customer service performances last year in four major categories, according to a high-profile airline quality study.

In 2008, there were more on-time arrivals, and the number of mishandled bags, customer complaints and denied boardings declined, according to the 19th annual Airline Quality Rating report.

One possible reason for the improved performance scores is a decline in system-wide capacity.

"We know the system performs better when it's less stressed by high passenger volume," said Dean Headley, one of the report's authors and an associate professor of marketing at Wichita State University in Kansas. "The economy scared away both business and leisure travelers in 2008."

The challenge for airlines will be to continue to improve on performance scores when the economy recovers and more people start flying again, researchers noted in the study.

The five airlines that scored the highest Airline Quality Ratings were:

1. Hawaiian.
2. AirTran.
3. Jet Blue.
4. Northwest.
5. Alaska.

US Airways was the most improved airline, while United's scores improved the least. The full report can be accessed at http://aqr.aero.

Retailers score high, too

Customer satisfaction for retailers went up last year, according to a recent American Customer Satisfaction Index (ACSI) study.

The overall score for retailers—which includes department and discount stores, supermarkets and gas stations—was up 1.3% to 75.2 on ACSI's 100-point scale. Lower gas prices contributed to consumers' satisfaction with gas stations, which helped push the overall score up. Kohls and Nordstrom led department stores with an ACSI score of 80.

The same ASCI study showed healthcare insurance providers scored a 73, 3% higher than last year's mark, in part because of gains by Blue Cross Blue Shield Association and Wellpoint. Other industries didn't fare as well. Customer satisfaction with banks fell 4% to a score of 75. The ACSI score for e-commerce, which includes online retailers Amazon.com and eBay, fell 2% to 80.

Overall, customer satisfaction with goods and services improved 0.9% to 75.7. That could be encouraging in today's economy, authors of this year's study wrote, because a similar uptick signaled the end of the recession in 2001. The authors cautioned, however, that consumer spending continues to weaken and people seem to be saving more.

Details on the study can be found at www.theacsi.org/index.php.

ELECTIONS

NIST UNVEILS DETAILS OF TESTING ELECTRONIC VOTING SYSTEMS

The National Institute of Standards and Technology (NIST) has opened for public comment detailed new methods for testing electronic voting systems' compliance with voluntary federal standards.

The new tests will replace multiple proprietary laboratory testing techniques with a single transparent set of tests that will help give voters and governments confidence that the systems are reliable, said Lynne Rosenthal, the manager of the NIST voting project. Manufacturers also will have a better understanding of how their systems must perform to comply with federal standards.

To receive federal certification from the U.S. Election Assistance Commission, new voting systems must meet the Voluntary Voting System Guidelines, which call for the testing of electronic voting systems using a prescribed set of test methods. The draft test suites—a series of documents, scripts and software programs—address various aspects of voting systems, such as hardware, usability and security.

NIST requests public comments on the draft by July 1. The new draft tests can be viewed at http://vote.nist.gov/voting-system-test-suites.htm.

FOOD SAFETY

DISCUSSIONS TO OVERHAUL FDA, FOOD-SAFETY SYSTEM BEGIN

In recent weeks, legislators in Washington, D.C., began to wrestle with different bills that address the way the Food and Drug Administration (FDA) operates and handles the U.S. food-safety system.

Some have suggested the FDA be split into two separate agencies: one with oversight over food regulation and the other to regulate drug safety and medical devices.[1]

Some contend the FDA is simply stretched too thin to regulate food properly. The agency partners with some state inspectors to oversee food processors, but with 44,000 plants under the FDA's jurisdiction, many are never checked.[2]

Others think the FDA should move away from all food-related activities. They believe inspections and testing should be shifted to a new Food Safety Administration under the Department of Health and Human Services.[3]

The food-safety system and the FDA's credibility have been damaged by recent high-profile events and recalls, including the salmonella outbreak involving peanuts that has killed nine people and sickened hundreds since September, as well as the recent pistachio recalls.

To address food-safety concerns and to build confidence in the system, perhaps a new and improved FDA is inevitable. ANSI-ASQ National Accreditation Board (ACLASS and ANAB brands) contends more needs to happen besides changing the organizational structure of the regulatory agency or shifting inspection responsibilities to others. Government must stress the importance of third-party accreditation, using third-party conformity assessment standards for those that touch the inspection process in order to support regulator activities in food safety, the board says.

In other words, auditors, inspectors, laboratories, manufacturers, growers or others with a role in the food-safety process must meet certain requirements and prove they are competent to perform a specific function.

"It is our belief that to truly have an effective food-safety system in the United States, we must have a level of oversight that works in partnership with U.S. regulators that provides confidence in the entire life cycle of the product," Keith Greenaway, ACLASS vice president, said in a prepared statement.

"Third-party accreditation consistently helps to provide for products, services and test results that meet or exceed customer or statutory requirements," he said.

The ANSI-ASQ National Accreditation Board said it would like to see third-party conformity assessment programs used for laboratory accreditation, food-safety management systems accreditation, product certification, personnel certification and inspection body accreditation. ASQ is also partnering with the ANSI-ASQ National Accreditation Board to convince legislators to include those provisions in the bills being discussed.

To offer insight or opinion on the topic, visit ASQ's food quality discussion board at www.asq.org/discussionBoards/forum.jspa?forumID=69 (case sensitive). More information about third-party accreditation is available at www.aclasscorp.com and www.anab.org.

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TOY SAFETY

ASTM TOY STANDARD ADDRESSES MAGNETS

ASTM International Committee F15 on Consumer Products has approved revisions to ASTM F963, Consumer Safety Specification for Toy Safety. Changes to the standard include revisions to the section on ingestion of magnetic components in toys.

ASTM F963 includes guidelines and test methods to prevent injuries from choking, sharp edges and other potential hazards. Revisions dealing with magnets account for incidents of ingestion of magnetic components that are small parts of a toy and reflect the age of children involved in the incidents.

The section on magnets now also includes special use and abuse requirements to prevent magnets from detaching from components during play.

For more information, go to www.astm.org.

Who's Who in Q

NAME: Jane Hoying.

RESIDENCE: Bay City, MI.

EDUCATION: Bachelor's degree in chemical engineering from the University of Dayton in Ohio.

CURRENT JOB: Manager at Shainin, an international consulting firm that specializes in problem solving and prevention.

PREVIOUS JOBS IN QUALITY: Hoying's first job was as a quality engineer responsible for a federally regulated safety product. There, problems had to be solved and every decision had to be sound. In many ways, she has continued to function as a quality engineer in every job since then as she advanced through positions in quality systems; process, manufacturing and industrial engineering; product design; first-line supervision; general supervision; engineering management; and problem-solving coordination.

INTRODUCTION TO QUALITY: Her mother's pearl of wisdom was "Anything worth doing is worth doing well or not at all." Hoying and her siblings were never chastised for poor performance. Her parents would simply ask, "Was that the best you could do?" The unspoken answer to that question corrected behavior and instilled the concept that high-quality results come from high-quality effort.

ASQ ACTIVITIES: Involved in Improving Performance in Practice, an ASQ/Automotive Industry Action Group medical community initiative to improve healthcare delivery.

OTHER ACTIVITIES/ACHIEVEMENTS: Saved clients tens of millions of dollars by developing a new problem-solving method to address complex problems thought to be unsolvable.

RECENT HONOR: ASQ Dorian Shainin Medal for Innovation in Problem Solving.

FAVORITE WAYS TO RELAX: Participant in competitive figure skating, home renovation, and fiber and textile design.

QUALITY QUOTE: Solving complex business or technical problems requires shifting your paradigm from a process-sequence perspective to a function-based perspective. Looking at how something fails to function distills a problem down to its bare essence, enabling complex interrelationships to be uncovered.

ASQNEWS

MEMBERS RECOGNIZED At the recent meeting for the U.S. technical advisory group to ISO/technical committee 176 in Dallas, several ASQ members received awards for their volunteer achievements. Those individuals recognized included: Buddy Cressionnie and Bill Brow with Unsung Hero Awards; Craig Johnson and Lawrence Wilson with Honorary Lifetime Membership Awards; and Baskar Kotte with the Outstanding Professional Achievement Award.

LEARN AND LEAD School superintendents are invited to attend ASQ's Educational Leadership Summit on June 18 and 19 in Fort Myers, FL. Educational leaders from throughout the country are scheduled to attend and share best practices from their school districts. Visit http://leadership.asq.org for more details.

STATE OF THE SOCIETY REPORT This year's State of the Society report, "Quality Now More Than Ever," is now available for viewing online. Visit the ASQ News section of the Media Room at www.asq.org/media-room/news/2009/index.html.

ONLINEONPAPER

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:

"What is most important when it comes to securing lasting change in an organization?"

- Committed leadership 63.2%
- The right people to drive the change 18.7%
- Workforce buy-in 14.8%
- Adequate resources 3.2%

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

"Whom do you think should shoulder most of the blame for the recent food-safety crises?"

- Growers and manufacturers
- State and federal regulators
- Third-party auditors
- Foreign suppliers

Mr. Pareto Head

BY MIKE CROSSEN

DATEINQUALITYHISTORY

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

May 16, 1924

Walter A. Shewhart mentioned a schematic control chart in a memo to his superiors at a Bell Laboratories factory in Cicero, IL. This was the first time control charts were ever talked about. The historic document was less than a full page and included the first sketch of a control chart, which has become an essential concept behind statistical process control.

SHEWHART

"That diagram, and the short text which preceded and followed it, set forth all of the essential principles and considerations which are involved in what we know today as process quality control," wrote Shewhart's superior, George D. Edwards, Bell's director of quality assurance at the time.

Shewhart, later called the father of statistical quality control, became a founding member of ASQ and the first honorary member. Edwards was the first president of ASQ from 1946-48.

Source: ASQ, www.asq.org/about-asq/who-we-are/bio_shewhart.html.

ASQ STUDY

HEALTHCARE CATCHES ON TO LEAN, SIX SIGMA

Many healthcare systems are still in the infancy stage of using lean and Six Sigma as cost-cutting methods, a recent ASQ benchmarking study revealed.

The ASQ Hospital Survey is the first study that looks at the implementation of lean and Six Sigma in U.S. hospitals. Seventy-seven hospitals participated in the online survey.

"During these turbulent economic times when healthcare costs continue to rise, it is crucial that U.S. hospitals look to methods like lean and Six Sigma to become more efficient," said James Levett, M.D., chair of ASQ's Healthcare Division and chief medical officer for the Physician's Clinic of Iowa in Cedar Rapids. The survey revealed:

- 53% of hospitals use some form of lean.
- 4% of hospitals have fully deployed lean.
- 42% of hospitals use some form of Six Sigma.
- 8% of hospitals have fully deployed Six Sigma.
- 11% of hospitals are not familiar with lean or Six Sigma.

Details of the survey can be found at www.asq.org/media-room/press-releases/2009/20090318-hospitals-see-benefits-lss.html.

Correction

In the March Career Corner column ("Make Your Own Luck," p. 55), QP incorrectly reproduced the author's original drawing (Figure 2). The correct figure would have shown cascading plan-do-study-act cycles within a true Fibonacci Spiral (see correct version at www.qualityprogress.com). The version that appeared showed a linear progression within an Archimedes Spiral.


AMERYKA
POŁNOCNA

Can Do

An effective **overseas food-safety audit** is possible—if you know what to expect

by Steven Wilson

In 50 Words Or Less

- The challenges inherent in food-safety audits become more problematic when foreign suppliers are targeted.
- Language and social barriers, as well as varying compliance requirements, are the biggest hurdles.
- With a careful plan and an emphasis on keeping things simple, auditors can overcome the challenges.

CONSUMERS HAVE BECOME increasingly wary of food safety, and for good reason. In the United States, the latest debacle involving the Peanut Corp. of America led to thousands of recalled products from hundreds of companies.[1] In China, melamine-tainted dairy products resulted in the deaths of six infants and sickened 300,000 more.[2] And, as of March, Canadian confidence in food safety remained low six months after the Listeria outbreak caused by tainted meats from Maple Leaf Foods.[3]

When it comes to imported foods, safety concerns are heightened, because there is even less involvement by evaluators in the processing activity, and regulators must rely more heavily on end-product inspection. This brings the effectiveness of auditors into question. As a result, auditors—private or government—must be even more diligent in performing their duties to ease the anxiety of consumers.

RECENT SCANDALS, such as the melamine scare that led supermarket workers to pull milk and other dairy products from shelves across China, have thrown the spotlight on the importance of effective food-safety audits.

Executing a food-systems audit, as with audits in any industry, brings with it a series of specific issues to consider. When performing an audit in a country that is not their own, however, auditors face additional challenges. With proper planning, those challenges can be overcome.

Have a plan

A strong audit plan is necessary in any situation. But it is especially important when auditors perform inspections outside their countries of origin. A strong audit plan allows the auditor to be flexible when encountering the unexpected—a normal occurrence in foreign countries. In these situations, the auditor will have to deal with transportation difficulties, language and social barriers, and differences in interpretation related to standards and regulations.

Right away, it is important to address misconceptions associated with overseas food systems that export goods. Most firms that export to other countries are frequently audited by other firms, as well as governments. As a result, the organizations make a strong commitment to compliance with standards and regulations, and they perform their due diligence in the production of their goods.

Many firms also implement and are registered to ISO 22000 (food-safety management) and ISO 9001 (quality management). In that case, an auditor probably won't find many issues with the hygiene of the operation, and the firm's management will be highly cooperative. In other words, the vast majority of the firms sending their products to other countries work diligently to offer a safe product.

HACCP and quality systems

One of the steps firms take to ensure a safe product is establishing a hazard analysis and critical control point (HACCP) plan. When evaluating those plans, the auditor may notice a cookie-cutter approach was employed, which means many of the plans will appear to be the same. This isn't necessarily a problem. In fact, many regulators encourage such templates, because it makes the job of auditing and evaluating much easier.

But not all facilities have exactly the same products or processes. Therefore, the hazards the facilities encounter may not be the same. But, because of the drive to have a complying plan on file, an issue can emerge: It is possible the firm did not perform a hazard analysis and therefore was not completely aware of the possible hazards that accompany its plan.

While many food-safety plans may be similar to one another in a template environment, they often are filled with an amount of information that is so overwhelming, it actually contributes to a systems failure. To put it simply, the system can collapse under its own weight.

A strong audit plan allows the auditor to be flexible when encountering **the unexpected.**

This failure is caused by extreme record-keeping practices, with the mentality that more information about the system is better. Because so much data is recorded and so many documents and records are in place, it is difficult for auditors (internal or external) to evaluate the success of the system. This volume of information also serves to keep auditors at the facility longer, frustrating and exasperating them, and waylaying the day-to-day operations of the firm's management.

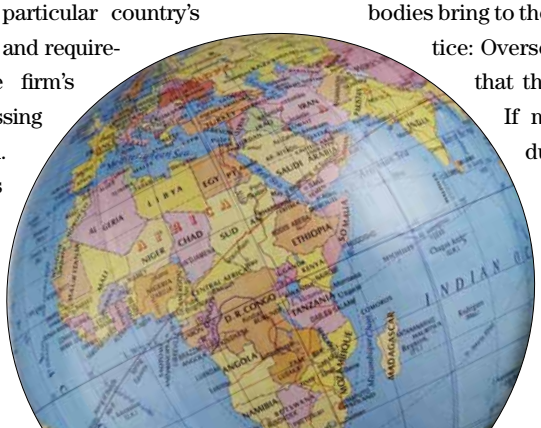
Because of the overabundance of records on file, the absence of some information isn't noticed. Incomplete information may then be recorded, which will lead to system failure.

Auditors must focus on gathering only the necessary information about HACCP and quality-system plans. When auditing facilities, the goal should be to get that information, determine compliance and identify what significant issues are present. Auditors often focus on an area of the plan that is troublesome but, upon further investigation, is a portion of the plan that didn't really affect the audit. Reducing the plan's scope makes it easier to implement and follow by the firm.

Stay up to date

Even with a well-thought-out plan in place, it is not unusual for certain hazards to be a countrywide problem. Often, this is due to the national regulatory authority's interpretation of the guidelines provided or conflict between the guidelines of differing importing countries. Although this issue is easily corrected, it can lead to other concerns regarding government requirements.

For example, many exporting facilities sell to buyers in several countries. This may result in a lack of full understanding of a particular country's regulatory guidelines and requirements, because the firm's management is missing the latest information.



As the internet has made more information easily available, people assume others have ready access to that information. This is not always the case. And even when the information is readily available, internet access is often not sufficient to download large files. In addition, many regulatory websites are difficult to navigate or offer only the order forms to obtain the necessary information. In both instances, the applicable information is difficult to obtain as a result.

Even when a firm is able to gather the requisite information, interpreting the requirements is often a problem. During one recent visit to an Asian country, for example, an inspector from an important regulatory authority indicated there was insufficient hot water in several of the facilities. The inspector provided the national authority with recommendations regarding proper water temperature. The national authority promptly declared this was the law of the foreign authority and referenced the information. It further insisted that all facilities install hot-water heaters to comply with this new law.

The only problem was that, in the end, the water got so hot that employees could not keep their hands under the water long enough to wash them. As a result, hand washing was listed as a deficiency more often than before, which opened the door to more instances of cross contamination. It was an unnecessary expense, and it only served to make the problem worse.

Under the influence

The differing opinions among individual regulating bodies bring to the forefront another problematic practice: Overseas firms are so desperate to comply that the regulator's word becomes gospel. If more than one regulator is present during an audit, chest-thumping often occurs to the point at which insignificant issues begin to appear critical.

The firm is so eager to sell its product that it will do anything to make the auditor happy. Often, the auditee is so eager to comply that the auditor does not have time to leave the facility before construction begins.

In one instance, a firm constructed an elaborate employee entrance that included three different foot baths 10 feet in length, an S-shaped hallway, strip curtains at each turn of the hall, self-closing doors with air curtains at each end, black paint on the walls and one insect destruction device at each turn. This overhaul was recommended by a particular auditor because a single fly had been observed in the facility.

Auditors must exercise caution with regard to issuing recommendations, because the word of the auditor is law to many facilities. The auditor needs to ask, "Is what I want a requirement or merely my idea of the perfect plant? Am I frustrated they are not heeding my advice? What is minimally necessary to comply with the regulations that concern my agency or company? Is this beyond the scope of the audit?" These questions have particular importance when auditing systems in other countries.

Talking points

Getting to the point at which an auditor's recommendations are misconstrued can be a challenge due to language and culture barriers. In most countries, English is spoken well enough that communication isn't a significant barrier. When determining compliance of a facility, however, extreme care must be exercised before a conclusion is reached.

For example, if an auditor traveled to Asia to evaluate sanitation in a seafood facility, he or she might find the employee restrooms do not have toilet paper. Instead, the auditor discovers a water source within reach—either a faucet, water well or even a bucket—that is the typical method of employee sanitation after using the restroom.

It is unusual to auditors from the United States, but as long as the employee properly washes and sanitizes his or her hands prior to entering the workplace, they have met the requirement. It is not unusual, however, for auditors to list a deficiency for lack of toilet supplies in the restrooms.

SOMETHING TO CHEW ON

If you think there are other crucial elements to be considered when performing a food-safety audit, share them with us. Just log on to www.qualityprogress.com and use the comment feature on this article's page.

Interviewing plant personnel in such instances may also be difficult. Even though the official the auditor is talking to may speak English, he or she still might not understand the question. This can lead to the listener drawing erroneous conclusions.

In one instance, while interviewing plant officials regarding the frequency of histamine analysis, the statements provided by the auditee did not match the records. The auditor was convinced the management official was lying. But careful questioning about the issue revealed that the official was answering yes when he was confused by the question. It was apparent (and this is common) that the auditee was not actually answering the question when he said yes or no. Instead, he was acknowledging that the auditor was speaking and that he heard the question.

Managing expectations

First and foremost, management must be held responsible for the system implemented in their facility. That sounds obvious, but the evidence indicates that many auditors tend to shy away from evaluating management and instead concentrate on issues such as sanitation deficiencies. If management should have caught the situation, it must be noted in the report.

It is not unusual for a senior management official—often the plant manager—to accompany the audit team throughout the audit. In some cases—again, because of the eagerness to please—this same official will act as taxi driver and will be at the airport to pick up the team and will return them there upon completion of the audit.

There is no loss for that kind of attention during the audit. But question managers about verification procedures or the general food system, and in many cases the auditor will encounter confusion from key management personnel who should know of the system. It's possible the verification system was not implemented correctly, but management didn't notice because the labor force is easy to influence.

Some firms have approximately 20,000 employees, all of whom fear losing their jobs. Therefore, auditors will see a strong motivation to follow instructions, even if those instructions are incorrect. In that case, if proper verifications are not in place and followed, employees can send the system off track. This is why management involvement is crucial.

Because it is common for employees to perform their duties as instructed with little to no variation,

The performance of auditors is being **called into question**, and the public is growing suspicious **of the entire profession.**

the "more is better" philosophy comes into play. In this situation, employees will go overboard to accomplish their assigned tasks. For instance, while the requirement for the concentration of chlorine in a hand dip is listed as 50 parts per million (ppm), the actual concentration might be closer to 200 ppm. While well intentioned, this is the type of employee error that occurs often if there is not diligent supervision.

Lowballing high tech

Even the best supervision, however, can't overcome a situation in which the firm relies on employees to keep records and perform redundant tasks. Strangely enough, in an environment in which the firm will pay extreme prices for unnecessary construction, it won't consider spending money on devices that will keep better records than an employee can.

For example, when inspecting a firm that stores fresh product in a tropical environment, an auditor might discover the coolers are not performing up to standards. Evaluating the records taken by employees and verifying the equipment may not indicate any significant issues. If the firm had purchased a simple digital thermometer, however, the data collected could illustrate an issue such as a faulty defrost cycle.

A variety of equally simple tools are available, including protein swabs for residue evaluation, microbial swab kits that can be incubated at room temperature to determine the sanitary nature of surfaces and analytical screening methods that can verify cleaning and processing procedures.

Overcoming suspicions

There is an increasing concern regarding the safety of the food supply. As a result, the performance of auditors is being called into question, and companies and the general public are growing suspicious of the entire profession. That groundswell of skepticism can be combatted, however. Perhaps the most effective way to do that is through certification and training.

HACCP and quality systems are well defined in nearly every country, and training in those areas is more frequent in recent years. In addition, many countries with emerging economies have developed hazard guides to streamline the hazard analysis process, and most industry and government personnel are well trained in HACCP principles. But this is not enough to ensure proper implementation of HACCP and quality systems.

Technical information is abundant, and many personnel can recite precise quotes about that information. But those same people may find it difficult to put that knowledge into play during an audit and, as a result, can't differentiate between minor and significant issues. This leads to more confusion with regard to compliance with the buyers' requirements.

Certification of auditors—private and government—should be emphasized. With certification comes a common language and sharper skills. Once those are in place, a better understanding of differing requirements will be possible. The proper differentiation between minor and significant issues will also become the norm, and the audit process will continue to improve. The result will be more support of partnerships between industry and government, and—most importantly—better quality food in the marketplace. QP

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STEVEN WILSON is chief quality officer of the U.S. Department of Commerce Seafood Inspection Program. He has a bachelor's degree in food science from Kansas State University and is completing his doctorate in food technology from Clemson University in South Carolina. Wilson is a member of ASQ, serves on the ASQ board of directors and is an ASQ-certified quality auditor, HACCP auditor and quality manager. He is the coeditor of The Certified HACCP Auditor Handbook.

A Lean Six Sigma BREAKTH

by Gary G. Jing

In 50 Words Or Less

- There are many workable ways to integrate lean and Six Sigma.
- While many of the methods are effective, they all have deficiencies.
- Comparing the two methods yields a comprehensive integration model that leverages the advantages of each.

ROUGH

Tiered, mutually exclusive approach gets more from each method

THE RELATIONSHIP between lean and Six Sigma has been a popular topic at major Six Sigma conferences and the subject of many books and articles.[1-7] This relationship may appear to be simple, but in practice it can be more challenging because there are so many ways to piece the two together.

Most of the time, people are exposed only to subsets of the two disciplines. From these subsets, the various perspectives on how to best integrate lean and Six Sigma reflect the unique characteristics of the method with which the practitioner is most familiar.

Interestingly, most of these integration models work even though they are always accompanied by various types of deficiencies. The success and efficiency of these models are highly dependent on many confounding factors that make independent evaluation of their relative merits difficult.

A collaborative and comprehensive comparison of the two programs at the nuts-and-bolts level will allow potential users to build their own customized integration perspective with the big picture in mind.

Terminology

Lean and Six Sigma convey a wide scope of meanings. People use them vaguely with different contents in mind, depending on the context. Lean and Six Sigma can refer to initiatives, programs, processes, systems, methods, tools or simply activities. Figure 1 shows the definitions of the terms lean, Six Sigma and lean Six Sigma (or lean sigma).

Online Figure 1 at www.qualityprogress.com shows how the world is viewed from a lean perspective. There are eight main wastes and six main losses, most negatively impacting two major competing business metrics: lead time and inventory. Online Figure 2 shows the main components of lean and one way to integrate them: the house of lean.

A Six Sigma viewpoint is different, coming from a perspective of defects. There are three major levels of meaning associated with the term Six Sigma:

1. As a statistical term and business metric.
2. As a business strategy and initiative.
3. As a problem solving and prevention system and a method called define, measure, analyze, improve and control (DMAIC).

Online Figure 3 shows a descriptive roadmap for the DMAIC problem solving approach. Online Figure 4 shows a pictorial view of the same method.

Comparison

Table 1 is a comprehensive comparison of lean and Six Sigma at the nuts-and-bolts level. As shown in the table, the relationship between lean and Six Sigma varies from complementary to confrontational, depending on what aspect is looked at. To avoid the bias from a partial view, I have made an effort to incorporate all comparison aspects I can find in the public domain, represented by books and articles in references noted earlier. One intent of this comparison is to provide an opportunity to see the bigger picture, although each individual only experiences part of it.

As shown, lean emphasizes more of the intuitive initial steps that everyone can apply in an improvement effort. Six Sigma emphasizes more comprehensive second-level, in-depth analyses that not everyone is capable of doing. Each method is more efficient in different areas.

Alone, each can achieve similar results at degraded efficiency. Combined, they may leverage each other, potentially producing more efficiency and effectiveness. Ideally, practitioners should learn both.

Integration formats

So, between event and project, which format is better? This is an important differentiator between lean and Six Sigma, and the answer to this question is tied to how resources are allocated.

Whether the team leader (or belt) and team members are available full or part time will dictate the format. When both are full time, it's essentially an event format, which usually needs to be wrapped up in days. When only the team leader is full time, it's a tightly controlled project. When all are part time, it's a loosely controlled project, which usually takes longer to complete.

Based on my observations, a monthlong project usually consumes no more resource hours than a weeklong event. Comparatively, the event format can be more efficient. The total resource-hour consumption remains the same, but the cycle time is much shorter. Additional advantages of a weeklong event format include increased group synergy and management attention.

The downside is that, due to the short timeframe,

Defining lean and Six Sigma / FIGURE 1

Lean program:
An improvement approach aimed primarily at improving efficiency by removing wastes

Six Sigma program:
An improvement approach aimed primarily at improving process capability by reducing variation

Lean Six Sigma program:
An improvement program or approach aimed at combining both lean and Six Sigma to improve efficiency and capability primarily by removing wastes and variation

Comparison between lean and Six Sigma / TABLE 1

Differentiation	Lean	Six Sigma
Primary interest	Remove waste.	Reduce variation.
Way they look at the world	Flow and waste.	Problem and detection.
Primary effect	Reduce waste and smooth flow.	Reduce defects by reducing variation.
Secondary effects	Less inventory, fast throughput, better performance, more uniform output, less variation and improved quality.	Improved quality, better performance, less waste, less inventory, fast throughput and uniform process output.
Format	Typically *kaizen* event format; concentrated resources in short timeframe; best for quick and initial gain.	Project format; resources spread over months; suitable for long-term and in-depth study.
Approach	Has selected sets of solutions for selected sets of situations: for example, 5S, visual control, setup reduction, lead time reduction.	All inclusive, generic approach to define, measure, analyze, improve and control; one size fits all.
Efficiency	More efficient in selected sets of situations.	Allows more thorough study and more science, but not as efficient in selected applications.
Limitation	Statistical data analysis not emphasized; relies more on intuition and common sense.	System view limited; may overspend when problems and solutions are simple and apparent.
Signature characteristics	Small, quick, easy and intuitive improvements frequently occur over time; everyone can do it.	Bigger, sophisticated solutions infrequently occur over long-term; star performer, not everyone can do it.
Technical difficulty	Focus on grass-roots, on the spot (*gemba*) and operator level activities and ownership.	Need some science.
Level of competency	Low (for every one).	High (not for everyone).
Tools	Six Sigma tools ~ lean tools + statistics.	

there is no time for in-depth or long-term studies. Certain activities, including data collection, tool preparation and once-a-month type transactions, may inherently require long cycle times. Because it can be difficult to get all needed resources together for an extended period of time, the project format is potentially more flexible and accommodating—but with reduced team synergy. Projects with a part-time team leader tend to take an even longer time.

Because there are advantages and disadvantages to each, it's better to have both formats available to accommodate different needs.

What about the workforce structure? Is it better to retain one workforce group to learn and apply lean and Six Sigma, or to keep a separate group for each? Because the expertise is in tiers, it may be more cost effective to structure the workforce in tiers.

In general, it's easier for Six Sigma practitioners to pick up lean than for lean practitioners to learn Six Sigma. One reason is that many good lean facilitators are starting from the associate degree level.

Some people use the expression a "one-two punch" to describe the lean-Six Sigma relationship[8]—this reflects the tier mentality. I promote the tiered structure

Proposed tiers in a lean Six Sigma career / TABLE 2

Career	Training: Lean facilitator	Lean master	Green Belt	Black Belt	Master Black Belt	
Lean facilitator	X					Equivalent level
Green Belt			X			
Lean Master		X	X			Equivalent level
Black Belt	X			X		
Master Black Belt		X		X	X	

shown in Table 2 for lean Six Sigma career development to maintain two separate but mutually inclusive tracks.

Lean facilitators and Green Belts (GB) are set at an equivalent level, as are lean masters and Black Belts (BB). I prefer to set a higher expectation for BBs to include some lean training.

It is certainly good if an organization can afford to bring everyone to the BB level. But if resources are constrained, it may be more cost effective to maintain a tiered workforce.

Table 3 shows various ways to differentiate, select and integrate lean and Six Sigma approaches. Usually, one or a combination of the criteria from Table 3 is used to decide a course.

The distinctions get blurred after reaching a certain depth because most process improvements can be achieved through either a lean or Six Sigma approach or many other approaches. Often, the decision depends on who is making the improvement and which approach he or she is most familiar with.

To understand this last statement requires some discussion of the meaning of the "best tool." Many people don't realize it is a relative expression. There is no best tool in the absolute sense. For a specific individual, the best tool is the tool with which he or she has the most proficiency.

It's often observed that different projects performed by the same belt have the same or similar structure, sequence and tool applications. People have the tendency to first use what they are most familiar with. Also, when someone is proficient with a tool, he or she may be able to use it far beyond what it was originally designed for.

For example, the theory of constraints (TOC) and failure mode effects analysis (FMEA) are considered part of the optional Six Sigma toolset. Yet, William Dettmer, who wrote several books on TOC, teaches classes on its use as a standalone framework, equivalent to DMAIC, to solve problems.

Some people consider FMEA to be one of the few key Six Sigma tools, while most practitioners treat it as just another choice among many. I've seen some FMEA experts rely solely on FMEA as a standalone framework to identify root causes and drive solutions for problems that can be handled as Six Sigma projects.

Some joke that when the only tool available (or the one they are most proficient with) is a hammer, everything becomes a nail. Interestingly, most of the time, this mentality works. You can insert a screw with a hammer, but it's not as efficient and effective as using a screwdriver.

If a problem is handled by a person who is more familiar with lean, he or she is more likely to take a lean approach. The same is true for Six Sigma.

So what kind of program structure with respect to lean and Six Sigma will potentially be more efficient overall? Is it preferable to choose one or the other, to use both while keeping them separate, or to combine them into a third form (lean Six Sigma or lean sigma)? I've seen them all used.

Two examples of the first structure where they are kept separate are a company called Heat & Hearth and its exclusive undertaking of lean, and Toyota's use of the Toyota Production System.

Some companies, such as Seagate Technology, do both lean and Six Sigma at a particular stage but keep them separate. Some companies loosely connect them at the project selection level.

Others more closely combine them but often end up incorporating one into another, with the hybrid form

Tier-based improvement activity integration model / TABLE 3

Choose approach	Lean (*kaizen*)	Six Sigma
By size	Small or tactical projects (< 1 month). The first step in improvement. The first punch.	Large or strategic projects (> 1 month). The second step in improvement. The second punch.
By timeframe (to solve)	Weeks	Months
By format	Full-time dedicated team—event	Part-time dedicated team—project
By nature	Time reduction and waste	Process variation
By the doer	Lean practitioner	Six Sigma practitioner

Most people differentiate by one or a combination of them.

In general, it's easier for **Six Sigma practitioners** to pick up lean than for **lean practitioners** to learn Six Sigma.

carrying the flavor of their original improvement initiative. Examples are lean for TBM, a consulting firm, and Six Sigma for Seagate.

What's interesting is that while all of these approaches have worked, they always are accompanied by various types of deficiencies. What really differentiates them is their relative efficiency. Each is more efficient in some situations but less in others.

Yet the overall efficiency is difficult to evaluate. The success of a model is highly dependent on many confounding factors, and the efficiency of the models is often muffled by higher level factors, usually making the relative merits and even the success or failure of these models hard to evaluate.

As part of the continuous improvement effort, the integration model has constantly evolved through many forms at different stages of deployment or at different facilities.

Various models in practice

First I'll review two typical integration models representing two opposite practices, and then I'll introduce a new, more comprehensive model to potentially better leverage the advantages of both.

The first model—the TBM model that incorporates Six Sigma into a lean framework—has the following features:

- Executes lean and Six Sigma activities in the event format, shown in the *kaizen* event example in Figure 2.
- The Six Sigma event features two or more consecutive events in a series that match DMAIC phases: for example, one weeklong event for the measure and analysis phases and one for the improve and control phases. Some firms schedule a weeklong event per phase.

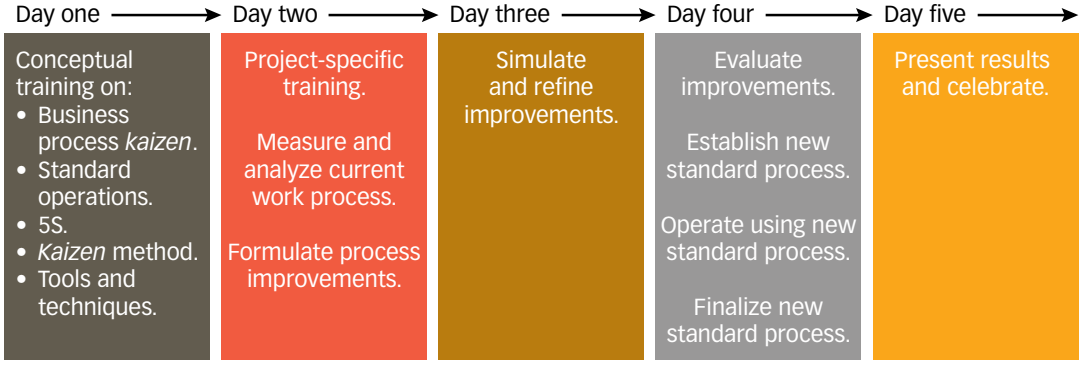
Figure 2's stepwise instruction for a *kaizen* event from TBM shows three of five DMAIC steps embedded in the activities during the week. In this case, define is done before the *kaizen* week to set up the event; control, although weaker than what a Six Sigma project requires, is also addressed through a 30-day follow-up.

This format works especially well when an organization relies on external consultants to run improvement activities because that's how consultants' time is allocated.

A model that incorporates lean into a Sigma framework (Seagate model) has the following features:

- Executes both lean and Six Sigma activities in a project format, as shown in Figure 3 (p. 30).

Sample stepwise instruction for *kaizen* event / FIGURE 2



Note: *Kaizen* breakthrough method from TBM Consulting.

- Most traditional *kaizen*-level improvements are handled through GB projects.
- The lean side of the effort focuses more on the higher level, supply chain activities.

This format misses the efficiency the event format can provide, which results in some activities dragging on longer.

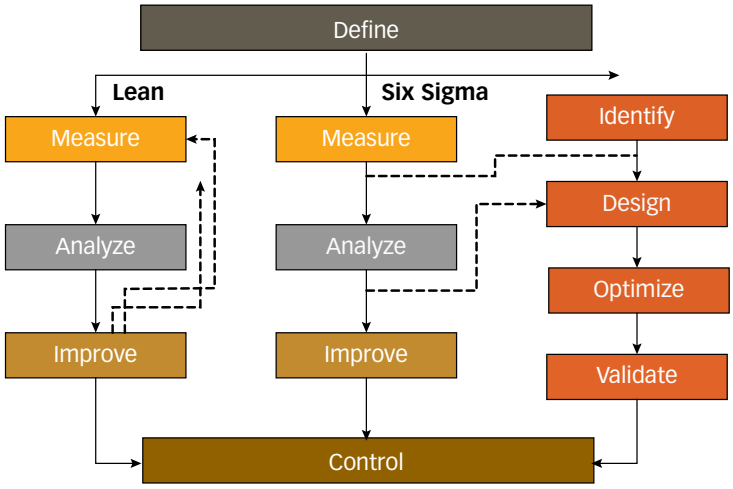
These two models represent two extreme cases of incorporating lean and Six Sigma. They both have proven to be successful deployments, carrying the style of their original improvement initiatives. Yet, neither fully uses the potential from both sides.

A tier-based mutually inclusive model to better leverage advantages from both lean and Six Sigma can potentially offer better efficiency and better use of resources and expertise with greater flexibility.

This tier-based mutually inclusive integration model features the following:

- Retains two workforce groups that co-exist in tiers.
- Uses one system to decide improvement activities (project selection), based on factors including size, timeframe, nature, practitioner and format, as shown in Table 3.
- Embed lean and Six Sigma activities into one improvement effort, starting with lean activities for low-hanging fruit and then trying Six Sigma activities for second level improvement—the aforementioned one-two punch.

Lean under Six Sigma framework / FIGURE 3



- Embed Six Sigma into *kaizen* events; for example, some *kaizen* events involve Six Sigma's design of experiments (DoE).
- Embed *kaizen* into Six Sigma projects; for example, use the *kaizen* event format for certain project deliverables when needed, or even for whole phases.

Example 1—Embed Six Sigma into *kaizen* events: A *kaizen* event was set up to mistake-proof a welding process for a plastic tube. In the industry, this welding process is called pure-bonding. Two plastic pieces are glued together after the surfaces are melted under heat, as shown in Online Figure 5.

The original event scope was as follows:

- Mistake-proof the weld process.
- Establish one-piece flow.
- Establish parts presentation.
- Update or create standard work.
- Develop a detailed training plan with a schedule.

During the event, the team realized the welding step might not be running at the optimum process settings. Three input factors affecting the welding result (heating time, left distance and right distance) were not well controlled, which affected the welding quality.

The team realized DoE could be used to optimize the welding settings. A Six Sigma belt was called in to set up a central composite design. The optimum setting was identified through response-surface analysis.

Example 2—Embed *kaizen* into Six Sigma projects: A Six Sigma project was created to improve the molding scrap reclamation process. Injection molding will always produce unusable residual materials as a byproduct. Some of the materials can be reused.

As part of the effort to address low-hanging-fruit opportunities to achieve initial gains, it's natural to 5S (sort, set in order, shine, standardize and sustain) the existing reclamation process.

The belt-in-training happened to be a lean manager who was proficient at facilitating *kaizen* events. He chose to do a mini-*kaizen* event to handle this part. It was treated as a standalone event, but at the same time was part of the Six Sigma project deliverables.

In practice, crossover may not be easy. Six Sigma trainees should consider the event format to complete some project deliverables, but few trainees do so because many of them don't have experience in facilitating events. The crossover won't happen until people develop proficiency in the other discipline.

Advantages

As shown, a tier-based mutually inclusive model has the following three advantages:

1. Avoids the pitfalls of running two independent lean and Six Sigma programs, while retaining the respective identities and efficiencies of both.
2. Minimizes the conflict between two independent lean and Six Sigma programs. Quite often, lean activities undermine the need for the data retention characterisitic of Six Sigma efforts; or, Six Sigma activities don't sufficiently leverage the lean efforts.
3. Uses the limited resources more efficiently. Since the requirement is lower for lean, the investment on human capital and training is less for lean. QP

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The proper blend of **lean and Six Sigma** will have your organization tasting success

The Right

In 50 Words Or Less

- Lean and Six Sigma are two powerful process improvement methods.
- They can be used in primitive process environments that don't require formal data collection practices, as well as mature process environments with advanced digital reporting.
- Managers must employ the differing philosophies of lean and Six Sigma to get maximum results.

Mix

by Aditya Bhalla

SIX SIGMA OFFERS a framework for process improvement based on objective data. W. Edwards Deming once said, "In God we trust, all others bring data." For many Six Sigma practitioners, that's become their undying motto.

By contrast, lean offers a framework for process improvement based on core principles of process waste elimination and introducing continuous flow in a process.

Some in the services industry have been late to adopt these respective methods. Using both approaches, there are some early wins that have galvanized many organizations. For every inspiring success, however, there are just as many stories about failed or compromised projects.

To avoid these failures and get maximum results, organizations must take into account the differing philosophies of lean and Six Sigma. In other words, organizations must find the right blend that accentuates the strengths of both.

Many organizations that combine lean and Six Sigma fall short of their goals because they have made some missteps and encountered psychological inertia when deploying the approach.

A spectrum of organizations has run into these obstacles—from those with primitive or loosely defined processes to those with structured, benchmarked process deployments. The examples provided with each of the six common missteps that follow have been altered to mask the identity of the organizations.

1. Excessive number crunching

Lean is based on the philosophy of *kaizen*, or continuous improvement, and emphasizes pace and action toward improvement on a continual basis. If the spirit of lean is followed, incremental improvements will occur naturally and not necessarily as a project-based activity driven by the statistical precision showcased by Six Sigma. Evolution—not revolution—is the key toward sustainability. It is important to note that lean does not advocate rash improvements.

All too often, projects are delayed in the name of scientifically collected data: spending time collecting data on the amount of work flowing in on any given day, devoting a large amount of time and work to any two stages in a process and misinterpreting that lean productivity improvement projects must have a time-and-motion study based on scientific precision.

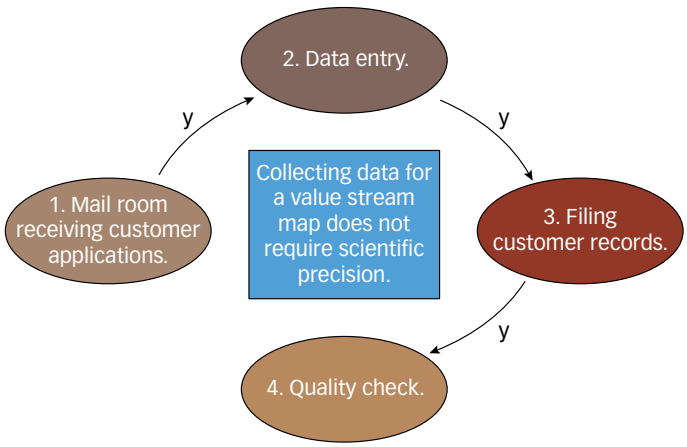
The following are two instances in which a project was delayed because of data collection and number crunching.

1. Value stream mapping: Creating a current state value stream map (a process flow representation at a higher level than flowcharts) shouldn't take more than two days for most processes (except processes that occur in different locations or those that occur sporadically). Analyzing a current state map and recommending a future state should not take more than two to three days. For some Six Sigma practitioners bred on the notions of projects with three to four-month timelines, such an accelerated pace is difficult to digest. For a lean value stream map study, capturing data by observing the process at the most representative time on the most representative day is sufficient to initiate improvement.

2. Six Sigma tollgate review mechanisms: One organization with primitive process definitions and manually collected (and mostly unreliable) data had its projects stuck in the define stage for several months. The delay was caused because the organization was waiting for management approval to create a digitized dashboard and automated workflow environment to capture accurate time-stamped data in the measure phase of Six Sigma. Why was management not approving a move forward? Because the organization's country head wanted the internal Six Sigma teams to demonstrate improvements within the current setup first before proposing a trite solution, such as automation. A lean study later showed there were ample opportunities for improvements within the current setup.

Figure 1 illustrates the scenario in which the team was stuck in the data collection step until automation was put in place.

Scientifically precise data collection / FIGURE 1



2. Lack of value stream management

A value stream manager is a person in authority who oversees the way work flows across an entity. This manager has the will and power to bust through barriers (corporate silos or bunkers) and enable work to flow seamlessly (also called continuous flow in lean) across departments and locations.

Barriers such as these can be an organization's Achilles' heel, especially for a large-sized organization.

Evolution—not revolution—is the **key toward sustainability.**

Many lean projects are compromised because real improvements are linked to changes that need to be implemented in other departments. An example of this is given in Figure 2.

Consider the case of a *Fortune* 500 multinational corporation in the telecom sector. Customers of this company log their complaints with front-office teams. These teams pass customer information to a client-resolution team. The job of the client-resolution team is to coordinate the work with the appropriate internal department (for example, billing or network operations center) toward a timely resolution (for example, 48 working hours).

The client-resolution team is missing its turnaround time targets by a wide margin. Under strong pressure from management, the team initiates a lean Six Sigma turnaround time reduction project.

Preliminary analysis at the define phase of the project reveals that this team is essentially playing the role of coordinator. They have little control in finding a solution to the problems. Additionally, there are no internal service level agreements governing the turnaround time of other departments. As a result, this team finds itself stuck between a rock and a hard place.

The management failed to realize the importance of having a value stream manager who could ensure the restructuring of the workflow across these different functions.

3. Not realizing waste is everywhere

Lean identifies the eight forms of waste as overproduction, inventory, transportation, motion, over-processing, waiting, defects and unused employee creativity. When exposed to these types of waste, many managers in the service industry find themselves unable to relate to these terms. They might say, "We don't have inventory in the service industry. That's a manufacturing problem. We don't have motion waste. Everything is done here on a computer in neat cubicles—not by workers on greasy shop floors."

Right? Not quite.

Consider the example of a data-entry operation. The data-entry staff is involved in creating customer accounts on computers. The supervisor hands hard-copy customer application files in lots of 20 to each computer operator.

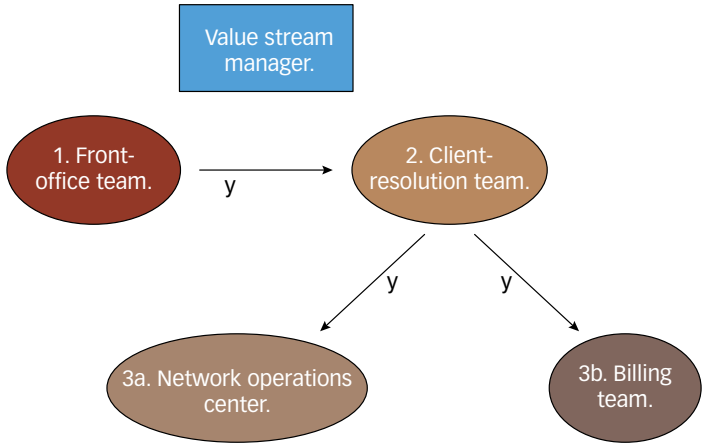
The operators put the individual files on the floor on one side of their desks, pick up files one at a time and place each one on the table. They enter the preliminary customer contact details on the first page of the physical file into the software program to create the unique customer identification. Then they enter the bill plan information found on the third page of the hard-copy application file into the software program by using the mouse to click on the button connecting to the bill plan screen. After the information has been entered, the operators put the file on the other side of the table for the next stage of the process.

An analysis of this scenario reveals motion waste and inventory waste:

Motion waste

- Picking up and putting files on the ground.
- Scouring and flipping through pages of the files to retrieve information scattered across different pages during data entry.
- Moving the computer mouse to click the button to

The importance of a value stream manager / FIGURE 2



Lean provides a **quick and easy answer** to the seemingly eternal struggle between **creative chaos and structured creation.**

launch the bill plan screen.

Inventory waste

- Piling the hard-copy application files of work to be done.
- Piling the hard-copy application files after the data has been entered and waiting for the next stage of processing.

The service industry must develop the keen eye to spot the waste that is everywhere—even in a digitized format, if not in the usual areas in the real world.

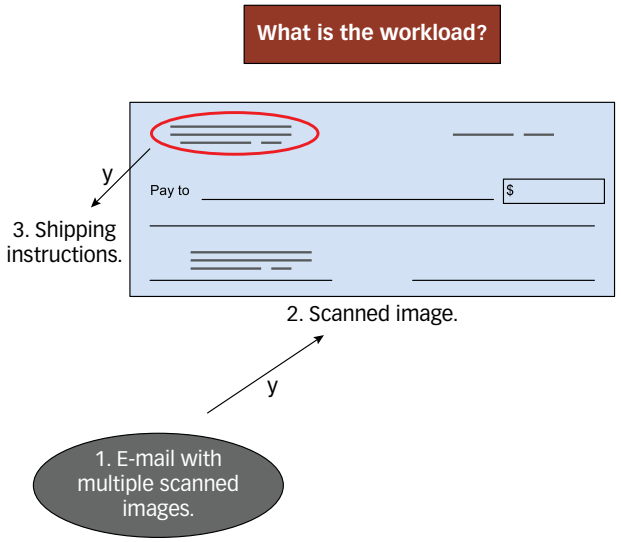
The road for lean Six Sigma implementers, however, is not that simple. The moment that managers relate to the meaning of waste in the service industry, many tend to fall into one of the following traps:

- They justify the waste, perhaps calling it value-enabling, and ignore the evidence and opportunity for improvements. This is easy to fix through training, by relating improvements to a business context and securing management support.
- They complain how improvement initiatives may squeeze every working second out of the workers and transform them into precision-controlled robots. Lean is about identifying and removing bad work practices (for example, extra processing steps) and bad process design issues (for example, poorly designed software or poorly designed ergonomics), not building robots. The end objective is to make the lives of staff simpler and more enjoyable.

Lean projects cannot succeed if they ignore the human dimension. Practitioners need a keen eye to spot user-unfriendly designs—the way a worker is seated or how data are structured on forms or computer screens.

For example, encouraging staff members to use six-point font on printouts for account reconciliation and expecting them to be productive without committing errors can be extremely challenging. Providing customers application forms with small fields in which to write information can delay a process if customers struggle to squeeze personal detail into limited space. Lean is all about eliminating complexity in the way work gets done.

Using the wrong data / FIGURE 3



4. Misjudging workload

The amount of work to be done in any shift eventually determines the scale of operations that can be sustained in a stress-free manner—or, as lean puts it, when processes are operating in a rhythm.

Consider the process of an organization that handles freight and logistics. Its back-office team receives instructions on goods that are being shipped. The instructions are received as scanned image attachments on an e-mail, as shown in Figure 3. The images contain the list of the goods being shipped. The back-office team has to tally the list with internal documents for further processing.

What would you consider as the workload? Is it the e-mails received per shift, the scanned images received per shift or the line item listing of goods being shipped?

Many managers have painfully discovered their teams are understaffed by mistakenly using the number of e-mails received or the scanned-images attachments as the volume of work to be done.

The most appropriate answer would be the line item listing of goods being shipped. The time spent processing any e-mail will eventually be determined by the number of line items mentioned in the image of goods being shipped.

5. Dismissing lean in service sector

This is a large area of psychological inertia in the service industry. Many in the service industry view manufacturing as neatly preconfigured widgets being mass produced by automated factories. They say the service industry, on the other hand, is about handling ambiguities and complexities.

The common refrain you hear from those in the service industry is that they cannot manage the productivity of teams that handle unique and complex cases that require thinking. Regardless of whether the manager oversees a team of lawyers, financial or medical underwriters, mortgage reviewers, software developers or business analysts handling enterprise resource planning platforms, this refrain doesn't change.

Lean provides a quick and easy answer to the seemingly eternal struggle between creative chaos and structured creation. A tenet of lean also comes in the answer to a well-known question: How do you eat an elephant? One bite at a time. In other words, lean can provide a practical approach to handle scenarios with customized requests of varying volume.

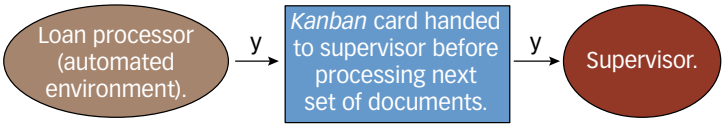
6. Overcomplicating activities

The inclination toward Japanese-sounding terms stems from the origin of lean at Toyota and the adoption of this method by other Japanese organizations before American researchers discovered its virtues.

This misstep is commonly found in organizations in which a sense of activity is assessed with an abundance of complex-sounding terms and complicated management presentations. A desperate attempt to impress audiences (and sometimes potential clients to win deals) results in the reckless use of terms like *heijunka*, *muda*, *muri*, *poka-yoke*, and *kanban*. No one seems to bother to check the validity or appropriateness of a tool or concept.

Figure 4 is part of an actual presentation made to impress clients. It captures a snapshot of a loan processing team. Before lean implementation and any consideration of lean principles, hard-copy loan files had been given to processors in lots of 50 as a daily quota to meet. After lean implementation, the team instituted an automated solution. Only after a processor finished one file would the processor receive the next file.

Irrelevant application of *kanban* / FIGURE 4



This is where the team made the mistake of implementing what they thought was a *kanban* system in which physical cards were given to the loan processors. After processors finished a certain number of files (perhaps 10), they had to present these cards to the supervisor seeking approval to process the next set of files.

This is a completely hilarious, irrelevant and wrong application of *kanban* and ends up introducing more waste by breaking the continuous flow of operations. However, it did give the team a false sense of accomplishment of having understood and implemented *kanban*, a concept covered by every lean author.

For such organizations, a Six Sigma deployment would be equally rigid and overblown with statistical intimidation and mathematical computations overriding common sense as the acceptable way of life.

For the leadership teams managing these initiatives and for clients outsourcing business to such organizations, it becomes a case of *caveat emptor*, or buyer beware.

Evolution—not revolution

Six Sigma and lean provide practitioners powerful concepts to improve processes and even design new ones. These can be effectively used in primitive process environments with no formal data collection practices and mature process environments with digital dashboards reporting process performance by the second. QP

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Heal

Use Baldrige criteria to **meet your goals** and **patient needs**

In 50 Words Or Less

- The Baldrige criteria provide a structure for improving quality and financial performance in healthcare institutions.
- The criteria help organizations meet the six Institute of Medicine aims of safety, effectiveness, patient-centered and equitable care, timeliness and efficiency.
- Data from Baldrige award recipients demonstrate improvements and sustained results.

Narrow thcare's QUALITY CHASM

by William Denney, Cynthia St. John and Liz Youngblood

TODAY'S HEALTHCARE LEADERS face the need to effectively manage both the clinical and business sides of their operations. This includes demonstrating cost reductions, overall organizational improvement and long-term sustainability.

Added to these responsibilities are the societal expectations that these leaders make radical changes to the healthcare infrastructure while it still consistently meet the needs of patients and that these leaders do so in a field that is quite complex. The bottom line is that hospitals have no choice but to move from basic compliance to organizational excellence.

Implementing the *Baldrige Healthcare Criteria for Performance Excellence*[1] within a healthcare organization can drive high-quality outcomes and improve financial performance. The Baldrige criteria provide a structure to help align and focus all areas of an organization with key stakeholder needs and expectations. In short, the criteria can transform healthcare.

In the midst of striving for organizational excellence, healthcare institutions are faced with a variety of challenges. For example, no one can deny that healthcare is a highly regulated industry. Staying up to date with changing requirements is costly in time and resources that don't generate additional revenue.

An organization that does not maintain compliance, however, will lose money in the form of penalties, decreases in payments, required reimbursement of funds received and even failure to qualify to serve certain payer categories.

Another challenge faced by full-service, acute care hospitals is providing healthcare to all, regardless of ability to pay. Emergency and subsequent healthcare services are provided regardless of whether a patient can pay for the services.

Many healthcare consumers cannot afford insurance. Others have insurance but cannot pay the increasing co-pay amounts and other consumer-funded portions of healthcare plans. This added financial burden on hospitals, along with the increasing regulatory compliance requirements, is cause for concern. Hospitals that are unable to meet these challenges end up closing their doors because they can't financially sustain their operations.

Additionally, consumers (patients) are much more involved in making healthcare decisions, and expectations for transparency have become the norm. Patient consumers decide what healthcare services they want to receive and where they want to receive them. These decisions are based on accessible information related to services, quality and other outcomes.

Furthermore, high-quality, cost-effective care with positive outcomes is expected. For consumers, this is a given; therefore, patient satisfaction has become a key driver in determining where patients will go to receive services.

All these factors create a challenging environment for healthcare institutions. Addressing these challenges and moving beyond them to create organizational excellence are critical to success and sustainability.

Quality and the IOM aims

Initial efforts to achieve improvement have frequently been associated with the Institute of Medicine (IOM) aims. In its landmark report *Crossing the Quality Chasm*, IOM acknowledged the existence of a pervasive quality gap and called for the urgent redesign of the U.S. healthcare system.[2]

The report set forth the following six aims for focused improvement:

- **Safety**—avoiding injuries to patients from the care intended to help them.
- **Effectiveness**—providing services based on scientific knowledge to all who could benefit while refraining from providing services to those unlikely to benefit.
- **Patient-centered care**—providing care that is respectful of and responsive to individual patient preferences, needs and values, and ensuring that patient values guide all clinical decisions.
- **Timeliness**—reducing wait times and sometimes harmful delays for those who receive and those who give care.
- **Efficiency**—avoiding waste, including unused equipment and supplies, ignored ideas and unnecessary expenditures of energy.
- **Equitable care**—providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location and socioeconomic status.

Intended to result in care that is safer, more reliable, more responsive, more integrated and more available, these aims became the focus of many healthcare institutions' quality efforts.

Since the report's release, some gains have been achieved. These topics continue to cause unrest within the healthcare industry, however—opportunities for improvement persist. In a time when great leaps forward are needed, progress is too often measured in small, incremental improvements. Leaders find themselves supporting and financing many seemingly good, but random, acts of improvement. Despite best intentions, costs continue to rise, patients remain dissatisfied, and process failures are widespread.

What is needed is a systematic way to align hospital improvement activities with strategic goals and to track focused measures that result in real change. Since its availability in 1999, the Baldrige healthcare criteria have been used by many hospitals to accom-

plish this alignment and tracking. The criteria represent a systems approach to improvement that is composed of six process categories and a seventh category for associated results:

1. Leadership.
2. Strategic planning.
3. Focus on patients, other customers and markets.
4. Measurement, analysis and knowledge management.
5. Workforce focus.
6. Process management.
7. Results.

The criteria have also been referred to as a leadership system and a sustainability model. But what they really represent is an integrated approach to improving a diverse and complicated organization and achieving sustainable results.

Baldrige and the IOM aims

While the criteria address key processes in an effective management system and are increasingly recognized as a framework to create and sustain quality outcomes, the greatest emphasis is placed on the outcomes achieved by these processes. Table 1 (p. 42) summarizes the Baldrige results criteria relative to the IOM aims.

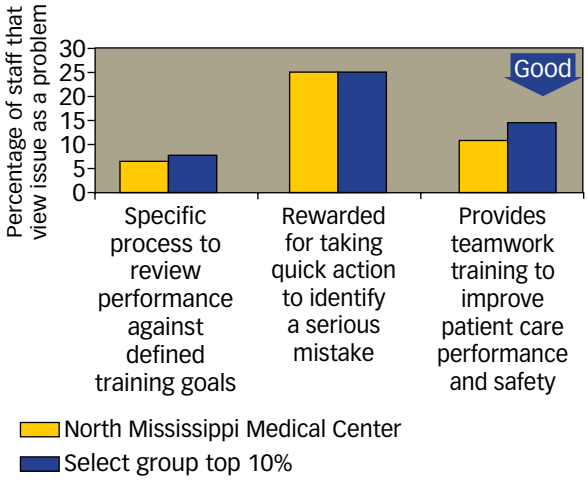
Systematic application of the criteria often corresponds with significant gains in IOM aim achievement. Following are examples of results from Baldrige recipients that impact IOM aims:

Safety: The provision of safe care is dependent on a variety of factors. It therefore follows that safety also touches many of the Baldrige results items. Most directly, the healthcare outcomes criteria (7.1) ask for levels, trends and comparative results relative to patient safety.

Also relevant, however, are workforce-focused outcomes due to the human factors often associated with medical errors. Workforce capability and capacity, including staffing levels and appropriate skills, are addressed by the workforce-focused outcomes criteria (7.4).

In addition, safe care is aligned with the Baldrige process effectiveness outcomes (7.5) and leadership outcomes (7.6). Key work-process measures, including those directly and indirectly related to the provision of safe care, are addressed in 7.5. Leadership sets the institution's strategic objectives and priorities and is responsible for monitoring progress toward these priorities (7.6), of which safe care should be paramount.

Patient safety culture example / FIGURE 1



Accreditation results (such as Joint Commission requirements) are also addressed in the leadership outcomes criteria.

Given the relation between the Baldrige results criteria and the IOM safety aim, it is not surprising that Baldrige award recipients often demonstrate stronger patient safety outcomes compared with their peers.

In Figure 1 from Baldrige award recipient North Mississippi Medical Center, as patient safety improvement becomes part of an organization's processes and culture, staff recognizes that actions to improve safety are visible and well implemented.

Figure 2 from St. Luke's Hospital of Kansas City shows that mortality rates were lower, which impacts other important measurements compared with national averages.

Lower mortality rates / FIGURE 2

	SLH	National average
Medical mortality	13.1%	15.3%
Surgical mortality	1.8%	15.3%
Physician rating	86%	33%
Accreditation score	92	91
Overall score	7669	5418
St. Luke's Hospital (SLH) Rank = 35 of 4,500 hospitals in United States		

Effectiveness: Evidence-based medicine has experienced continued refinement, with specific treatment strategies demonstrating consistently better results for patients with specific presenting conditions.

The delivery of effective care, as defined by the IOM, relates to providing services to all who could benefit, while refraining from providing services to those not likely to benefit—in other words, the effective use of evidence-based medicine as available and appropriate. These practices and their corresponding results are addressed in the healthcare outcomes criteria (7.1).

In addition to patient safety outcomes identified earlier, the healthcare outcomes criteria ask for levels, trends and comparative results relative to healthcare outcomes and patients' functional status.

An additional means by which overall effectiveness is achieved is through the effective design, implementation and improvement of healthcare delivery processes. These processes are measured by item 7.5, process effectiveness outcomes. In particular, 7.5 asks for current levels and trends for the operational performance of key work processes, including productivity, cycle time and other appropriate measures of process effectiveness.

Table 1 also identifies the workforce-focused item (7.4) as relevant to the IOM effectiveness aim. This connection is based on the importance of workplace climate and engagement, particularly related to openness to new ideas, approaches and improvement opportunities to ensure ongoing gains in effectiveness.

Baldrige award recipients generally demonstrate stronger effectiveness-related outcomes compared with their peers. Looking to clinical measures of effectiveness (see Online Figure 1 at www.qualityprogress.com), one Baldrige award recipient shows results that are better than measurements from the Centers for Medicare and Medicaid Services (CMS). As shown in Online Figure 2, the recipient performed better than local competitors and as good as the best in the country, as measured by the Agency for Healthcare Research and Quality (AHRQ).

Patient-centered care: The IOM aim of patient-centered care emphasizes responsiveness to patient preferences, needs and values. Similarly, category 3 of the Baldrige criteria and corresponding item 7.2 in the results section address patient and other customer-focused processes and outcomes.

In particular, the results criteria ask for levels, trends and comparative data relative to patient/customer satisfaction and dissatisfaction, perceived value, retention and positive referral. These measures provide an indication of how a healthcare institution is performing relative to patient-centered care.

Similar to the aims already discussed, Baldrige award recipients tend to demonstrate stronger patient-centered outcomes compared with their peers. Figure 3 shows high scores for patient loyalty at Bronson Methodist Hospital, a Baldrige recipient. Table 2 shows a comparison of customer value at award recipient Baptist Hospital Inc. in Pensacola, FL, and comparable institutions.

Timeliness: In Baldrige terminology, timeliness is one aspect of the process effectiveness outcomes criteria (7.5).

In addition to the general operational performance of work systems and key work processes, time-based measures play a large role in the criteria, given the significance of time performance to improving overall performance. Appropriate measures and indicators of work system performance may include just-in-time delivery of healthcare and related services, plus other indicators that demonstrate responsiveness, such as cycle times, turnaround times, time to new healthcare service introduction and order fulfillment time.

Given the inherent emphasis on time-based measures of performance, Baldrige award recipients regularly demonstrate reduced times on key measures as compared with their peers. For example, Online Figure 3 shows process speed improvement at Rob-

Baldrige results and IOM aims / TABLE 1

Baldrige results ⇒ **IOM aims ⇓** *Care is:*	7.1 Healthcare outcomes	7.2 Patient and other customer-focused outcomes	7.3 Financial and market outcomes	7.4 Workforce-focused outcomes	7.5 Process effectiveness outcomes	7.6 Leadership outcomes
1. Safe	•			•	•	•
2. Effective	•			•	•	•
3. Patient-centered		•				
4. Timely					•	
5. Efficient			•	•	•	
6. Equitable	•					•

IOM = Institute of Medicine

ert Wood Johnson University Hospital Hamilton, NJ, a Baldrige winner, compared with Joint Commission results. Online Figure 4 shows a comparison between the timeliness of antibiotics given and length of stay at Bronson Methodist Hospital.

Efficiency: Also closely related to the timely delivery of care and services is the efficiency with which healthcare processes are delivered. Efficiency encompasses all forms of waste avoidance, including equipment, supplies, human resources and even ignored ideas.

The aim of providing efficient care is related to multiple Baldrige results items:

- Financial and market outcomes (item 7.3) addresses financial performance measures, including levels and trends for budget performance—a measure of financial efficiency.
- Workforce-focused outcomes (7.4) take into consideration the concept of avoiding waste in the form of ignored ideas. As noted earlier in reference to the IOM effectiveness aim, the importance of workplace climate and workforce engagement—particularly related to openness to new ideas, approaches and improvement opportunities—can also significantly impact efficiency.
- Process effectiveness outcomes (7.5) address the operational performance of work systems and key work processes, including productivity and efficiency measures. Indicators of process efficiency might include work system performance that demonstrates increased cost savings, higher productivity or waste reduction, such as the reduction of repeat diagnostic tests and cost reduction.

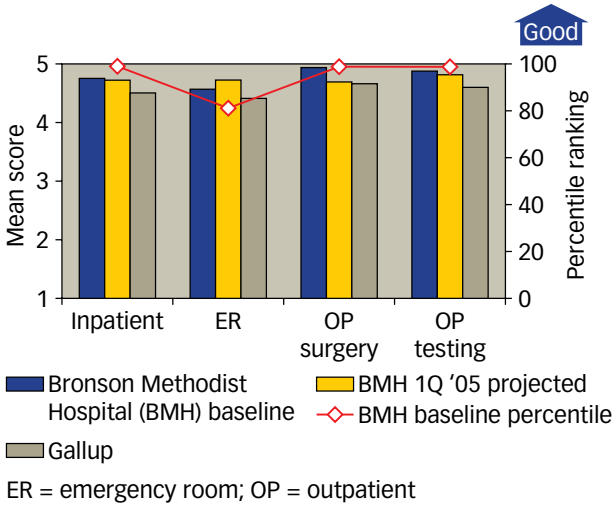
Baldrige award recipients tend to demonstrate stronger efficiency-related outcomes compared with their peers. Figure 4 (p. 44) shows how St. Luke's Hospital of Kansas City increased its profit margins by eliminating internal inefficiencies. In Online Figure 5, despite increases in volume, Baptist Hospital Inc. tended to create the capacity for fast response times and best-in-class performance.

Equitable care: Healthcare results (7.1) address key measures of healthcare outcomes, including functional status.

Although many Baldrige recipients serve lower income and rural patients, their healthcare outcomes are generally equal to or better than facilities serving more affluent communities. Results such as these support the aim of equitable care.

In addition, leadership results (7.6) measure a variety of factors, including support of key communities and contribution to the health of the community the institution serves, regardless of its characteristics.

Loyalty and likeliness to return / FIGURE 3

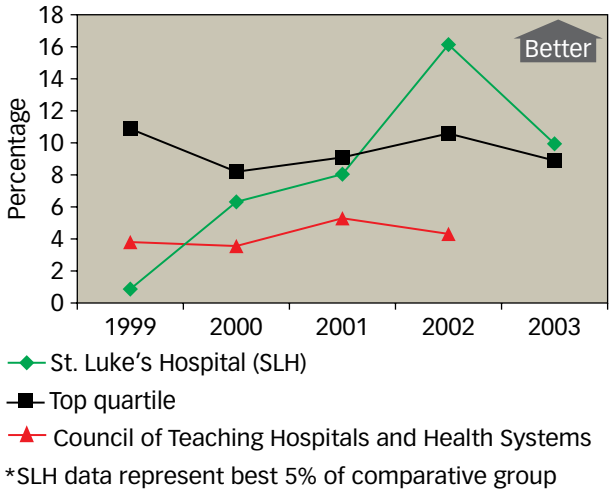


ER = emergency room; OP = outpatient

Customer survey scores / TABLE 2

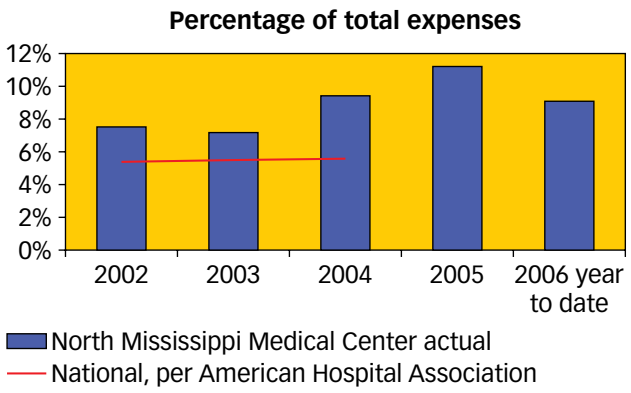
Baptist Hospital Inc. (BHI)			
Issue	**BHI**	**A**	**B**
Care/services Patients are kept sufficiently informed about their condition/treatment.	+84	79	76
Pain is well controlled.	84	80	77
Personnel show concern for patients' well-being.	+88	78	73
Overall quality of health care provided is excellent.	+83	78	74
Phone representatives at hospital are helpful.	+84	77	73
Sufficient personal attention is given to patients.	+83	77	70
Patient needs are met promptly.	+79	73	70
Waiting time for tests and treatment is reasonable.	+77	71	68
Emotional Patient needs are understood.	+78	71	62
Location/environment Parking is convenient.	+76	62	49
Nurses Nurses show good attitide toward patient requests.	+89	79	78
Physicians Overall quality of care provided by physician is excellent.	83	80	80
+ = Significantly above competition (A and B)			

Margin comparison / FIGURE 4



*SLH data represent best 5% of comparative group

Uncompensated cost comparison / FIGURE 5



Baldrige recipients tend to be able to spend more on uncompensated and charity care than comparable institutions. Figure 5 shows how Baldrige recipient North Mississippi Medical Center posted uncompensated expenses above a national average. Online Figure 6 shows how setting a percentage of operating margin in an environment of increased efficiency and financial improvement resulted in increased charity care at Baldrige award recipient SSM Healthcare.

BALDRIGE RESULTS

Are you interested in learning more about the exceptional business results achieved by Baldrige recipients? Go to www.quality.nist.gov/Contacts_Profiles.htm (case sensitive).

Getting started

An organization can start using the Baldrige criteria to create a change in culture leading to an improvement in quality by completing two steps: the organizational profile and the self-assessment.

Step one—organizational profile: The profile serves as the DNA for an organization. It provides clarity about who you are, what you do, for whom you do it, what they expect, with whom you are competing and collaborating, your key strategic challenges and advantages, and the approach you use to improve performance.

Although the questions that must be answered are seemingly straightforward, within many organizations the responses have traditionally been treated as implicit assumptions rather than explicit assertions. Arriving at a collective and uniform response to each question provides focus to the leadership team and organization. This collective consciousness becomes the context within which the organization operates and against which it manages its performance.

Step two—self-assessment: The profile describes who you are and the environment in which you operate. The self-assessment describes how you currently perform relative to the Baldrige criteria.

Current practices are reviewed and summarized in the areas of leadership, strategic planning, customer focus, measurement/analysis, knowledge management, workforce focus, process management and results.

Although often an impressive document in its own right, the true value of this process comes from using the information to identify the organization's strengths and opportunities for improvement, which are based on its responses to the criteria and placed in the context of what it stated was important in its profile. The opportunities for improvement represent gaps that can be prioritized, translated into goals and integrated into the organization's strategic planning and performance management processes.

Completing the profile and self-assessment help an organization readily see its gaps and current barriers to success. Systematically using this information in the strategic planning process will enable the development and achievement of meaningful goals and improvements.

Not just an award

The Baldrige criteria are not about receiving an award. In healthcare and hospitals, there are many quality awards and recognitions, but few nationally

recognized systematic and integrated approaches for sustainable improvement.

There is a misconception that the criteria are difficult to use and understand, are costly or that it takes a long time to see benefit. In fact, the criteria are easy to understand. But changing an organization's culture to use the criteria can be a challenge. It requires leadership commitment to drive excellence. A committed leadership team can effectively create the culture change required to begin using the criteria within the organization. If this is done, the payoff can be almost immediate.

There is a growing recognition within healthcare of the value of the Baldrige criteria. In 2008, 50% of the applicants that applied for feedback from the Baldrige program were from the healthcare sector. The same is true for many state programs. Most Baldrige award recipients prepared themselves to succeed at the national level by participating in their state program.

Whatever the route taken, the results show that the Baldrige criteria can provide a structured way for healthcare institutions to meet many of the seemingly overwhelming challenges they face today. QP

REFERENCES

1. *Baldrige Healthcare Criteria for Performance Excellence*, National Institute of Standards and Technology, 2008.
2. *Crossing the Quality Chasm*, Institute of Medicine, 2001.

RESOURCES

To learn more about the Baldrige criteria, go to www.quality.nist.gov.
For more information about state Baldrige-based programs, go to www.baldrigepe.org/alliance.
Baldrige recipient information is available at www.quality.nist.gov/Contacts_Profiles.htm (case sensitive).

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TAKE a BITE out of Inefficie

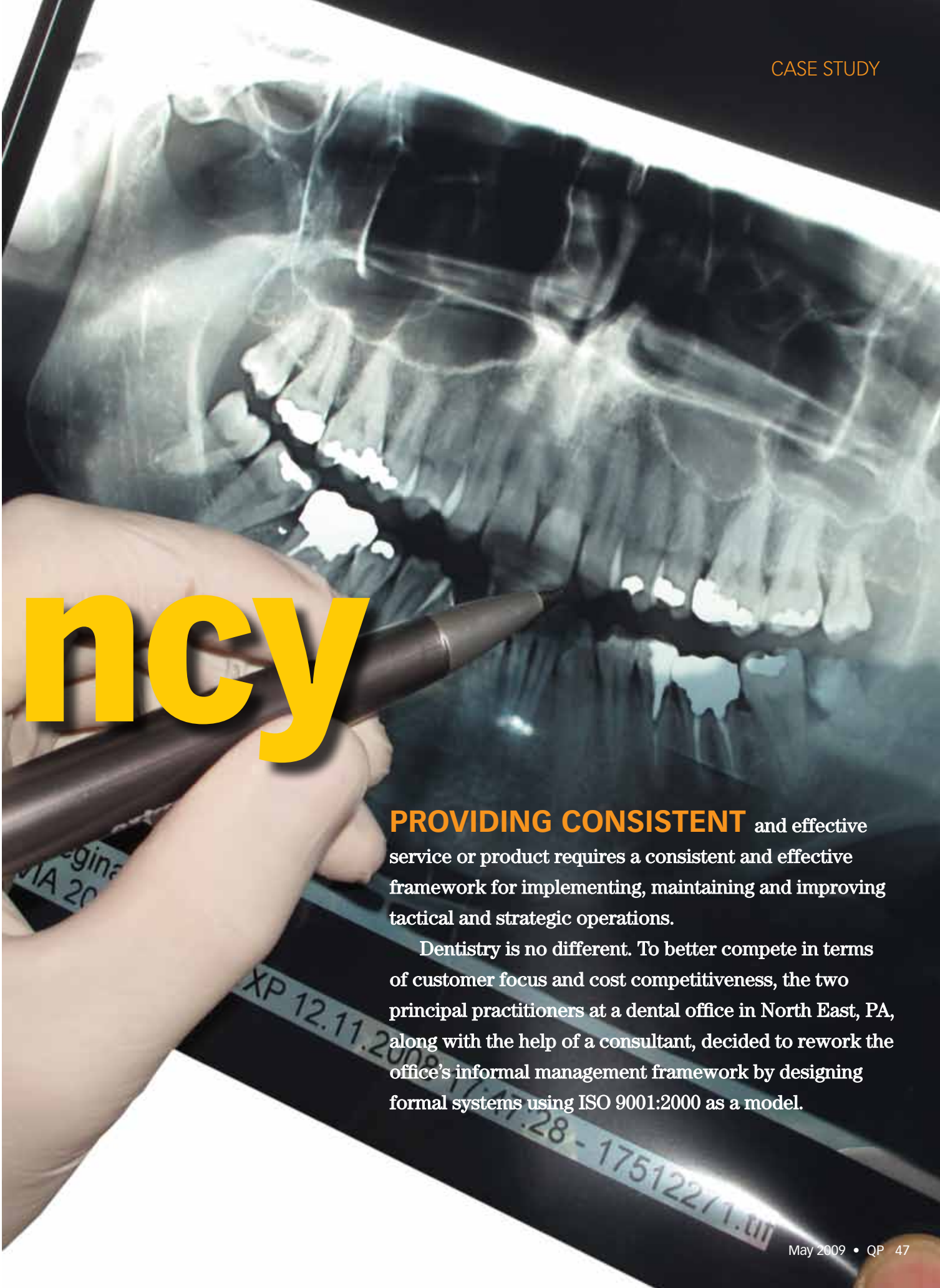
In 50 Words Or Less

- A dental office in Pennsylvania used ISO 9001:2000 to construct a comprehensive equipment management system (EMS).
- The system helped the staff track the dental equipment and follow how the items were being installed, maintained and repaired.
- The EMS helped reduce repair visits dramatically and avoid unnecessary downtime.

Dental practice uses **ISO 9001:2000** to drill into equipment management

by Dina Nuhfer, D.M.D., and Thomas Walters, D.M.D.

ncy



PROVIDING CONSISTENT and effective service or product requires a consistent and effective framework for implementing, maintaining and improving tactical and strategic operations.

Dentistry is no different. To better compete in terms of customer focus and cost competitiveness, the two principal practitioners at a dental office in North East, PA, along with the help of a consultant, decided to rework the office's informal management framework by designing formal systems using ISO 9001:2000 as a model.

Although we were not necessarily interested in achieving accreditation to that standard, we were interested in using its framework to better manage areas such as purchasing, materials, facilities, HR, process control, infection control, deviations, change, documents and records, and management engagement.

We designed our quality management system (QMS) with an eye on business priority and risk to the practice. Given the equipment-dependent nature of the business and the cost of external equipment repair, we all agreed that equipment management posed the most significant risk.

The story about the design of the equipment management processes begins with Bob. Bob was a nice guy. He regularly visited the office, ready to work. He was on the Christmas card list, we knew about his family and we understood many of his personal likes and dislikes. He was just like a staff member, but that was the problem. He wasn't a staff member. He was our equipment repair guy.

Needless to say, the equipment repair guy should not be like a member of the office staff. Thus began our quest to implement a comprehensive equipment management system designed by our office and championed by our staff, in the spirit of ISO 9001:2000, sections 7.5.1 (control of production and service provision), 7.5.2 (validation of processes for production and service provision) and 7.6 (control of monitoring and measuring devices).[1]

As a result, the equipment management system encompassed the critical points of installation, qualification for use, repair, requalification and maintenance. You might be surprised to know that most medical practices, either dental or medical, do not implement such critical points as fully as required by ISO 9001 version 2000. As a result, equipment may be unpredictable or unreliable, impacting the efficacy and efficiency of care.

For example, have you ever questioned the validity of a result at the doctor's office, such as your blood pressure or weight? Or perhaps you have even witnessed malfunctioning equipment, such as a dental hand piece, the tool the dentist uses for drilling, at your appointment. Maybe the hand piece wouldn't spin to its prescribed speed, and there you sat, a victim of endless drilling.

After all the juggling you did to schedule this visit, maybe the sterilizer was broken and your appointment had to be rescheduled. These scenarios might provide objective evidence of weaknesses in that office's equipment management.

With the understanding that these processes are unique and not well-implemented in many dental and medical offices, here are the steps we took to overcome the weaknesses in our own system.

Making a list

The equipment management system in our practice focuses on critical equipment, or equipment that can adversely impact the safety, quality, purity and effectiveness of any dental procedure. This includes the sterilizer, hand pieces, the dental chair and laboratory equipment. It excludes items such as our fax machine. As such, our equipment management system currently encompasses 45 pieces of equipment.

In the first step, we identified all the pieces of equipment in the practice and made sure a manufacturer's manual was available for each. We listed each piece of equipment on a master equipment list (MEL) and identified its make and model, location, unique identifier (such as serial number), the date it was put into use (if we knew it) and the date it was permanently removed from use.

The MEL is a living document. As equipment is purchased and put into use or items are permanently retired, the list is updated. The MEL allows us to know at any given time what we have and what we don't have. Not only is it valuable for equipment control, but it is also crucial for disaster preparedness.

Checking maintenance

In the next step, we established any maintenance and calibration requirements for each type of equipment on the MEL by going through each manufacturer's manual. Maintenance functions were required for every piece of equipment within the scope of the equipment management system. Verification activities were required for some equipment and no routine calibration requirements were identified for any equipment.

We built a spreadsheet of equipment maintenance and verification functions based on whether they needed to be done every day, every week, every month, every year or after every procedure. Staff members performed these functions and documented the performance, as we quickly subscribed to the adage "what isn't documented didn't happen."

Our patients trust us to have their **best interests at heart,** and they believe we will ensure that **all conditions are acceptable.**

Repairman Bob reviewed the spreadsheets to ensure all functions were captured. Interestingly, there were discrepancies between Bob's and the manufacturer's recommendations. From a risk management perspective in healthcare, we believe the manufacturer's manual is the bible of equipment management. Not only is risk assumed, but not following the manufacturer's guidelines also might violate equipment warranty. We went straight to the manufacturer and got its final recommendation in writing. We maintain that documentation for the life of the equipment as part of the manufacturer's manual.

An equipment file (EF) was established for each piece of equipment, which allows for all documentation for that piece of equipment to be captured and maintained. Bob was invited to a big, exciting (well, exciting to us) training session in which he went through each type of critical equipment on the MEL and reviewed how to perform maintenance and verification functions for our staff. After the training session, we had the ability to take responsibility for our current critical equipment. But what would we do about any new equipment?

Adding to the list

Did you ever buy a piece of equipment, such as a vacuum cleaner, and it wasn't exactly right? To prevent this in our dental practice, our staff must prepare the user requirements and specifications for each type of equipment considered before the purchase, which is done through our change management process. This change management process was designed to meet the intent of ISO 9001:2000 clause 5.4.2, QMS planning.

Equipment is an integral part of our QMS, and as such, any changes to equipment have the potential to compromise the integrity of the QMS. Thus, equipment changes must occur in a planned and controlled way.

So, in using our change management system, we consider:

- What is the intent of the equipment?
- Does it need a particular voltage to work?
- Does it output anything (such as light curing)?
- How is that output measured?
- Will it fit in the space available?
- Does it require a certain amount of space as an air buffer?
- Can we afford it?
- What's the cost and benefit of purchasing it?
- What are the maintenance requirements?
- Will the equipment provide any type of measurements? If so, in what units and to what accuracy?
- Are there calibration requirements? If so, how we will manage those calibration processes with regard to ISO 17025?

For example, ISO 17025 provides the specifications for calibration laboratories. Although our dental practice is not a calibration lab and does not calibrate in house, any new equipment that may need calibration to a true standard may need to be sent out to an ISO 17025-accredited lab on a periodic basis. The accreditation to that standard may be part of our vendor qualification process for the calibration lab.

At this stage, there is much to consider. This is best done during a brainstorming session with all potential users—not only the dentists. In some ways, the dentists might be somewhat removed from the actual use of the equipment, and might actually be considered customers of this brainstorming session. In that case, the group will need to listen to that voice of the customer, who might simply say, "I need the equipment to do this."[2]

We take brainstorming seriously, however, so we try to generate a storm and not a light drizzle of specifications and requirements. After we get a healthy list, the team can go through the feedback and establish the specifications and requirements necessary.

At some point, we will finally have the equipment (which was obtained from an approved supplier) and now we want to use it. Gone are the days when a dentist could just plug it in and hope for the best or put the responsibility on the vendor to do it right.

Following protocol

In an effort to manage the implementation of the equipment, our practice's research led us to use a protocol of qualification that includes installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ).[3]

IQ: For us, IQ means inspecting the equipment when it comes in the door. Is it in good shape? Is anything broken? Are any parts missing? Are there any assembly problems? Did it arrive on time? This inspection is documented and maintained in the EF that will be created for this piece of equipment. Further, and more importantly, the equipment will then be installed according to the manufacturer's instructions. We identify the installation requirements, capturing them on a form we check off as we go. This includes requirements that address leveling, space, voltage and atmospheric recommendations.

OQ: After a satisfactory IQ, we move to the OQ. Again, we determine all the OQ tests, prior to executing them. The tests are linked to the requirements and specifications we generated prior to the purchase of the equipment with the intent of answering, "Does this equipment do what it's supposed to do?"

For example, if we are buying a new dental chair, one specification and user requirement might be that it consistently moves up and down, many times a day and many days in a row. In testing, the chair goes up and down enough times to simulate perhaps one week's worth of use. In other words, we try to stress the equipment.

Are there other tests that we might consider? Sure, and we know those tests by examining the user requirements and specifications we generated some time ago, looking to see if anything lends itself to a test of some sort. We assume nothing.

For example, if a light is supposed to illuminate when the chair is operating, we ensure it is illuminated and document the result. If the headrest is supposed to be adjustable, we ensure it is and document it.

PQ: After a satisfactory OQ, we move to the PQ to demonstrate that the equipment will operate satisfactorily under normal and boundary use. We take the OQ one step further by expanding those tests to simulate actual performance. In keeping with the dental chair example, we might find people of varioius body types—a child, an average adult and a large man—who will be lifted in the chair, and we repeat the OQ we did earlier, except with these people. We might not even need humans—we could use analogous weights.

All of the documentation of this qualification will go into the EF. When the equipment is ready for use, our change management process drives us to update all procedures to include the MEL and maintenance schedules for the equipment. When all of these changes are completed, the entire file is reviewed, including the change management and qualification documentation, and the equipment is released to the live environment. This release date is documented in the EF.

Any problems with the qualification are brought to the attention of the vendor for its complementary fix, and such documentation is filed with our vendor approval files, which are part of our purchasing management system. When such problems arise, the equipment is not released into service until an adjustment or repair is made, and it is requalified using the same protocol.

As healthcare providers, our patients trust us to have their best interests at heart, and they believe we will ensure all conditions are acceptable and even optimal for treatment. As such, we are ultimately responsible for our equipment.

Often, dentists and doctors mistakenly allow vendors to install equipment, while the healthcare providers provide no oversight or approval for the protocol used. For us, it's fine to have the vendor do the IQ-OQ-PQ in our office, but we still must approve the vendor's plan for qualification and the results of that qualification.

Breakdowns will occur

We take all these steps to have qualified equipment that meets our needs and our patients' needs. That equipment is maintained and verified just as the manufacturer prescribed. But that doesn't mean it won't occasionally malfunction.

When that happens, we take that equipment out of service. We complete an equipment malfunction form that will become part of that equipment's EF. In some cases, we can perform the repair on our own. Sometimes, it's an opportunity to have a nice visit with Bob. In either case, once the equipment is repaired, we determine whether an

ANOTHER CASE STUDY
Visit www.qualityprogress.com to read a January 2009 QP article called "ISO-lating the Problem." It chronicles how two healthcare organizations used ISO 9001:2000 to improve efficiency and the bottom line.

Our equipment management system **delivered immediate rewards** and saved us from **unnecessary downtime.**

IQ-OQ-PQ is necessary. This is at our discretion, but we shoot for the best we can do for an OQ and PQ.

The most important thing to remember is to ensure the documentation of the malfunctions. After all, you might see a trend that otherwise wouldn't be noted. We review the equipment malfunction forms periodically to detect such trends. Because our quality system is still in its childhood, our equipment management measurement has not yet graduated to the point of using statistical techniques, such as mean time between failures.

When currently examining trends, we look for time elapsed between problems (frequency of occurrence), similarities among the identified problems and impact of problems—even across equipment, similar to a weighted Pareto analysis. For example, blown bulbs in the dental light might be indicative of a circuit problem. Repeated bulb problems in different lights might point to a facility problem. We keep spare parts in one place to avoid spending money on parts that we already have.

The bottom line

What's been the big impact? We have reduced the annual cost of equipment repair visits by 67%, which has led to gains in efficiency we can use to keep patient costs stable. Additionally, we have more time to focus on the core service of dentistry because staff members are not distracted by performing in-house fixes or calling Bob.

For example, the vacuum system that operates our dental units malfunctioned every two weeks. In turn, the equipment used by our dentists and hygienists had less suction for patients receiving treatment. This limited or even halted production while staff struggled to make the system operable again. After getting the manual for the system and implementing the equipment management system, that issue has virtually disappeared.

That's just the beginning. The equipment management system functions have become an integral part of our newly established QMS by providing the staff with more autonomy, more responsibility and more empowerment. This QMS structure, coupled with these new staff attributes, is integral to the practice's mission: "Through persistent attention to our patients, we will deliver affordable and exceptional dental care from childhood to adulthood in a compassionate setting."

Fewer surprises

Our dental practice's comprehensive equipment management system delivered immediate rewards and saved us from unnecessary downtime. It has changed our day-to-day operation from reactive to preventive. With prescribed maintenance functions, comprehensive qualification and defective equipment management, our workday has become much more predictable, unencumbered by surprise equipment problems.

For us, it was a lot of work, because it was part of our first foray onto the quality management stage. So far, the show has been good. We understand that we don't need to spend as much time with our equipment repair technician. We choose to see other people instead, such as patients. It's not that we don't think of Bob. In fact, we just sent him a postcard and wrote: "Enjoying our work. Glad you're not here." QP

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DINA NUHFER is a dentist in North East, PA. She received her doctorate from the school of dental medicine at the University of Pittsburgh. ASQ's Erie, PA, section recently recognized Nuhfer's practice for its commitment to patient care as evidenced by the success of its QMS.

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Quality for Life™

Quality for Life is an exciting new program developed by ASQ to share the stories of quality professionals for whom quality is more than a profession. These individuals personify social responsibility; using their passion, commitment, and skills to make a difference in their communities and throughout the world.

The picture above exemplifies the spirit of the Quality for Life initiative. Stephen Hacker, ASQ board member, has helped coach government leaders in the African country of Botswana, which has led to effective and efficient governance. Botswana has been ranked Africa's no. 1 county for transparency and absence of economic crime, no. 1 in annual GDP growth over the past decade, and the country enjoys an 80-percent literacy rate.

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STORIES CAN ALSO BE SUBMITTED TO **qualityforlife@asq.org.**

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Theme

The world is ever-changing, but quality's ability to have a positive impact on the world is constant. The range and scope of how and where quality can be applied is constantly growing, and it's spreading into more and more aspects of our work and our lives. The fundamentals of quality haven't changed much over the years, but our openness and awareness of where and how quality tools, techniques, and philosophies can be applied has.

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BY DILIP SHAH

Balanced Budget

A well-rounded approach to documenting measurement uncertainty

IN THE LAST edition of this column (March 2009, p. 52), I discussed Type-A and Type-B contributors of measurement uncertainty and what goes into a measurement budget. In this installment, I will outline a process for building that budget.

The process follows seven steps:

1. Identify the uncertainty contributors in the measurement process and classify the uncertainty as Type A or Type B.[1]
2. Assign one of the four distribution types to uncertainty contributors (normal, rectangular, triangular or U-shaped).
3. Convert the magnitude of the uncertainty contributor to standard uncertainty (see Table 1).

Typical uncertainty contributors that should be considered for any measurement process (calibration or test) are:

Resolution of the unit under test (UUT).[2] Resolution is classified as Type B with a rectangular distribution. To convert resolution to standard uncertainty, the smallest division or digit of the instrument is divided by the square root of 12 if the information about the way the instrument resolves itself (how the digit increments or decrements) is known. If no other information is available, the resolution is divided by the square root of three.

The uncertainty stated for the calibration of the standard used to calibrate the UUT. This standard is normally calibrated by an ISO 17025-accredited laboratory (for traceable calibration) and is stated as an expanded uncertainty at $k = 2$ with a confidence interval of approximately 95%.

Because you normally would not know the combined uncertainty of the standard, it is considered to be Type B. To convert the expanded uncertainty to standard uncertainty, it is divided by the k-value on the uncertainty report. If the k-value is not provided, the uncertainty reported is treated as standard uncertainty.

The manufacturer's specification for the accuracy of the instrument. Equipment manufacturers state specifications in different formats, so the user has to interpret them correctly to apply the specifications to their measurement uncertainty analysis.

The specification or tolerance is treated as Type-B uncertainty and is normally assigned a rectangular distribution. To convert the specification value to standard uncertainty, divide it by the square root of three.

Personnel. Many test and calibration processes involve human interaction that can influence the test and calibration results. If the repeatability analysis is performed using statistical analysis, it is considered Type-A uncertainty and is normally treated as Gaussian (normal) distribution.

If the repeatability or reproducibility data is reported from published literature with no supporting data, it should be considered as Type-B uncertainty with a rectangular distribution.[3] The variation in method is normally captured in the repeatability data. In some cases, however, a separate analysis is required.

The environmental factors that have an impact on the measurement. Normally, one thinks of temperature (dimensional measurement) and relative humidity. But there can be other factors, including vibration (mass measurement), cleanliness (particle count), altitude and acceleration due to gravity (mass measurement).

The temperature measurements are normally cyclical in nature, and the distribution attribute of the cyclical pattern is U-shaped. The U-shaped distribution is converted to standard uncertainty by dividing the magnitude of the contributor by the square root of 2.

Converting to standard uncertainty / TABLE 1

Distribution	Divide by	Divisor	1/divisor
Normal	1	1.0000	1.0000
Rectangular	Square root of 3	1.7321	0.5774
Triangular	Square root of 6	2.4495	0.4082
U-shaped	Square root of 2	1.4142	0.7071
Resolution	Square root of 12	3.4641	0.2887

MEASURED RESPONSE

How does this process of building a budget stack up to your experiences? Is there more to add, or could it be simplified? Let us know by e-mailing your comments to editor@asq.org.

Measurement uncertainty budget / FIGURE 1

Company	Just Mike It!
Parameter	Dimensional—length
Nominal or range	0–1 inch
Primary equipment	0–1" micrometer
Personnel	I.M.A. Metrologist
Date	10-Mar-09
Standards used	Gage block

Type-A uncertainty

Uncertainty description	Uncertainty	Distribution	Degrees of freedom	Divisor	Standard uncertainty	Variance
Micrometer repeatability (0.9000" gage block)	28.2E-6	normal	9	1	28.2E-6	7.96E-10
				Combined Type-A uncertainty	28.2E-6	796.0E-12

Type-B uncertainty

Uncertainty description	Uncertainty	Distribution	Degrees of freedom	Divisor	Standard uncertainty	Variance
Gage block specification: +/- 0.000003 in.	3.0E-6	Rectangular	Infinite	1.7321	1.73E-06	3.00E-12
Coefficient of thermal expansion of gage block: 0.000006 in/in/C	10.8E-6	U-shaped	Infinite	1.4142	7.64E-06	5.83E-11
Micrometer resolution	10.0E-6	Resolution	Infinite	3.4641	2.89E-06	8.33E-12
Gage block uncertainty	1.00E-06	U (k = 2)	Infinite	2	5.00E-07	2.50E-13
				Combined Type-B uncertainty	8.4E-6	69.9E-12

Combined uncertainty results		Distribution	Divide by	Divisor	1/divisor
Type-A standard uncertainty	28.2E-6	Rectangular	Square root of 3	1.7321	0.5774
Type-A variance	796.0E-12	Triangular	Square root of 6	2.4495	0.4082
		U-shaped	Square root of 2	1.4142	0.7071
Type-B standard uncertainty	8.4E-6	Resolution	Square root of 12	3.4641	0.2887
Type-B variance	69.9E-12	Coverage factor (k)	Confidence level		
		1.00	68.27		
Type-AB (combined) standard uncertainty	29.4E-6	1.65	90.00		
Type-AB (combined) variance	865.9E-12	1.65	90.00		
		2.00	95.45		
Effective degrees of freedom	10.65	2.58	99.00		
Coverage factor (k)	2	3.00	99.73		
Expanded uncertainty	5.853E-05				

Comments (It is important to document all supporting information here)

Note: The laboratory temperature environment is 20 degrees Celsius +/- 2 degrees Celsius

Micrometer repeatability study

1	0.90007
2	0.90006
3	0.90005
4	0.90001
5	0.90003
6	0.90002
7	0.90002
8	0.90009
9	0.90001
10	0.90006
Sum	9.000419
Mean	0.900042
Standard deviation	0.000028
Degrees of freedom	9

If there isn't sufficient information to assign a distribution to an uncertainty contributor, ISO Guide 98:2008 recommends that you assign the most conservative distribution (rectangular distribution).[4]

Continuing the seven steps of the process:

4. Document your findings in an uncertainty budget.
5. Combine uncertainty using the root sum square method.
6. Assign the appropriate k-factor multiplier to combined uncertainty to report expanded uncertainty.
7. Document in an uncertainty report with the appropriate information.

It is good practice to document the uncertainty budgets using a spreadsheet template, which should be validated for calculations. One such example is shown in Figure 1. All spreadsheet cells with formulas should be protected from accidental alteration.

Measurement uncertainty budgets are estimates of the measurement error in a process and vary for the same piece of equipment or a process, depending on the laboratory's operating environment. Thus, it is not a good idea to adopt someone else's budget, as it may not be a true estimate of the user's measurement error. QP

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❍ Analyst	❍ Contractor	❍ Inspector	❍ Owner	❍ Six Sigma Green Belt	❍ Technician
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A Win-Win Situation

Benefit from ASQ's Fellows Mentoring Program

HOW WOULD you like to:

- Apply, reinforce and enhance your knowledge and skills?
- Tap into resources you'd forgotten you have?
- Uncover new opportunities through collaboration?
- Lead an individual toward discovering and achieving his or her potential?
- Be truly appreciated for what you do?
- Build prestige for your sponsoring professional society (ASQ)?
- Attain the satisfaction of being the person who guided the successes of another person?
- Learn a different life perspective—different culture, lifestyle, ethnicity and practices?
- Attain the above benefits with a minimum time expenditure and no monetary cost?

When I was invited to join ASQ's Fellows Mentoring Program, I signed on immediately. It was a no-cost opportunity to sharpen my knowledge and skills and focus my management, consulting and career-coaching experience on helping a person who wanted and appreciated guidance.

The person I mentor has management experience and a college education. He is striving to establish a consulting business in his native, English-speaking African country. New to ASQ, he took advantage of the mentoring program.

We have exchanged photos, talked once by phone and maintain nearly weekly contact via e-mail. Our exchanges are a mix of activity updates, document and strategy critiques, and personal chitchat.

Lucky for me, English is his primary language. His goal is to get large companies with in-country facilities to embrace environmental, health and safety issues and certification to ISO 14000, the environmental management standard.

We treat each other as **equals** with **common objectives.**

Initially, I worried a bit about whether I would be able to establish a relationship if the person I was assigned to mentor did not share a lot of the same concerns, issues and needs. I reflected on my less-than-enjoyable stint as an instructor for English as a second language. My expectation was to help U.S. residents learn English to enhance their job opportunities and eventually attain citizenship. It didn't turn out that way. Most of the people assigned to me were all non-U.S. residents whose motivation was to learn enough English to better enjoy their vacations in the United States.

Good matching process

For the Fellows Mentoring Program, ASQ's matching process worked well. The person I mentor needs the kind of guidance I can provide. He is a professional and belongs to ASQ. He has a compatible background and experience. We can, and now do, treat each other as equals with common objectives. Our mentoring relationship has been ongoing for nearly a year now, and we plan to continue.

The time I spend exchanging e-mails with him is 30 to 60 minutes per week. My only out-of-pocket expense was the postage to send him a copy of my *Certified Manager of Quality/Organizational Excellence Handbook*.[1] For this infinitesimal investment of time and money, I keep my knowledge updated and my coaching skills honed, help another professional and add to ASQ's reputation. It is an extremely rewarding win-win situation. QP

REFERENCE

Russell T. Westcott, ed., *Certified Manager of Quality/Organizational Excellence Handbook*, ASQ Quality Press, 2006.

CALLING MENTORS AND MENTEES

For information about the ASQ Fellows Mentoring Program, go to www.asq.org/members/communities/mentoring/about.html or contact Karen Prosser at kprosser@asq.org.

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Grab the Brass Ring

Financial crisis creates opportunity to contribute and shine

REMEMBER GOING TO the amusement park or the county fair and riding the carousel or merry-go-round? During the ride, there was sometimes a brass ring you could grab from a dispenser. It took some dexterity to snatch the ring from the dispenser as the carousel rotated. And not every ring was brass. There was a large number of iron rings and just a few brass ones. Getting the brass ring usually earned the rider some sort of prize.

In today's business world, we're taking

a ride on another merry-go-round. If you can catch the brass ring, good things can still happen to you: wealth, success or some other prize. For statisticians and other quality professionals, the brass ring is the opportunity to help their organizations create better bottom-line results through a continuing flow of successfully completed improvement projects.

The financial meltdown has created this imperative and opportunity. Statisticians and quality professionals are uniquely qualified and are arguably better positioned than any other profession to help deal with this crisis. The opportunity exists to use statistical thinking and methods and improvement processes, such as lean Six Sigma, to help your employer deal with this crisis. W. Edwards Deming admonished us that "survival is not mandatory." We live in difficult times, which are epitomized in the fable of *The Lion and Gazelle*.

THE LION AND GAZELLE

Every morning in Africa, a gazelle wakes up. It knows it must run faster than the fastest lion or it will be killed.

Every morning, a lion wakes up. It knows it must outrun the slowest gazelle or it will starve to death.

The moral: It doesn't matter if you are a lion or a gazelle. When the sun comes up, you better be running.

Process improvement advances

Things are different today in the field of process improvement. The profession has learned much during the 15 or so years since Six Sigma, lean and lean Six Sigma have produced millions—perhaps billions—of dollars in improvements around the world. Now is the time to rethink what we have learned and to put it to even more effective use to help our organizations respond to the financial meltdown. This could be our finest hour.

What has changed that can help us be more successful? Some important advances include:

- IT is making higher-quality data more readily available.
- We have powerful, more user-friendly statistical software that is well on its way to becoming ubiquitous.
- We have a better understanding of how to identify, select and execute projects that cross functions and add significantly to the bottom line.
- There is more awareness by management of the effectiveness of data-based approaches.
- There is better understanding of what is needed to get organizations to adopt data-based approaches.

But how do you harness these advances and get your organization to use them? *Approaches to Consider* summarizes some suggestions, and other details follow. Use these for what works in your environment and think about how you can implement the rest in the future.

Addressing cost pressures

Begin by providing leadership to your organization. Make a commitment to help the organization and do what it takes to deliver on this commitment. Explain every opportunity in financial terms, including impact and when it will appear in the bottom line. Find those hidden factories (hidden operations in processes beyond the factory floor[1]), which are the big sources of wasted effort that increase costs and decrease capacity.

Be proactive. Find projects and get support from management to form a team to work the project. Don't wait for someone to bring the project to you or invite you to join a team. Have a business focus: "This

is what I believe should be done, and this is what will happen to the bottom line when we are successful."

Be willing to take risks. High risks typically produce high rewards.

Have a sense of urgency. Remember that quick action can build credibility and enable work on the longer-term projects.

Get the support of upper management, form partnerships and find a Champion to help with the business and political issues.

Show me the money. Become a partner with the finance department folks and get them to determine what the projects are worth. Partnering with finance will not only help you determine what the project is really worth, but it will also provide an ally in defending the value of the project and help you follow the money to identify where large amounts of money are being spent. This usually turns out to be an opportunity for large financial improvements.

Remember what the prolific bank robber Willie Sutton said when he was asked why he targeted banks: "Because that's where the money is."

Quick wins, big impact

Focus on projects that will begin to return bottom-line results quickly—often before the project is even completed. In a financial crisis, we need to find quick cost reductions. Deming taught that improving quality typically reduces cost. High priority projects in these times are those that deliver bottom-line results quickly and in large amounts.

Look for these quick wins, otherwise known as low-hanging fruit. Improvements that are easy to implement can have a big impact. Quick wins are still out there because we live in a dynamic world. Murphy's Law and O'Toole's commentary (O'Toole says Murphy is an optimist) are alive and well.

Look for problems with the flow of information and materials, nonvalue added work and waste of all kinds that a value stream mapping exercise can identify. Where can speeding up the process have a big benefit? The flow of information and material occurs between steps in the process. Opportunities for improvement also exist within process steps.

The goal is to understand the value-adding transformation that goes on within the process steps and the associated cause and effect relationships of the process variables (*X*s) and the process outputs (*Y*s).[2]

It is also important to rethink the tools you use and recommend the organization adopt. Consider the following:

- Use define, measure, analyze, improve and control (DMAIC) as your framework for general purpose problem solving and process improvement.[3] A big benefit of DMAIC is that data collection and use is part of the framework and is expressly addressed in the measure step. DMAIC uses data-based tools (process stability, process capability, gage R&R studies, regression modeling, design of experiments [DoE] and statistical process control [SPC]), and knowledge-based tools (process maps, value stream maps, cause and effect matrix and control plans). As a result, subject matter and tribal knowledge is collected and used along with the hard data.
- The combination of data and process

APPROACHES TO CONSIDER

Make a personal commitment to help the organization succeed.

- Be proactive and provide leadership.
- Get the involvement of management and form partnerships.
- Quickly deliver bottom-line impact.
- Identify and implement quick fixes.
- Focus on improvement, not training, and make broad use of design, measure, analyze, improve and control.
- Develop and deliver your message for management.
- Re-energize lean Six Sigma.
- Analyze long-term performance of key process metrics for core processes.
- For the long term, prepare to expand the improvement approach to a holistic approach.

YOUR MESSAGE TO MANAGEMENT

When your organization is in trouble with rising costs, smaller revenues and smaller credit lines, consider approaching management with these messages:

- "A different approach is needed. Albert Einstein admonished us that 'the significant problems we face today cannot be solved at the same level of thinking we were at when we created them.'"[1]
- "A better way is to adopt scientific management and greater use of data. We have the tools. Now is the time to put them to work."
- "Some companies are already using data analytics to develop a competitive advantage."[2]
- "We have the software to collect and analyze the data."
- "We need to complete improvement projects and integrate the approach with how we run the business."
- "I suggest that we do the following …"
- Be ever vigilant for ways to save money and pursue new opportunities.
- Management commitment and involvement are needed. Training won't do it alone.

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knowledge produces process understanding needed for process improvement. You can't successfully improve or control a process you don't understand. DMAIC works in a variety of situations and cultures. It is easy to learn and easy to apply, and has a few key tools that are linked and sequenced with one another as part of an overall improvement framework. DMAIC is arguably the most effective and widely used problem solving and process-improvement framework in the world today.[4]

- Focus on improvement and problem solving tied to the bottom line. Methods such as lean Six Sigma, DoE and SPC should not be the focus. Improvement methods come and go, but improvement will always be needed, and bottom-line results never go out of style.
- It's about improvement, not training.

Training can help build the skills. As a primary organizational focus, however, training is a low-yield strategy.

> "Statisticians and quality professionals are **uniquely qualified to help deal with this crisis;** arguably better positioned than any other professional."

Review and regenerate

If your organization has been doing some form of lean, Six Sigma or lean Six Sigma for a few years, it may be a good time to review the direction and success of the initiative.

It has been known for some time that improvement initiatives go stale after a while, and regeneration every two to three years will keep the initiative fresh and focused. Now might be a good time to review your organization's project selection process and focus the initiative on cost reduction.

It is helpful to think early about your message to your management regarding what you are proposing. Each situation is different. *Your Message to Management* (p. 59) offers ideas on a place for you to start.

If all else fails, one strategy to get management's attention that has always worked for me is to get recent data on key performance metrics for one or more key processes. Plot the data over time using a combination of time plots and control charts. Almost always, important trends, shifts or cycles will be found that lead to significant improvements.

In one instance, a plot of the data

showed level changes in process performance that correlated with different operating shifts. Each shift reset the process when workers came on duty because "they knew how to run the process better than the other shifts." Standard operating procedures (SOP) were being ignored. Process variation increased significantly.

The plant manager was very upset when he saw the excessive variation and its root cause. He ordered an immediate return to SOP. A bottom-line improvement of $300,000 was realized from this simple, but elegant strategy: collect process data, create some plots, interpret what you see in the plots and take action.

Long term, you should consider using holistic improvement and leading the implementation of an overall improvement process that works everywhere in the organization—on all types of problems and processes. Holistic improvement may be the focus of the next generation of improvement methods.[5]

Grab the brass ring

Statisticians and quality professionals: Now is your time. You have the necessary knowledge, skills and experience. Grab the brass ring. Commit to yourself and to your organization to make a difference and deliver bottom-line results. Re-energize your focus on data-based improvement. Move with a sense of urgency to help your organization get ahead and stay ahead. QP

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3. Ronald D. Snee and Roger W. Hoerl, *Leading Six Sigma—A Step by Step Guide Based on the Experience With General Electric and Other Six Sigma Companies,* FT Prentice Hall, 2003.
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RONALD D. SNEE is founder and president of Snee Associates LLC in Newark, DE. He has a doctorate in applied and mathematical statistics from Rutgers University in New Brunswick, NJ. Snee has received the ASQ Shewhart and Grant medals, is an ASQ fellow and is an academician in the International Academy for Quality.

BY R. DAN REID

Major Upgrade

New FMEA manual offers more flexibility

THE NEW fourth edition of the Chrysler, Ford and General Motors (GM) *Potential Failure Mode and Effects Analysis (FMEA) Reference Manual*,[1] which was released last year, is a significant upgrade from the third edition published in 2001. It is available from the Automotive Industry Action Group (AIAG).

ASQ defines FMEA as "a systematized group of activities to recognize and evaluate the potential failure of a product or process and its effects, identify actions that could eliminate or reduce the occurrence of the potential failure and document the process."[2]

The new edition itself says FMEA is "an analytical methodology used to ensure that potential problems have been considered and addressed throughout the product and process development process (APQP—advanced product quality planning)."[3]

FMEA is an effective tool for quantifying risk so it can be analyzed, prioritized, mitigated and eliminated. FMEA can be applied in all types of organizations—from manufacturing to service. To be optimal, FMEA should be performed by a cross-functional team during product or process development as part of the APQP process.

Chrysler, Ford and GM first published the common FMEA reference manual in 1993 as a result of discussion during a 1988 ASQ Automotive Division conference. Suppliers at that conference reported to a panel of the original equipment manufacturing (OEM) purchasing vice presidents that there was money to be saved by harmonizing the various company-specific requirements existing at that time.

Subsequent supplier feedback indicated FMEA was one of the priority topics to work on, so committees were formed under the auspices of AIAG to begin work on this and a number of other projects, such as APQP, measurement systems analysis, production part approval and statistical process control.[4]

More flexibility

The two types of FMEA—design and process—are addressed in the new edition, along with three possible scopes—system, subsystem or component. There is more flexibility in creating and assessing risk with FMEA in this edition. Appendix A contains new optional forms: six for design FMEA and eight for process FMEA.

FMEA can be applied in all types of organizations—from manufacturing to service.

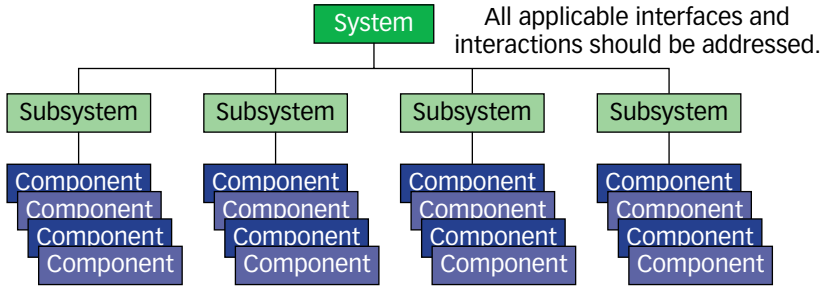
Users can choose forms that highlight certain relationships between the data—such as prevention controls to occurrence ranking—to facilitate sorting by date, to assist in determination of failure modes or to provide consistency between the process flow chart, the process FMEA and control plan. These replace one standard form for each type in the previous editions.

Earlier editions quantified risk solely by use of a risk priority number (RPN) calculated by multiplying ratings for severity (S) of problem by likelihood of occurrence (O), by likelihood of detection (D), or S x O x D = RPN.

In the years since the initial release of the FMEA reference manual, some automotive customers strongly emphasized supplier RPN reduction programs. In some cases, suppliers were mandated to work to reduce all RPNs under a certain value (40, for example).

Use of such arbitrary thresholds is not recommended in the new edition.

Failure mode effects analysis scopes / FIGURE 1



TIPS FOR EFFECTIVE FMEAs

A good failure mode effects analysis (FMEA) should:

- Be completed across to the right side of the FMEA form, which is the area for recomputing the risk after initial efforts have been taken to reduce the initial high risk rating in some cases—for example, risk priority number (RPN).
- List multiple effects for each mode and multiple causes for each effect. Generally, there is not a 1:1 relationship because any given failure mode could have many effects.
- List actions taken on high severity and high RPN or other risk ratings, aimed at preventing the occurrence of a potential failure. Responsibility for the actions taken should be assigned and tracked to completion.
- Include efforts to error-proof the design and process.
- Ensure that measurement uncertainty is known and adequate for applicable metrics.
- Identify characteristics that should be designated as special or critical on the control plan so actions can be planned and implemented to mitigate the effects of the potential failure. This should include reference to a contingency plan to protect your customer from receiving noncompliant product.
- Carefully consider the risk (for example, safety, quality, equipment and resource) and the efficiency of methods used, actions taken and contingency planning.
- Consider the major types of design failures (materials, processes, costs) or the major types of process failures (too much, too little, missing or wrong). —*R.D.R.*

Organizations should be working on the highest priority risks regardless of the rating criteria or values. High severity ratings should always be addressed.

Appendix C in the new edition offers other alternative risk analysis criteria for use with the FMEA. One interesting alternative is called SOD or SD. It is a non-arithmetic combination of the ratings shown earlier. For example, for severity = 6, occurrence = 3 and detection = 7, the SOD rating would be 637. The SD calculation is the same, excluding the occurrence value. So the SD rating for the previous example would be 67. The various SOD ratings would then be sorted in numerical descending order to get the highest severity scenarios at the top of the list.

Appendix D in the fourth edition lists some alternative techniques to FMEA for analyzing risk. These include failure mode, effect and criticality analysis, design review based on failure modes, and fault tree analysis. Examples of some of these are provided in the appendix. These techniques can complement the use of FMEA, but their use as a replacement for FMEA may be subject to customer approval.

FMEA scope

The fourth edition indicates that the scope establishes the boundary of the FMEA analysis.[5] The scope can be system, subsystem or component (see Figure 1). A system consists of many subsystems, which consists of many components. The links and interactions among parts within the scope and with other subsystems or systems also have to be addressed.

The revision lists a number of tools that can help define the appropriate scope, which should dictate the appropriate team membership. These tools include block diagrams, process flow charts, schematics and bills of material.

Other improvements

The suggested evaluation criteria for S, O and D ratings provided in the new edition have been enhanced to be more meaningful to real world analysis and use.[6] In some cases, they provide more consideration for the effects on the vehicle. They continue to provide 10 ranking options per table, which provides adequate discrimination for prioritization in the final calculations.

In addition to an index and list of helpful references, the revision, like previous editions, has numerous examples and diagrams to provide improved guidance. There is a new section on linking FMEAs to other documents, including the block diagram and the design verification plan and report.

Using the new benchmark FMEA process with these tips should ensure an effective risk mitigation process in your organization. QP

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4. See R. Dan Reid, "TS-16949–Where Did It Come From," *Quality Progress*, March 2005, pg. 32, for more background information.
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6. Chrysler LLC, Ford Motor Co. and General Motors, see reference 1, p. i.

R. DAN REID, an ASQ fellow and certified quality engineer, is a purchasing manager at General Motors Powertrain. He is co-author of ISO/TS 16949; the Chrysler, Ford, GM APQP, PPAP and Potential FMEA *manuals; ISO 9001:2000; ISO IWA 1; and AIAG's new* Business Operating Systems for Health Care Organizations.

MORE ON FMEA

Learn much more about failure mode effects analysis. Search for the term "FMEA" at QP's website at www.qualityprogress.com to find 56 articles on the topic.

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QP REVIEWS

Proving Continuous Improvement With Profit Ability

Russ Jones, ASQ Quality Press, 2008, 292 pp., $44 list, $26 member (book).

For the wealth of knowledge and guidance this book provides, it's a great bargain. And even if it wasn't, every manager in the manufacturing and service industries—including quality managers, those running continuous improvement projects and even financial managers—should have this book to study and apply the lessons found within.

While return on investment is addressed, the primary focus is return on assets (ROA), which, as Jones states, "is used to measure continuous improvement because it helps determine whether net profit and asset investment are in balance." With a focus on seven critical business elements, he recommends these goals for project teams:

1. Increase market coverage to increase sales dollars.
2. Reduce labor and nonlabor expenses per sales dollar.
3. Reduce lead times to minimize work-in-process inventory investment.
4. Minimize product and component inventory investment by reducing manufacturing and purchasing setup costs to reduce lot sizes.
5. Maximize capital asset utilization.
6. Control the customer invoice collection period to minimize the accounts receivable investment.
7. Maximize employee asset utilization by using project teams and training them to identify, evaluate and implement projects.

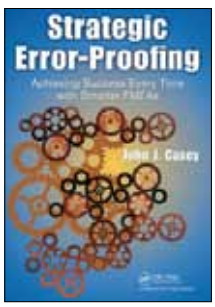
The author's argument is that with a systematic investment of people, time and money specifically devoted to continuous improvement initiatives, an organization can double its ROA in three to five years. The book also provides insight, guidance and tools for setting goals and empowering employee teams; techniques for evaluating and ranking projects; and how-to information, forms and charts.

Although this book addresses a number of concepts and methods with which many quality professionals are already familiar, it is unique in its integration of the concepts, techniques and tools, all while focusing on ROA. It is a must-read for serious continuous improvement practitioners.

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

Strategic Error-Proofing

John J. Casey, CRC Press, 2009, 135 pp., $34.95 (book).



John Casey is a veteran of the automotive industry, and this book is the result of his years of experience in the field. The book is clearly biased toward manufacturing, but with a little thought, Casey's strategy can be applied to processes in other industries.

Casey's success every time (SET) method is not the traditional approach of identifying and mitigating potential failure modes to avoid defects. He changes the paradigm from error detection and prevention to identifying what needs to go right to produce a good part and assuring that it does.

SET provides a roadmap for breaking down each process step into three levels:

1. Part—selecting and placing each part.
2. Setup—orienting and aligning parts using tools and fixtures.
3. Parameter—monitoring important parameters in which value is added to a part.

Casey advocates replacing failure mode effects analysis with his more proactive SET approach and then strategically applying error proofing at each process level.

Casey provides an excellent comparison of tools and terminology prior to describing SET and suggests numerous tools unique to SET that can help identify and rate error-proofing devices. Identifying what needs to go right and applying error-proofing devices to make sure it does ensures a good part is made every time. For operations, the easiest path becomes the correct path.

Anyone tasked with improving quality will want a copy of this book. Casey's approach is simple and pragmatic, but it requires a cognitive shift in the traditional approach to quality improvement.

Reviewed by James R. Kotterman
Michigan Manufacturing Technology Center
Plymouth, MI

Adrenaline Junkies and Template Zombies

Tom DeMarco, Peter Hruschka, Tim Lister, Steve McMenamin, James Robertson and Suzanne Robertson, Dorset House Publishing, 2008, 238 pp., $35.95 (book).

This is an unusual book, in style and in content. While the collaborative effort focuses on software development methods, the authors, who are

recognized experts in the discipline, try to emulate the work of architect Christopher Alexander. In his many books, Alexander identified a few hundred architectural patterns. The authors of this book use a similar approach, identifying 86 software development patterns.

In one of the sections, for example, the authors deal with what they call the data quality pattern and describe in two pages how it is not unusual for the quality of database software to exceed the quality of the data it processes. Companies tend to see an aggregate problem of software and data, and because the software is always easier to fix than the data, companies set out to fix or replace the software.

The chapter concludes with an apocalyptic description: "The major cause of declining data quality over time is change. This spoilage in the asset we call 'corporate data' can only be repaired by a manual fix. Imagining otherwise puts off the day of reckoning."

The book is fun to read, although the names of the patterns are a bit too creative and thus require some guessing as to their content and scope. The informal descriptive style makes this good reading, but some readers will find it necessary to organize the material in a different way for future reference.

Overall, this work is a fresh change from formal and structured books on software development. It shows that software development experts can also have fun and write in an accessible and thought-provoking way. Practitioners who want confirmation they are not alone in the trenches and academics interested in real-world applications will find it of interest.

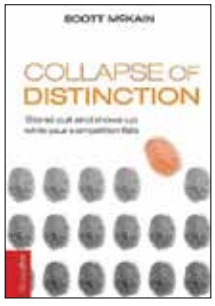
Reviewed by Ron S. Kenett
KPA Ltd.
Raanana, Israel

Collapse of Distinction

Scott McKain, Thomas Nelson (publisher), 2009, 224 pp., $24.95 (book).

In this book, McKain, chair of the consulting firm McKain Performance Group Inc. and of holding company Obsidian Enterprises, provides a pragmatic guide to helping businesses differentiate from their competition.

McKain examines how many American companies have found themselves in a



market of sameness, exemplified by his view of the customer experience in today's big-box retail, fast-food and insurance industries. He explains his cornerstones of distinction that will help businesses separate from the rest of the market.

These cornerstones include developing clarity of purpose and identity with customers, stimulating and steering creativity within an organization, effectively communicating what a business is about and what it stands for, and focusing on the experience of the customer.

McKain integrates useful, practical suggestions that help connect the concepts with his target audience, which is senior-level executives and board leadership. In doing so, he eschews the glib tone commonly found in so many management guides.

McKain adds situational examples of how firms he has worked with have succeeded by using his ideas. The suggested supplemental readings and website resources further enhance this work, which rises to the top of the heavily saturated management and leadership genre.

Reviewed by Dale Farris
Groves, TX

RECENT RELEASES

Process Improvement Using Six Sigma

Rama Shankar, ASQ Quality Press, 128 pp., $31 list, $18 member (book).

The Advanced Materials Revolution

Sandford L. Moskowitz, Wiley and Sons, 255 pp., $74.95 (book).

The Supply-Based Advantage

Stephen C. Rogers, AMACOM, 368 pp., $39.95 (book).

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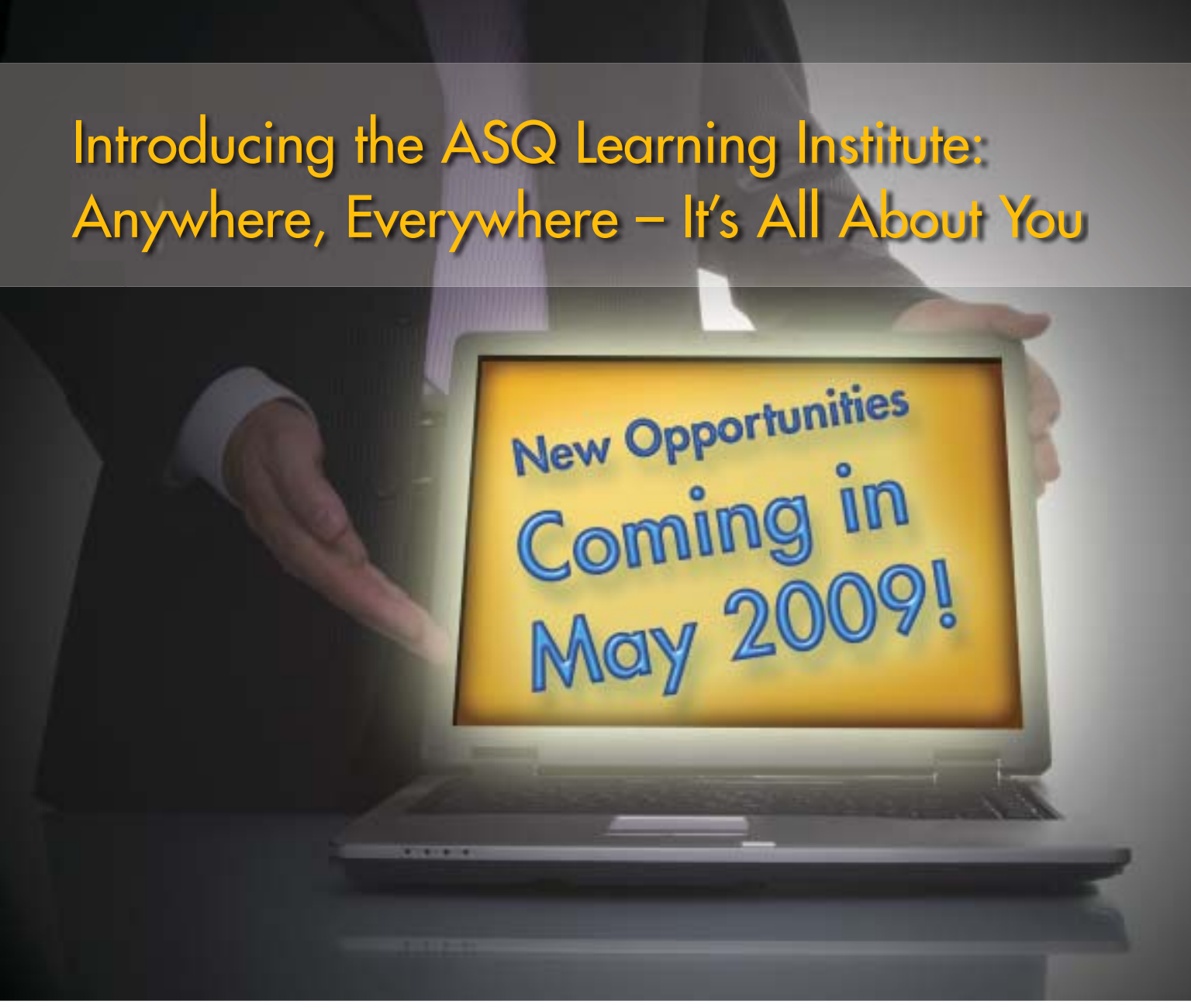

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Sample Wise

Settling on a suitable sample size for your project is half the battle

SELECTING THE correct sample size is often the most difficult aspect of any project. Rules of thumb are important because they promote discussion that facilitates the selection of an optimal sample size.

The three key components of sample-size selection are:

1. How accurate or confident you need to be: This is based on the alpha/beta error you select. If we need to be only 50% confident (flip a coin: $\alpha = 0.5$), then the next two components don't matter. A sample of one would suffice.
2. How precise you need to be: Precision relates to the ability to understand the variation in the data. If the data can't vary at all, then the other two components don't matter. Again, a sample of one would suffice.
3. The differences you are trying to measure: Larger differences allow for easier decisions. If the differences you are trying to measure are enormous—for example, red versus blue or 0.1 versus 100,000—then the other two components don't matter. A sample of one would suffice.

Of course, assumptions always apply, and many other considerations affect sample-size selection.

These considerations include: sampling cost, purpose, approach, method, capturing a reasonable amount of data variation, the type of model being developed, the underlying data distribution—such as normal or exponential—and the type of statistical tools being used.

Rules of thumb

I developed and named all but the last rule of thumb in the following list:

- Trial-and-error sampling (≥ three samples): Pick three pieces of each sample to compare new and old data to be approximately 80% confidence in the results.
- Design of experiments sampling (≥ eight samples): For most manufacturing situations in which differences to be tested are typically large (reasonable extremes), test costs are relatively high and desired statistical confidence is low (for example, turning knobs on machines). A Taguchi L8 or 2^3 full factorial design will likely produce high-confidence results using only eight or more samples.
- Central limit theorem (CLT) sampling (≥ 30 samples): Picking samples in groups of 30 or more will take advantage of the CLT and will ensure data normalcy in the distribution of those groups. Note that a single sample of 30 doesn't use the CLT.
- Reliability sampling (60 samples): Per Beta tables, 60 samples without any failures equates to 95% confidence in 95% reliability.
- Shewhart sampling (≥ 100 samples): When developing statistical process control, Shewhart recommended that 25 sets of four samples be taken as a rule of thumb to assess process stability.
- Human survey sampling (≥ 500 samples): To capture a reasonable amount of human variation—such as race, religion, location, sex and age—rules of thumb vary between 500 and 2,000 samples.
- STRUT sampling (various): Calculated using a formula outlined in "STRUTS: Statistical Rules of Thumb,"[1] in which

$$n = \frac{16}{\Delta^2}$$

and

$$\Delta = \frac{\mu_1 - \mu_2}{\sigma}.$$

There are **lots of ways** to accurately calculate **sample sizes.**

Some advice

Again, use these rules for planning and discussion purposes only. They might not apply to your situation. There are a lot of ways to accurately calculate samples sizes. Statistics books have parametric formulas and tables for just about any distribution type, or you can do an internet search for "sample size calculator." Additionally, you can use the rule of threes outlined in Tony Gojanovic's QP article.[2] QP

REFERENCES

1. Gerald van Belle, "STRUTS: Statistical Rules of Thumb," Departments of Environmental Health and Biostatistics, University of Washington, 1998.
2. Tony Gojanovic, "Zero Defect Sampling," *Quality Progress*, November 2007.

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