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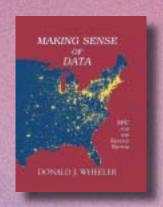
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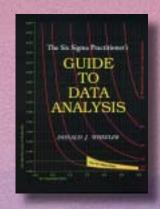
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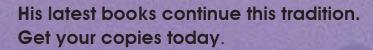
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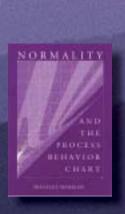


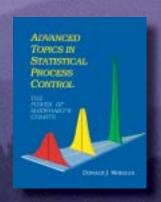


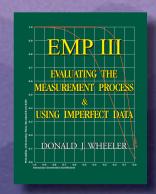


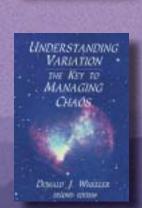
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### **UPFRONT**



# QUALITY PROGRESS

# Love It/Hate It

### Six Sigma has its fans and its foes

**NOTHING STIRS UP** controversy within the quality community quite like Six Sigma. Based on letters, comments and articles, I think it's safe to say Six Sigma might just be one of the most revered—and possibly one of the most reveiled—quality methods to date.

Its detractors cite the approach's rigidity, saying it hinders innovation and creativity required for breakthrough improvement and invention. Proponents credit it with streamlining processes, reducing defects and saving companies millions—even billions—of dollars.

And even though it's been widely deployed throughout industry for more than a decade, some still refer to Six Sigma as a "flavor of the month." Whatever that means, and whether it's true, the fact remains that Six Sigma's use is still widespread—even more now that it's combined with lean.

Will Six Sigma survive into the next decade? The answer to that question seems to depend on who you ask. Two articles in this issue offer different looks at pros and cons of the method.

In "Critical Stage" (p. 22), author A.H. "Jack" West looks at Six Sigma's impact and offers six ways quality professionals can ensure its continued effectiveness. In "Tune Up" (p. 16), authors I. Elaine Allen and Thomas Davenport advocate using Six Sigma—at times combining it with other improvement methods—to maximize effectiveness and achieve optimal results

"Overall, an organization must be prepared and skillful to deploy variations of process management initiatives—implementing disciplined process management tools such as Six Sigma but also valuing disruptive innovation and change to develop new products and processes," they write.

Where do you stand? Have your opinions on the method changed over time? Has Six Sigma succeeded or failed in your workplace? What are Six Sigma's greatest strengths, and what are its future challenges? To weigh in on the Six Sigma debate, use the "comment" tool on these articles' pages at www.qualityprogress.com, e-mail editor@asq.org or visit the QP discussion board.

As debate rages over U.S. healthcare reform, we've added an audio interview with former Treasury Secretary Paul O'Neill to QP's website, www.qualityprogress.com, where he discusses ways to improve healthcare quality and advocates striving for perfection. An outspoken—and well spoken—leader, O'Neill's comments will reinspire the "good isn't good enough" belief inherent in quality professionals. The print interview, published in June, can also be accessed via the home page. QP

Seiche Sanders

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idre sanders

# INBOX

QUALITY PROGRESS

The following letters were posted using the comment tool on the QP website. To share your thoughts on QP articles, visit www.qualityprogress.com.

### Where's the care?

In his article ("Dare to Care," July 2009, pp. 34-41), Janusz Godyn makes a lot of good

points. One of the things I have pushed, but with little success, is to measure quality of care by monitoring the actual outcomes as compared to the planned outcomes. Doing that would minimize one concern Godyn mentions:

"The results of the treatment would be compared to a benchmark to judge quality of care. The relative results of the treatment would form a quality score ... However, quantitative measurement of medical outcomes is difficult. As a result, hospitals and overseeing institutions also tend to focus on compliance with processes that are believed to instead lead to higher quality of care ... This model shares the first model's weakness: The comparison of best evidence-based practices requires two medical cases to be extremely similar. Unfortunately, the multidimensionality of the problem confounds comparability."

I agree with his statements and offer the measure of what was planned for outcomes compared to what actually happened. This should account for the differences in patient demographics and the difficulties inherent in comparing to best-practice protocols and measuring the quality of care directly.

I would also suggest using a performance index of several measures. This index would be the result of examining a variety of areas and then weighting them to account



for relative importance. These measures could be used mostly for quality of care but also for quality of service.

Marvin M. Christensen Baton Rouge, LA

For more letters on Godyn's article, visit the Inbox section at www.qualityprogress.com.

### **Culture change**

Excellent point put forward by Peter Sherman and James Vono ("All Ears," July 2009, pp. 16-23), followed by a succinct management accounting refresher.

Unfortunately, in the world dominated by Jerry Maguire-style management, with a mantra of "Show me the money," the Joseph Jurans and W. Edwards Demings of the world go to Japan to use quality principles.

The sad part of today's business culture is that quality is left to a few engineers and engineering managers in the lab or on the manufacturing line, where they are limited to creating reports or graphs that don't spell out business issues and cost impacts.

My take is that the problem lies on both sides of the table (management and quality professionals). Everyone needs to see quality as an integral part of the business, with real costs associated with it—the lack of it—be it from inefficient processes, rework, poor customer satisfaction or market-share losses due to recalls or regulatory issues.

It's high time to change the perception from "quality is engineering's business" to "quality is everyone's business."

> Shree Balachandran Melbourne, Australia

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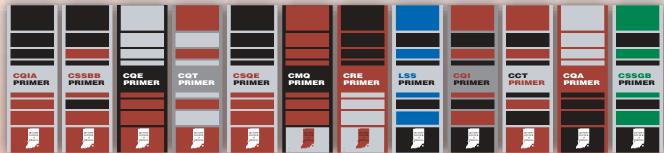
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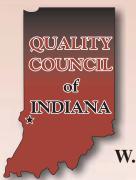
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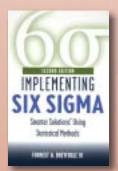
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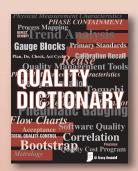
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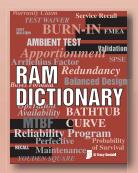
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# PERTANSWE

### Who's accountable?

Q: I need a point clarified about accountability in a learning organization. In a recent QP article ("Know Thyself," April 2009, pp. 30-36), Robert Warda wrote, "there is no shortage of accountability ... [it] just manifests itself in different forms."

Such as what? What does accountability look like? How do you foster an environment that supports an understanding that to take risks means that sometimes we fail, yet still hold individuals accountable for poor performance? Maybe the better question is: How do you differentiate underperforming employees from people who took risks and who might not have succeeded?

> Andrea Hufstedler Quality assurance Boehringer Ingelheim Roxane Inc. Columbus, OH

A: You raise a very interesting and difficult question about accountability—one that is still very much on the minds of leaders across all types of organizations.

To me, accountability falls into two broad categories: behavioral and resultsoriented. Behavioral accountability includes categories you typically see in situations involving HR (policies or procedures). As vou know, there are countless books and papers written about this, and it was not really related to the focus of my article. But, my two cents is that the best organizations use methods that are meant to correct the behaviors and not be punitive in any way.

My article mentions accountability in terms of being results oriented. In that case, the focus is on what was learned and what will be done differently the next time around. Implicit in that statement is that the person who made the "mistake" will continue to be accountable to get the

expected result. Their engagement and obligation continues. The role of the leader in that situation is to help ensure employees learn the correct lesson and that the outcome isn't repeated.

In learning-oriented organizations, the person who erred would also be responsible for sharing his or her failures with the rest of the organization so others can also learn from it. Being "obsessed" with failure means we highlight and celebrate them as opportunities to learn and fix issues, particularly if we can avoid them in the first place.

Remember, it was Thomas Edison who said, "I have not failed. I've just found 10,000 ways that won't work."1 The parts of this process that are critical are the dissemination of lessons learned (good and bad) and the mentoring that takes place to continue to work on the problem and not make the same errors more than once.

> Robert P. Warda Administrator, research operations Mayo Clinic Rochester, MN

### REFERENCE

1. QuoteDB, www.quotedb.com/quotes/1351.

### **Reduction explanation**

O: As a quality professional, I see "cost reduction" as a broad term that offers many opportunities for organizational improvement—from design concept to product disposal. But in the real world, cost reduction and workforce reduction have become synonymous. Why? I don't think management knows the difference.

> Inam Ur-Rahman Quality system specialist Philadelphia

A: I agree with your broad-scoped definition of cost reduction. In truth, there are

multiple components behind an organization's expenses and its opportunities to reduce those expenses.

To some degree, it appears your question is rooted in, or springs from, a perspective of a manufacturing environment. After spending 25 years in manufacturing, I'm all too aware that cost reduction does, indeed, have a broad definition. This isn't the case in the service sector, however, where so much of an organization's budget depends on labor.

One way to get a perspective on this question is to consult the Bureau of Economic Analysis, which is a warehouse for Gross Domestic Product (GDP) data.1 Take a look at the manufacturing sector, and the light starts to shine on the case in point.

Comparing the GDP numbers for 1959 and 2008, you find some very sobering data. In 1959, manufacturing was 26.1% of the total GDP. In 2008, manufacturing was 11.5%. This represents an approximately 56% reduction of the GDP coming from manufacturing. There are many conclusions that can be drawn from this, but one thing that stands out in particular is that more of our economy is rooted in the service sector.

For another perspective on this guestion, especially if you are in the service industry, consult your organization's CFO. Ask the CFO about budgets and what percentage of the operating budget is devoted to labor. You may be surprised by the answer.

In some service areas, labor may occupy in the neighborhood of 80% of the budget. When this is the case, cost reductions need to be associated with labor. If a business is not manufacturing oriented, there are no raw materials—none to procure, none for which you can substitute a less-expensive alternative.



### Being "obsessed" with failure means we highlight and celebrate errors as opportunities to learn.

Management is in the difficult position of needing to make the hard decisions to keep organizations afloat in difficult times. As such, it needs to work with what it has. If the bulk of the budget is occupied by labor costs, when it comes time to reduce the budget, there is no alternative.

> Keith Wagoner Certified quality engineer Charlotte, NC

### REFERENCE

1. Bureau of Economic Analysis, "Gross Domestic Product: First Quarter 2009 (Final)," www.bea.gov/newsreleases, national/gdp/2009/pdf/gdp109f.pdf.

### FOR MORE INFORMATION

Snee, Ronald D., "Grab the Brass Ring," Quality Progress, May 2009, pp. 58-61.

### Finding value

Q: In the July 2008 edition of QP, the author of the letter "Predictable confusion" (Inbox, p. 11) uses the term "confidence interval" and provides the following example: "A 95% confidence interval on a mean signifies there is a 95% chance the population's average will fall within values predicted by the sample data."

What raises my curiosity is that the use of the words "chance" and "will fall" can be a little confusing. Why? Because if we have a certain population, it will have a certain average. It is fixed, even if we don't know its exact value. If we choose

any interval, we can't really calculate the chances of an average value falling within its range. Average value either is or isn't in that interval.

I have read that although a Bayesian approach allows for the expressions used in the letter, the classic approach does not.

Andrzej Proniewicz Student of quality management Poznan University of Technology, Poland

A: When speaking of populations, you are correct; there are no chances or percentages. But confidence intervals and prediction intervals are calculated from a sample and not the population. Remember, statistics is about making estimates of the population based on a sampling of data.

In reading your question, I now realize that even though it is acceptable to say there is a "95% chance that the population mean will fall within the confidence interval," the reverse is a more accurate statement. Here's how it should be phrased: "There is a 95% chance the confidence interval will surround or include the population mean."

You are correct in saying a population will have a certain average. If you take the time to measure the entire population, you can calculate that average. When taking a sample, however, the sample average will

not precisely equal the population average. The confidence interval is a function of the sample average, the sample variation, sample size and a degree of confidence (in this case, 95%).

Let me further try to explain this by using an example. Let's say you are doing a study to determine the average height of a Polish citizen. You measure the height of two Polish citizens and obtain an average. How confident are you that your calculated sample average is representative of the population average?

You're unsure, so you increase the sample size of your study and measure every Polish citizen except for the ones that are currently out of the country. Now how confident are you that your sample average is representative of the population average?

Calculating a confidence interval on your sample mean will quantify the concept just described. Almost all statistical software will be able to do this calculation for you, and you should be able to find out how to do this in most statistical textbooks. If the university has a copy of Juran's Quality Handbook, the section titled "Basic Statistical Methods" has a very good explanation of confidence intervals.1

> Dave Carroll Quality assurance engineer Panduit Corp. Tinley Park, IL

### 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.

### REFERENCE

1. Joseph M. Juran and A. Blanton Godfrey, Juran's Quality Handbook, fifth edition, McGraw-Hill Professional, 1998, section 44, p. 44.42.

# KEEPINGCURRE

### Permanent Residency

### **U.S.** regulators hope to improve China's exports with office in Beijing

By opening an office in Beijing and establishing a permanent, physical presence in a country under great international scrutiny for its exports, U.S. regulators are hopeful they can ensure Chinese products are safe for Americans.

Plans for the U.S. Consumer Product Safety Commission (CPSC) to establish its first permanent office in China's capital city must be approved by the Chinese government, but the office is ready to open next month.

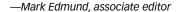
"I naturally feel it is a step in the right direction, and it will give agencies and manufacturers in China an immediate point of contact for questions and direction regarding consumer product regulatory requirements, without having to somehow try to communicate with Washington, D.C.," said Randall Goodden, chairman of ASQ's product safety and liability prevention interest group.

These U.S. regulators plan to educate Chinese manufacturers about new requirements under the Consumer Product Safety Improvement Act, which went

into effect in August. The act imposes tough standards for lead and chemicals in products intended for children age 12 and under.<sup>1</sup> Goodden, who visits China regularly to conduct product safety and product liability prevention seminars, said the Chinese government was already looking to improve the way its manufacturers complied with regulatory requirements. The government has invested in new testing equipment and inspection capabilities for inspectors visiting each province, he said.

John Surak, a food safety consultant and ASQ member, said the proposed CPSC office in Beijing "shows that the U.S. is serious," but U.S. companies should also be serious about importing products from China.

"It's a good idea, but I don't think this takes care of all the problems," Surak said. "Companies importing from China have to take on the responsibility to ensure that products are safe. You can't just do everything by e-mail. You have to have people go over there and be there and do audits."



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**MANUFACTURING** 

### SURVEY: MANUFACTURING EXECS CAUTIOUSLY OPTIMISTIC

As the economy struggles to gain momentum, 57% of manufacturing executives are cautiously optimistic about the outlook for the next six months, and more than two-thirds (70%) plan to keep staff levels steady, according to a recent survey by Baker Tilly.

While many executives are guardedly optimistic, there are pockets of pessimism, especially among small companies, according to the survey.

Executives are more pessimistic about the outlook for the

manufacturing sector than the economy, with slightly less than half (47%) expressing optimism.

The key factor dampening the manufacturing outlook is the lack of customer demand, which was cited by nearly half of respondents (45%) as the greatest challenge to the expansion of their companies.

For more on the survey, visit www.bakertilly.com/userfiles/ News%20Release-MfgSurvey-072109.pdf (case sensitive).





**DATA QUALITY** 

### **BUSINESSES STILL STRUGGLE** WITH DATA QUALITY

Large businesses continue to struggle with measuring and maintaining data quality, according to a recent Pitney Bowes report.

While many survey respondents said good quality data was a major corporate asset, they also admitted that measuring and improving data quality across a business remains challenging. The lack of interest from top executives was cited most often as the barrier to data-quality initiatives.

Of the companies surveyed, 37% said they have a data-quality initiative in place, and 17% said they have no plans to begin a data-quality initiative.

For more details from the report, titled "The State of Data Quality Today," visit http://gw.vtrenz. net/?hok8w99t1r.



**FUTURE OF QUALITY** 

### **NIST, ASQ HOST DIALOGUE** ON FUTURE OF QUALITY

Organizations and entrepreneurs that have achieved success through quality should be held up as examples so they can inspire others to pursue quality and organizational excellence and make a difference.

That's one of the messages that came from discussions among business, education and healthcare leaders at a recent summit hosted by the National Institute of Standards and Technology (NIST) and ASQ.

Leaders from high-profile companies and organizations such as Motorola, Google, IBM, Best Buy, Pfizer and Hewlett-Packard—participated in the event and talked about the future of quality and what directions quality can take to make a lasting impact on business and industry.

NIST and ASQ were preparing a complete report of the dialogue that took place at the June meeting and planned to release the report soon.

# Who's Who i

NAME: Nada Y. Fida.

RESIDENCE: Jeddah, Saudi Arabia.

**EDUCATION**: Fida holds a bachelor's degree in microbiology from King Abdul-Aziz University in Jeddah, Saudi Arabia, and a master's degree in total quality management from the Arab Academy for Science, Technology and Maritime Transport in Alexandria, Egypt.



**CURRENT JOB:** Fida works as a laboratory analyst for Saudi Arabian Airlines (the national carrier of the kingdom) Medical Services, responsible for its quality management system and preparation activities for certifying the laboratory to ISO 17025.

ASQ ACTIVITIES: Fida has been an ASQ member since 2007.

OTHER ACTIVITIES/ACHIEVEMENTS: Recently, Fida participated in the second Quality Conference Dubai. She has been appointed as a consultant for the International Academy for Training. She is a quality management systems lead auditor, certified by the International Registrar of Certified Auditors to ISO 9001, an environment management systems lead auditor to ISO 14001 and a professional certified trainer from Canada.

Fida is also a member of the Saudi Quality Council and the International Training Academy of Canada. To promote quality awareness among women in the Saudi community, Fida volunteers her time and speaks at public and private education institutions.

**RECENT HONOR:** Star lady of the week in the *Okaz* newspaper in June.

PUBLISHED: More than 30 presentations and lectures on different quality topics, including quality and education, in Saudi Arabia and the Arabian Gulf region.

**QUALITY QUOTE**: Quality professionals and practitioners must work hard to influence public opinion on the relevance and importance of quality issues. My personal and ultimate goal is to transfer methods and approaches from different cultures to enable successful implementation and deployment of quality programs and applications in Saudi Arabia.

# KEEPINGCURRENT



### **QUICK POLL RESULTS**

Each month at www.qualityprogress.com, visitors can take a short, informal survey, and we post the results.

Here are the numbers from the most recent Quick Poll:

### "What has the biggest impact on customer satisfaction?"

•	Quality of the product or service.	81.7%
•	Price of the product or service.	10%
•	Competition's offerings.	4.3%
•	Current economic climate.	4%

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

### "Is Six Sigma on the way out?"

- · Yes.
- No.
- · Can't predict.

### **BE SOCIAL**

There's more to QP online than just the magazine's website. Join the *Quality Progress* magazine group on LinkedIn, become a fan of *Quality Progress* on Facebook or follow QP editors on Twitter (ASQ\_Seiche, ASQ\_Mark, ASQ\_Brett and ASQ\_Nicole). It's just another way to stay connected to QP and other quality professionals to answer questions or discuss today's hot topics.

### **SHORTRUNS**

companies that certify recyclers of electronic equipment under the Environmental Protection Agency's Responsible Recycling Practices now can be accredited by the ANSI-ASQ National Accreditation Board. For more information, visit www. anab.org.

### **SKATEPARK OWNERS AND OPERA-**

TORS, as well as equipment designers and manufacturers, will be the users of a new American Society for Testing and Materials (ASTM) standard. ASTM F2334, Guide for Above Ground Public Use Skatepark Facilities, was developed by subcommittee F08.66 on sports facilities. The standard addresses basic safety and performance requirements related to skatepark equipment within an above-ground public skatepark facility. For details, visit http://astmnewsroom.org/default.aspx?pageid=1844.

**HEALTHCARE** 

### **JOINT CONFERENCE SET**

ASQ and the Society of Health Systems (SHS) are planning a joint conference early next year focused on healthcare quality and process improvement.

Healthcare quality professionals, performance improvement specialists and other healthcare professionals are invited to gather Feb. 25-28, 2010, in Atlanta for education sessions, daily workshops and the chance to network with one another.

SHS, a society within the Institute of Industrial Engineers, is the largest professional association focused on the needs and advancement of health-care performance improvement professionals and concepts.

More information about the conference and the related activities will be available in the coming months at www.shsweb.org and www.asq.org. **AWARDS** 

# FEIGENBAUM HONORED BY RUSSIAN QUALITY GROUP



The Russian Organization for Quality (ROQ) has awarded Armand V. Feigenbaum with the group's Ilyin Medal for his scientific expertise and contributions to quality management.

Genady Petrovitch Voronin, president of ROQ, awarded Feigenbaum the medal, which is named after Ivan Aleksandrovich Ilyin, a Russian philosopher and futurist considered

"the poet laureate of the modern Russian quality movement." Established in 2001, the ROQ is one of the newest quality organizations in the world.

### **ASQNEWS**

STUDY GUIDES Handbooks to help prepare for each of ASQ's 14 certification exams have been released. Each of the 14 handbooks is organized to reflect the respective bodies of knowledge and includes sample questions and exams. Prices of the books range from \$69 to \$139. Call ASQ at 1-800-248-1946 for specific pricing and ordering information.

**AUDIT CONFERENCE** ASQ's Audit Division will hold its 19th annual conference Oct. 15-16 in Tucson, AZ. The conference will focus on the auditor's role in achieving an effective audit result to provide management with accurate data to make decisions. Visit www.asq.org/conferences/audit/ index.html for more information.

**CGW AWARDS GRANT** The Partnership for Education in Ashtabula County (PEAC) in Ohio has received a \$15,000 Community Good Works (CGW) continuation grant, the largest education grant awarded by ASQ and the second CGW grant presented to PEAC for its community partnership

initiative. The program supports quality improvement efforts in five school districts. For more information about the grant criteria and application process, visit www.asq.org/communities/ good-works.

PACT WITH WUHAN ASQ has signed an agreement with the Institute of Quality Development Strategy (IQDS) of Wuhan University in China to cooperate in academics, project research and student involvement. As part of the pact, ASQ agreed to make its quality body of knowledge and related material available to IQDS. Find details at www.asq.org/media-room/ press-releases/2009/20090720wuhan-university.html.

**CONNECTING TO BRAZIL** Former ASQ President Jerry Mairani was a keynote speaker at the 10th International Congress for Change Management and the 14th Quality Awards event held recently in Porto Alegre, Brazil. About 2,500 people attended. ASO's Food, Drug and Cosmetic Division hosted an exhibit at the event, the first time it had done so in Brazil.

# **ASQ: HEALTHCARE**

**CAPITOL** 

**REFORM REQUIRES IMPROVEMENT TOOLS** 

Process improvement tools must be used to free up resources to meet the wide-ranging aims of healthcare reform efforts in the United States, ASQ representatives recently told members of Congress.

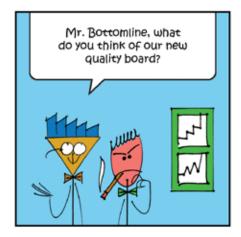
In a white paper delivered during recent committee meetings on Capitol Hill, ASQ outlined five areas of healthcare reform most in need of attention: waste, incentive alignment, IT implementation, sustainable culture change and workforce education.

Breakthroughs in healthcare reform can result from approaching the situation like a company might approach designing a new product that is less costly and more effective, ASQ contends in its white paper. The document was developed by the ASQ Healthcare Division as part of ASQ's advocacy efforts in Washington, D.C.

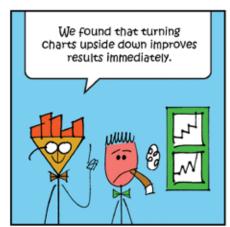
To read the paper or an executive summary, visit www.asq.org/advocacy/issues-actions/ 20090806-quality-healthcare-reform.html.

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

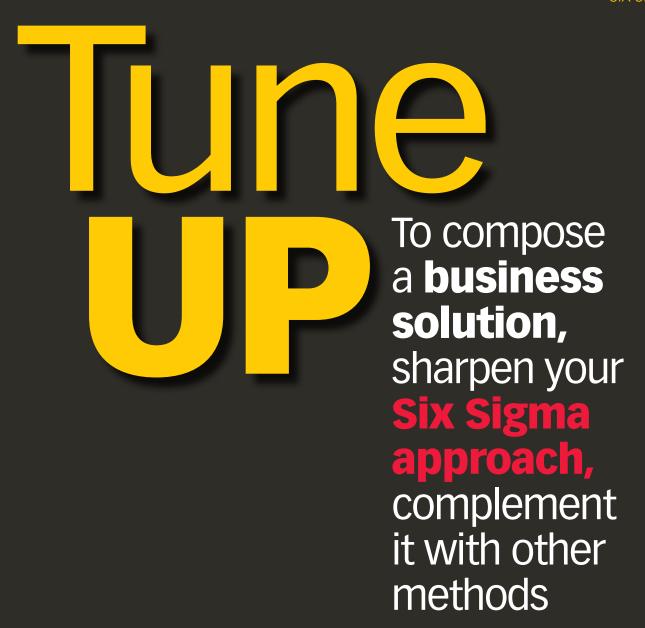
### Mr. Pareto Head BY MIKE CROSSEN











SIX SIGMA HAS many meanings. In its simplest context, Six Sigma can be defined statistically as the attempt to achieve near perfection by having no more than 3.4 errors per million opportunities or being 99.997% correct (or defect-free).

In business, Six Sigma can be defined more holistically as the total process an organization follows to achieve this near-perfection level with respect to defects, opportunities or some other measurable quantity. For some organizations, Six Sigma is simply an effort to streamline business processes. Many organizations in the past 30 years have embraced this broader notion of Six Sigma as a way to improve quality and reduce costs.

During the last 10 years, and especially in the last three, increasing criticism has been heaped on the Six Sigma approach. Specific criticisms include:

- · Six Sigma necessitates a top-down adoption process by senior executives.
- The lean philosophy has made Six Sigma unnecessary.
- · Six Sigma only can be implemented using a team approach and specially trained project teams.
- · There's extensive work and investment required to train and educate Green Belts (GB), Black Belts (BB) and Master Black Belts (MBB) about special terms and definitions for the Six Sigma process.
- · Implementing Six Sigma lacks an information systems approach.
- Six Sigma fails to give enough attention to (and sometimes ignores) the human factor in process change.
- Six Sigma can hinder innovation and strategic change.

Are these legitimate claims? Is Six Sigma in need of an overhaul? What can we do to sharpen the approach and make it more effective? After outlining a basic Six Sigma implementation, we'll further explore some of these downsides and offer a hybrid approach using Six Sigma and methods of process innovation.

### Six Sigma defined

Arguably, Six Sigma has become one of the most popular management methods since Motorola Inc. introduced it in 1986 as a statistical method to reduce variation in electronic manufacturing processes.

Today, the term Six Sigma is used as an all-encompassing business performance method all over the world in all types of organizations, institutions and corporations. In a Bain & Co. global survey of executives on management trends earlier this year, about one-third of executives reported their companies use Six Sigma.1

According to Motorola, Six Sigma has three different levels: its metric definition, as a method to achieve the 3.4 metric and as a management system.<sup>2</sup> Outside Motorola, of course, the term is used in many different ways.

Almost a decade after Motorola took the Six Sigma plunge, General Electric (GE) implemented the approach and made a well-publicized splash. Then-CEO Jack Welch contended Six Sigma had saved GE more than three-quarters of a billion dollars by 1998.3 More organizations wanted to dive in and were buying in to the concept, and Six Sigma became a branded corporate management initiative for manufacturers and others. Today, Six Sigma has become an industry in its own right, involving training, consulting and implementation of Six Sigma programs.

As a mathematical metric, Six Sigma can be used as a scale for quality. As a methodology, Six Sigma has evolved from a metric to a way to examine process improvement in an organization and understand how to sustain that improvement. This business improvement method focuses on:

- · Understanding and managing customer requirements.
- · Aligning key business processes to achieve those requirements.
- · Using rigorous data analysis to minimize variation in those processes.
- Driving rapid and sustainable improvement into business processes.

In its broad conception, Six Sigma became a total business system model for process improvement to help organizations:

- · Align their business strategies to critical improvement efforts.
- · Mobilize teams to attack high-impact projects for continuous improvement.
- Accelerate improved business results.
- Oversee these efforts to ensure improvements are

The most common, well-defined approach to achieving Six Sigma results is the define, measure, analyze, improve and control (DMAIC) process. This approach is similar to Walter Shewhart and W. Edwards Deming's4 plan-do-check-act (PDCA) cycle, but it has more well-defined stages.

DMAIC was designed as a method for leaders to prioritize potential improvement projects based on the probability that such projects would result in financial benefit to the organization,<sup>5</sup> making it a top-down approach to continuous improvement. The DMAIC process is deemed a success if, when implemented, it identifies and eliminates waste in an organization. It generally results in incremental (1% to 10%) improvements in the business processes (usually relatively small) where it is applied.

Techniques implemented within the Six Sigma process are neither statistically sophisticated nor necessarily high tech. Instead, they are consistent measures

### Six Sigma strategy and other process control methods can be integrated with an organization's pursuit of breakthrough innovation.

applied within the DMAIC rubric. Six Sigma employs a handful of methods and a small group of in-house technical leaders to become an implementaton team trained at a high level of proficiency in the application of these techniques. Buy-in from the top of the organization and education of the entire organization, however, is essential for a Six Sigma project to succeed. Organizations also must invest in training BBs and educating all employees.

The following steps are also necessary to successfully implement a Six Sigma project:

- Senior leaders must initially be trained in Six Sigma principles and tools needed to prepare their organization for success.
- In manufacturing and customer-relations areas, systems are developed to stay in close contact with customers, employees and suppliers. Methods of obtaining and evaluating customer, employee and supplier input must be developed.
- Remedial-skills education must be provided to ensure adequate levels of literacy and numeracy are possessed by all employees.
- A framework for continuous process improvement-which includes a system of indicators for monitoring progress and success-must be developed. These metrics are designed around the organization's strategic goals.
- Business processes to be targeted are chosen by management, and Six Sigma projects are conducted to improve business performance linked to measurable financial results. This requires knowledge of the organization's abilities and constraints.
- · Six Sigma projects are conducted by individual employees and teams led by GBs and assisted by BBs who must be trained and certified in advance.

Six Sigma can be viewed as a rigorous and highly structured approach to eliminating waste and introducing efficiencies and consistencies. It is also a demanding form of a change program, requiring high levels of commitment and resource deployment.

### Hitting the wrong notes

As mentioned earlier, critics have argued Six Sigma is less than beneficial for companies to implement for the following reasons:

It stifles innovation: As advocated by Motorola and GE, Six Sigma should permeate every area of an organization and be implemented with efficiency and consistency. In the implementation of a top-down, systematic approach to customer relationships and production, however, innovative thinking may be sacrificed or lost. This suggestion is based on Six Sigma's structured work processes and low tolerance for risk.

Six Sigma is designed to inject more efficiency and productivity into an organization or company system and, in doing so, to reduce variability. Innovation and entrepreneurial behavior, however, foster the opposite culture, focusing more on new markets, technologies and business models.6 Some companies, such as 3M, adopted Six Sigma but later backed away because of its perceived negative impact on innovation. This occurs despite the existence of variations of Six Sigma intended to address innovation and product development, such as design for Six Sigma.8

It's a program, not a philosophy: In terms of competition in an industry, all companies are pressured to adopt a program such as Six Sigma to systematically improve their businesses. But this improvement may reach a threshold in which further incremental improvement is either impossible or costly.9

Six Sigma is a program that is fitted to the organization rather than a management philosophy<sup>10</sup> for future growth. Since 1986, newer tools, such as lean, have been introduced and are closer to a management philosophy than a management tool. Six Sigma is an exclusionary approach that, while endorsed from the top down, is implemented by a specialized project team with its own hierarchical designations, and the rest of the members of the organization are bystanders to this project and process. In an ideal approach to quality, all employees should be process improvers.11

It is possible, however, to implement only one or two aspects of the Six Sigma process, such as Six Sigma Lite.12 That may limit the sustainability of the improvements. Success is often short term because most Six Sigma tools do not consider all factors that may impact the long-term sustainability of those improvements. Even a comprehensive approach to Six Sigma (and lean) does not sufficiently address the human element in organizations and recommends behavioral approaches to change should be incorporated in order to ensure sustainability.13

There are limits to its success: Another shortcoming of the classical Six Sigma approach is that it does not attempt to achieve radical change in broad, cross-functional business processes. While such radical change has a high risk of failure,14 in some situations it may be necessary to achieve business objectives. Some firms, including Motorola, have added components to Six Sigma to address more radical forms of process change.

Since Six Sigma's inception in the 1980s, there have been incredible changes in information systems and IT infrastructure. An entire class of technologies, known as business process management (BPM) tools, exist to map, monitor and manage workflow in business processes.<sup>15</sup> Other important technologies, such as enterprise resource planning (ERP) systems, can provide substantial levels of support for business processes, as well as constraints on designing and improving business processes. 16 Classical Six Sigma, and most variants of it, do not incorporate or take advantage of any of these IT tools.

Substandard bottom-line results: Perhaps most important, Six Sigma may not actually improve an organization's performance-at least as measured by stock price. After a firm implements Six Sigma, it's usually assumed the firm's stock price will rise or outperform the S&P 500 index. But there are mixed results.

Critics often point to one nonrandom study of 58 companies following purported Six Sigma implementations. The survey showed 91% of these companies underperformed compared to the S&P 500.17 Some have argued, however, the survey's examination period of the company's stocks was too short. In a smaller sample of firms, 95% of them outperformed the S&P 500.18 Both sides agreed, however, that an evaluation of the fidelity of the Six Sigma implementation at these companies may show wide variability in adherence to the methodology, and such high-level studies are like comparing apples to oranges.

### Perfect harmony

If Six Sigma is going to thrive in the new millennium, it must take on one of two different attributes.

It can become a term that encompasses broad process improvement tools, such as lean, total quality management (TQM), business process reengineering, "Work-Out" (a highly participative process improvement approach used by GE) or IT-enabled business process management.

Or it can be a well-defined but narrow tool to be applied when and where appropriate.

The overarching concept has become the most common approach. The Babson College Institute for Process Management surveyed 35 companies in 2005 and found that more than one-third had a unified approach to process management (though not all of them referred to it as Six Sigma). The rise of lean Six Sigma approaches—which are employed by GE, Kodak, Xerox, the U.S. Army and many other organizations—is a partial version of this trend.

If an organization chooses to adopt the narrowly defined version of Six Sigma, it should probably focus on the original orientation of the term—a statistically focused approach to reducing product defects. Most organizations would still need additional approaches to process improvement and quality, but at least there would be less confusion about what the Six Sigma approach means.

Overall, an organization must be prepared and skillful to deploy variations of process management initiatives—implementing disciplined process management tools such as Six Sigma but also valuing disruptive innovation and change to develop new products and processes. Balancing these objectives isn't easy. It requires discipline to improve current business operations to be competitive in the short term while exploring innovative changes for the long term.

Translating this ambidextrous approach into practice may take several approaches. It may mean not implementing Six Sigma as a solution in all areas of an organization or training managers to handle the inconsistencies between innovation and efficiency. It may mean implementing or fostering adherence to one approach followed by the second approach.

GE is a good example of a company that values what Chairman and CEO Jeff Immelt calls "imagination breakthroughs" and continuous process improvement with strong buy-in at all levels.19

This ambidextrous approach may mean employing a broad approach to process improvement and quality that includes incremental process improvement and radical process innovation in the overall toolkit.

Johnson & Johnson, for example, employs this broad approach in its "Process Excellence" program. Its process improvement tools draw from Six Sigma, lean and its own "Design Excellence" approaches. The primary drawback of this approach is that practitioners need to be familiar with a broad array of tools and need to know which tools to apply in what circumstances. Some companies may also find it more difficult to engage the attention of their managers and employees with a "non-branded" approach.

There is solid evidence that Six Sigma strategy and other process control methods (TQM, lean and ISO 9000) can be integrated with an organization's simultaneous pursuit of breakthrough innovation.

Researchers studied 35 companies that attempted to embrace process control and breakthrough innovation.<sup>20</sup> Organizations that initially implemented Six Sigma in at least some of their business areas were successful 90% of the time in introducing innovation within their organization. Organizations pursuing innovation in the absence of any process control implementation were successful less than 35% of the time.

This implies there's added synergy between Six Sigma processes and fostering innovation when implemented within the same organization. The discipline of a Six Sigma-oriented process improvement program seems to provide a fruitful context for later innovation efforts.

This suggests Six Sigma should be implemented carefully and only within appropriate areas of the organization, but innovation should also be fostered. When an organization becomes ambidextrous, this will provide competitive advantage in both areas. QP

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THOMAS H. DAVENPORT holds the president's chair in the Information Technology Management Division and co-directs the Working Knowledge Research Center at Babson College. He has written, co-authored or edited 12 books, including the first books on business process reengineering, knowledge management and the business use of enterprise systems, and has written hundreds of articles and columns for such

publications as Harvard Business Review, Sloan Management Review and CIO. The most recent book he co-authored is Competing on Analytics: The New Science of Winning (Harvard Business School Press, 2007)

# CRITICAL Stage

### In 50 Words Or Less

- After a decade of widespread use, there are still questions about Six Sigma's impact.
- Quality professionals have benefited from the method's popularity but run the risk of diluting its impact.
- With a few precautions, it's possible to keep Six Sigma from being another flavor of the month.

What Six Sigma has accomplished and whether it's on the way out

by A.H. "Jack" West

HAS SIX SIGMA been a good thing? While this is a straightforward question, there isn't a simple answer.

An attempt to find an answer may include the use of several surrogate indicators—but, as I'll prove later, none of those provide the clear, convincing, comprehensive answer for which we're looking. Nonetheless, I believe those indicators provide evidence that illuminate the subject.

Because just about everyone involved in the quality profession has an opinion about Six Sigma, it's possible the answer to the question depends on whom you ask. It's also possible the more important question is what can be done to strengthen Six Sigma. But more on that later, including a thought experiment that may illuminate a few things. First, it's important to make a few distinctions about Six Sigma.

During the last decade, Six Sigma has been one of the quality movement's most, if not the most, widely deployed and extensively written-about methods. QP's first article on Six Sigma appeared in 1998, so it's safe to assume that with more than a decade of coverage, readers are familiar with the basic aspects of Six Sigma and with its more recent iteration, lean Six Sigma (LSS).

### Time for an intervention

That being said, I would like to draw a distinction between the technical LSS method used by belts to make breakthrough improvements and the LSS method used as a strategic organizational intervention.

In the case of the latter, LSS starts with a business leader directing its implementation. Responsibilities are assigned, resources allocated and accountability established. Projects are selected, assigned and managed by a Champion, who is accountable for the overall success of LSS within the organization. Belts are assigned to projects that implement the define, measure, analyze, improve and control (DMAIC) method to make dramatic improvements to a process.

Regular project reviews are conducted by the leadership team, and the results of the LSS program are an integral aspect of the organization's balanced scorecard. Lessons learned and improvement techniques developed on one project are rapidly adopted across the enterprise. Iconic examples of this type of LSS implementation include Motorola, AlliedSignal, General Electric (GE) and Bank of America.

An alternative implementation is undertaken by organizations that learn of others' successes using LSS and try to implement it without investing in the support infrastructure required to capitalize on a full-scale implementation.

This approach involves training one or a small cohort of individuals as Black Belts or Green Belts. These individuals have the ability to implement the DMAIC method to make dramatic improvements to a process. In many cases, however, they do not have properly defined projects, effective project reviews or the support infrastructure afforded by a full-scale deployment.

Under these conditions, the impact of projects on defined business objectives is considerably weakened. This has been supported by a recent survey published in Six Sigma Forum Magazine that found the leading causes of LSS project failures are lack of management support and the projects not being linked to finances.1

Anecdotal and personal evidence suggest that many, if not most, trial interventions fail to achieve their desired effect. This is primarily due to the organization's lack of a structured forcing function that selects appropriate LSS projects, manages them to completion and disseminates the results across the enterprise.

### LSS interest

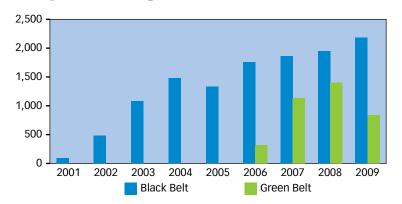
LSS has been and continues to be the subject of considerable press coverage and thus has been characterized as everything from a boon to productivity, effectiveness and organizational performance to an innovation killer and a gigantic waste of resources.<sup>2</sup> As a result, there's plenty of evidence on both sides of this controversy that allows quality practitioners to draw some conclusions and learn a few lessons.

The interest within the community of quality practitioners has been strong, as several indicators show. For example, LSS has been the subject of a large number of articles within the quality community. In fact, the total number of published works on LSS in the industry's four leading magazines, including this one, more than doubled—from 13 in 2001 to 34 in 2002—before dropping off in the last four years.

Another indicator of interest in LSS by quality practitioners is the number of people taking the Certified Six Sigma Black Belt and Certified Six Sigma Green Belt examinations, which have shown a steady increase (see Figure 1).

LSS has also become a hot topic at the World Conference on Quality and Improvement (formerly the Annual Quality Congress) and ASQ's Lean Six Sigma Con-

### People taking BB, GB exams / FIGURE 1



ference, as shown by the number of papers presented (see Figure 2).

The general press has also taken notice of LSS, as illustrated by Figure 3, which shows the relative number of articles published by year.3

The number of books covering a subject naturally tends to follow the trend of papers and articles published. The chart in Figure 4 bears this out and shows the number of books recorded at the Library of Congress with Six Sigma in the title.

### **Brace for impact**

It has been established that LSS has generated a lot of interest and activity among the general business community, as well as the practitioners of the quality sciences. The next issue that needs to be resolved is whether LSS has a positive impact on organizations that implement it or on the quality practitioners who employ it.

Let's look at the evidence for organizations first. The literature is replete with articles and books about the savings reaped by organizations that implemented LSS as a strategic initiative. This evidence appears in virtually all segments of the economy and is so ubiquitous and pervasive that there is no need to recount it here.

We've all heard the mantra that correlation does not prove causality, and I'm not attempting to circumvent that. It may be instructive, however, to determine if the stock prices of companies that are most frequently associated with LSS have benefited from that relationship.

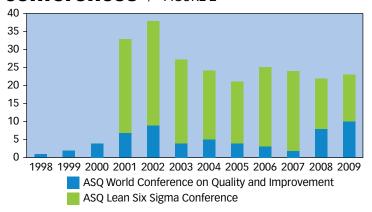
When we look at the stock prices of the iconic organizations-Motorola, Bank of American and GEcompared to the Standard and Poor's (S&P) 500 index, it appears their performances have not been outstanding (see Figure 5, p. 26).

Considering the performance of these iconic LSS organizations relative to a well-established benchmark, we find they have not outperformed the market. Certainly, there are lurking variables and exogenous factors in each of these cases, but the evidence is compelling that implementing LSS did not prevent these companies from befalling the same fate as their peers.

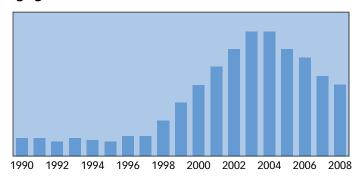
### What does it all mean?

Based on the evidence presented, it's easy to come to a few conclusions. The evidence that LSS has generated a great deal of interest in the quality community and in the general business world is compelling. There is

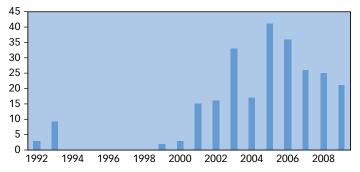
### LSS papers at annual conferences / FIGURE 2



### LSS articles published by year / FIGURE 3



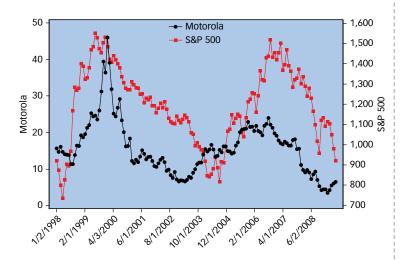
### Six Sigma books at the Library of Congress / FIGURE 4

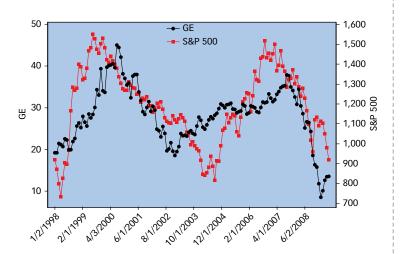


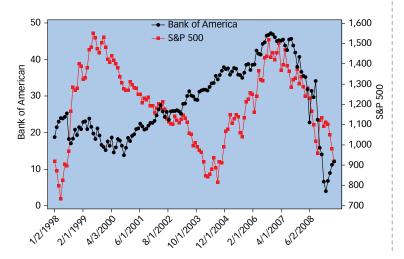
also a large body of anecdotal evidence that LSS has made major contributions to enhancing organizational performance.

In the quality realm, LSS has been very good to many quality practitioners by:

### **Six Sigma companies VS. S&P 500** / FIGURE 5







- Renewing interest in the quality arts and sciences.
- Establishing a tested, proven and widely recognized framework for the use of quality tools.
- Creating the demand for a large number of userfriendly software packages that enable practitioners to perform complex calculations and simula-
- Providing quality professionals access to and credibility with top managers of many organizations.

But the benefits quality practitioners have realized over the years are hardly limited to LSS. We have also benefited from waves of organizational interest and management attention that resulted from quality circles, total quality management (TQM), ISO 9000 and the Malcolm Baldrige National Quality Award.

My concern is that we have moved from each of these very worthwhile methods to the next without quantifying the impact of or fully capitalizing on the opportunities each has afforded us. These failures are illustrated by the inability to respond to the following questions:

- 1. How, if at all, did organizations that adopted TQM outperform the organizations that did not adopt it?
- 2. Which aspects of quality circles are effective within the North American culture, and which are not?
- 3. Is the quality of the products and services produced by companies registered to ISO 9000 superior to similar companies that are not registered?

I submit that unless and until quality practitioners develop the tools to anticipate and respond to these questions, the discipline will not be held in the same esteem as the practitioners of other disciplines that already have the ear of business executives.

### How to move forward

The following are some suggestions for how to keep LSS from being just one more wave of interest, assuming it's not too late (some would say it is).

- 1. Quantify the contributions to our organization's success. We must do this in the well-established language of management: money. Mikel Harry, one of the original architects of Six Sigma at Motorola, teaches that the scorekeeper for LSS should use the established and generally accepted methods of financial analysis, not just those created by the quality field. This is a message we have failed to heed far too often.
- 2. Apply our skills to make improvements in all parts of the organization. We can't limit our abili-

### **Poor decisions** can overwhelm or **cancel** the gains that are made from efficiency or effectiveness improvements.

ties to operations in which processes are the most obvious and, thus, are easiest to analyze and improve.

- 3. Refine our analysis and presentation skills. We must be able to demonstrate the links between quality, customer satisfaction, return on investment and social responsibility. If we can't present a credible business case, we can't demonstrate the value proposition of the quality initiative for executives.
- 4. Stay up to date. We need to be clued in to the latest developments in process improvement methods and be able to relate the potential impact of those methods to the organization's critical business obiectives.
- 5. Use our analytical, problem-solving and forecasting skills. Our organizations constantly face strategic decisions that double as opportunities for quality professionals to make significant contributions. In these situations, poor decisions can overwhelm or cancel the gains that are made from efficiency or effectiveness improvements.
- 6. Don't kill LSS by diluting it. Blan Godfrey warned several years ago this was the biggest danger facing LSS. I believe this danger has only grown as organizations and individuals seek to do more with less during the current economic downturn. The benefit of LSS is that those trained in the discipline can see things that are not obvious to everyone else. Don't lose this benefit by failing to fully implement LSS methods. They must be refined to enhance the ability to see things differently. As Einstein said, "We can't solve problems by using the same kind of thinking we used when we created them."4

In closing, here's a thought experiment that may prevent us from being put in a difficult situation when we want to evaluate the effectiveness of LSS or another initiative sometime in the future.

You're employed by a midsize consumer-products company that finds itself in competition with another firm identical to yours in every way. To distinguish itself from the competition, your company adopts LSS (or another initiative), with you at the forefront of the

- What data would you start collecting on the day of implementation that, within some reasonable time period, would enable you to determine unequivocally the effectiveness of the intervention?
- With your response to the previous question in mind, you're asked to devise a data-collection system for your organization that would enable you to respond to this question: How have you, your organization or the initiative contributed to the success of the enterprise?
- How will you present these findings to a skeptical, manage-by-the-numbers manager who needs to be shown that the efforts of the organization actually produced value?

Being able to answer those questions is a step in the right direction to being better prepared to manage strategic quality changes in the future. QP

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### **HEALING POWER**

Have lean and Six Sigma's effectiveness been diluted, or does your organization use them as they were intended? Share your story by using the comment tool on this article's page at www.qualityprogress.com.

# EXIGATION

RECENT DATA FROM the Organization for Economic Cooperation and Development indicate the United States ranks 12th among major industrialized countries in higher education attainment. Several other countries are close behind. At the same

### In 50 Words Or Less

- A crisis is looming in the nation's higher education system, a commission recently found.
- A panel of experts recommended the education system embrace a strategy of continuous innovation and quality improvement.
- The Academic Quality Improvement Process, an accreditation alternative for higher education institutions, may help stave off this crisis.

time, data from the U.S. Department of Labor suggest postsecondary education will be more important than ever for workers hoping to fill the fastest-growing jobs in the new economy.<sup>2</sup>

In 2006, the Spellings Commission—named after then-Secretary of Education Margaret Spellings—issued a comprehensive report about the state of higher education in the United States called "A Test of Leadership—Charting the Future of U.S. Higher Education." It was the cumulative work of several high-level college and industry leaders in the United States. Colleges, universities and accreditation institutions anxiously anticipated the results of the commission's yearlong study.



Change in higher education was long overdue, and conditions were critical, the commission reported.4 "In tomorrow's world, a nation's wealth will derive from its capacity to educate, attract and retain citizens who are able to work smarter and learn faster-making educational achievement ever more important for individuals and for society at large."5

The commission's findings (Table 1) and recommendations (Table 2) serve as a backdrop to the realities of quality issues in U.S. higher education today. Even though the commission's report was released three years ago, the issues and concerns it identified remain in the spotlight as the Obama administration sets its sights on improving the state of higher education and community colleges.

One of the changes paramount to improving higher education, the commission believed, was that colleges and universities must embrace a culture of continuous innovation and quality improvement. 6 The commission also emphasized, however, that accreditation bodies could play a pivotal role in re-engineering higher education.

### Accreditation one of the keys

Accreditation is the process by which a third-party body ensures a college or university meets established guidelines and standards as outlined by the U.S. Department of Education.7 In addition, accreditation ensures colleges and universities are considered for federal and state investment dollars for continual operation and upkeep. Without accreditation, colleges and universities are forced to rely primarily on private money for ongoing operations and upkeep.

Six regional accreditation agencies and several specialized accreditation agencies in the United States perform institutional accreditations. The largest is North Central Accreditation, with headquarters in Chicago, which serves as the accreditation body for degreegranting institutions of higher education in 19 states.8

### **Academic Quality Improvement Process**

Before the report was issued, the Higher Learning Commission of North Central Accreditation (HLC NCA) offered its member institutions an accreditation alternative—called the Academic Quality Improvement Process (AQIP)—based on continuous innovation and quality improvement principles.

Including elements from Baldrige criteria, total quality management, continuous improvement, W. Edwards Deming's 14 Points and ISO 9000, AQIP is divided into nine categories (see Table 3, p. 33) requiring participation from the subscribing college or university.

In addition to these categories, AQIP audits compliance to the HLC NCA five criteria required for accredita-

### **Spellings Commission findings** / TABLE 1

Finding	What does the finding mean?		
Education is more important.	In today's knowledge-driven society, higher education has never been more important for full participation in a technological, democratic, global society. Now more than ever, change is necessary.		
Participation by all is an issue.  Many Americans are not prepared to participate in and complete higher education—especially under nontraditional groups that are an ever-greater proportion of the population and a major source of new the United States.			
Prohibitive costing issues.			
Broken financial-aid systems.  Financial-aid programs at federal, state, institutional and private levels are confusing, complex, inefficient duplicative and often do not direct aid to students who truly need it. Need-based financial aid is not keel with rising tuition.			
Quality learning outcomes.	Even as we must increase quality in learning outcomes and the economic value of education, disturbing signs suggest we are moving the wrong way. This decreases the ability of institutions to produce citizens to lead and compete in the 21st century global marketplace.		
Institutional performance accountability.  There is inadequate transparency and accountability for measuring institutional performance, which is more necessary to maintain public trust in higher education.			
R&D for new skill sets, policies.	Innovations in institutional capacity, effectiveness and productivity are impeded by out-of-touch governmental and institutional policies created for simpler workforce needs. More basic research is required to better understand new skill sets needed for the future.		

### **Spellings Commission recommendations** / TABLE 2

Recommendation	What does the recommendation mean?
More educational opportunity, access, success.	Students need increased access to and success in higher education. Increased efforts must be committed to improve student preparation and persistence. Non-academic barriers must be removed and aid to low-income students increased.
Restructure financial aid and costing systems.	Student financial-aid systems must be restructured and new incentives created to improve measurement and management of costs and institutional productivity to reduce education costs and increase the ability of governments to finance education.
Performance-based accountability measures.	Institutions must determine and implement serious measures and metrics to meet performance-based challenges. Measures and metrics should not be based on previous reputations and politics, but on a robust culture of accountability, transparency and change.
Transform to a knowledge economy.	Academic programs and institutions must transform to meet changes in a knowledge economy and use continuous innovation, quality improvement, new pedagogy, curricula and technologies to improve, particularly in science and mathematical literacy.
Lifelong higher education, continuous learning.	Access to high-quality, affordable education and training must be continuous via national lifelong learning strategies to help everyone understand the importance of preparing for and participating in ongoing higher education.
Commit strategic resources to key knowledge areas.	Increased federal investment is needed to compete globally. There must be a major commitment to attract the brightest minds and to create leaders of American innovation in strategic areas such as science, engineering, medicine and other knowledge-intensive professions.

tion, which are explained in Table 4 (p. 33). The AQIP accreditation path, along with adherence to HLC NCA guidelines, functions as a quality assurance system and a quality improvement tool to ensure compliance to the five accreditation criteria, followed closely by documented evidence of progress in the nine AQIP categories.

Building on the HLC NCA strengths as defined in the five criteria, the nine AQIP categories offer an even greater level of detail for continuous improvement. HLC NCA accreditation systems can form the baseline for even greater robustness toward customer satisfaction and serving all stakeholders.

### **AQIP** in action

The path to AQIP reaccreditation is a multi-step process. The institution must already be accredited by the HLC NCA through the conventional process and have had two comprehensive visits. Institutions are required to understand continuous quality improvement principles and AQIP. Here are steps to consider when heading down the AQIP path.

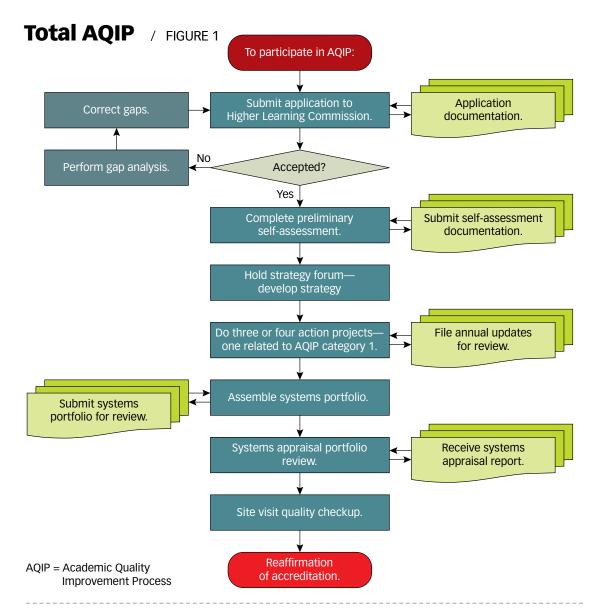
Talk it through: Institutions interested in AQIP are encouraged to hold campuswide discussions to stimulate conversation and curiosity about the process, to understand the work involved and to see if this process for reaccreditation serves the needs of the campus and stakeholders. This is one of the 14 Points of the quality system management process outlined by Deming.

Point 14 states, "Put everybody in the company to work to accomplish the transformation. The transformation is everybody's job."9

If the institution chooses to participate in AQIP, the date for reaccreditation is scheduled seven years ahead rather than the 10-year cycle for traditional reaccreditation. This allows the institution to participate in a full seven-year cycle of AQIP. An AQIP review panel evaluates an institution's application for participation and, based on several criteria, recommends the institution for acceptance in the AQIP.

Look inside: Upon acceptance, the institution completes a preliminary self-assessment that provides evidence the organization has looked at itself holistically as a set of systems and processes, rather than a collection of offices, departments, and academic or administrative units. During the early stages, part of the strength in the process relates to the identification and correction of problems based on gap analysis of the application process. As with most quality improvement systems, the internal assessments and reviews in preparation for external review are one of the key strengths. AQIP is no exception, and the early stages provide opportunity for such actions.

Although specific methods will vary by institution, participation in AQIP follows a distinctive path. Significantly, many of the steps and procedures are consistent with HLC NCA systems. Thus, much work already in



place for HLC NCA also can be used for the AQIP. Figure 1 shows the total process as a process flow chart.

Set strategy: Every institution must complete a strategy forum—a facilitated peer review process designed to help it select, critically examine and commit to a set of strategies and action projects that will drive continuous quality improvement. The institution must create action projects designed to strengthen the institution's commitment to continuous improvement

### GET INVOLVED

Additional information about joining AQIP as a peer reviewer can be found on the Higher Learning Commission North Central Accreditation website at www.aqip.org.

and advance the institution's goals. Each institution concentrates on three or four action projects at a time. At least one action project relates directly to AQIP category 1, "helping students learn." Institutions participating in AQIP file annual updates on the progress or completion of their action projects.

During the first four years of participation, an organization assembles a systems portfolio. The systems portfolio consists of an organizational overview and details each of the major systems used to accomplish the organization's mission and vision. The institution answers questions related to context, process, results and improvements for each of the nine categories. The systems portfolio is designed to help the accreditation bureau, and the institution itself, understand key strengths and ambitions, challenges and conflicts the institution faces.

**Systems checkup:** The next step is a comprehensive systems appraisal, which is designed to produce a report that reflects to the institution its maturity in each of the nine categories and provides an incubator for future action projects. During the seven-year cycle, AQIP requires a site visit—called a quality checkup—from two or more trained evaluators. Quality checkups occur in the last two years of the seven-year cycle and address the institution's compliance with the accreditation criteria.

Finally, after the seven-year continuous improvement initiative, the organization is ready for its reaffirmation of accreditation. This is a summation of the current systems portfolio, action project results, systems appraisals, review of the five criteria for accreditation and any other interaction with AQIP that ultimately results in the reaffirmation of accreditation.

The timing is such that the systems portfolio and action projects are reviewed every year. Every four years, a systems appraisal and strategy forum are conducted. Every seven years, a quality checkup and reaffirmation of accreditation are completed. The cycle, like every continuous improvement journey, starts again—building on the success of the past cycle and further refining the continuous improvement activities.

Peer reviewers conduct the system appraisals, action project reviews and system portfolio reviews. These people may come from academia or the public and private sectors, and they are trained to provide insightful reviews and recommendations by the AQIP leadership team in biannual sessions.

The inclusion and participation of non-academics in particular is considered key to the process, because quality systems' knowledge from outside of academia

### **AQIP nine categories** / TABLE 3

AQIP category	Explanation		
1. Helping students learn.	How do we ensure students are learning? What support is provided, and how do we know it is working?		
Accomplishing other distinct objectives.	What objectives are unique to a specific area of study or inquiry in the student's major?		
3. Understanding students' and other stakeholders' needs.	Aside from students, who else are stakeholders, and how do we ensure their needs are being met?		
4. Valuing people.	How do our policies, systems and procedures ensure and demonstrate we place the highest value on our people?		
5. Leading and communicating.	How do we ensure consistent, effective leadership and communication in our community and for preparing students in the future?		
6. Supporting institutional operations.	How do we engage all students, faculty and staff in supporting and enhancing institutional operations?		
7. Measuring effectiveness.	What characteristics are identified and metrics used to measure our successes, and how are data collected, analyzed and documented?		
8. Planning continuous improvement.	What policies, procedures and systems are in place to engage all in strategic planning for the future?		
9. Building collaborative relationships.	What collaborative efforts have been built or are being built with our stakeholders, and how do we support and grow them?		

can be integrated objectively and unobtrusively. The teams and individual reviews are led by senior team leaders who provide counseling and mentoring to junior reviewers. The mentoring cycle repeats itself, building and strengthening the technical capabilities of the peer review corps.

### Addressing the quality crisis

As shown in the flow chart and description of main

### HLC NCA five criteria for accreditation / TARIE 4

HLC NCA criteria	Explanation	
1. Mission and integrity.	What is the institutional mission, and how do we ensure the mission is accomplished?	
2. Preparing for the future.	How do we ensure our students are adequately prepared to meet the challenges of the future?	
3. Student learning and effective teaching.	What teaching strategies are used to ensure learning is occurring, and how do we gauge this as outcomes?	
4. Acquisition, discovery and application of knowledge.	How do we ensure more than mere memorization of facts and figures occurs based on discovery and application of knowledge?	
5. Engagement and service.	How do we ensure lifelong engagement of our students and faculty in a community of service?	
HLC NCA = Higher Learning Commission of North Central Accreditation		

### Addressing the quality crisis in higher education / TABLE 5

Spellings Commission recommendation	HLC NCA criteria	AQIP category	AQIP process step and possible opportunity	Spellings Commission finding in context of AQIP and other relationships		
More educational opportunity, access, success.	Mission and integrity.	Understanding students' and other stakeholders' needs.	Application, strategy forum, gap analysis, quality checkup.	Education is more important: AQIP places this at the forefront of its institutional mission and considers it the main driver for all.		
Restructure financial aid and costing systems.	Preparing for the future.	Supporting institutional operations, leading and communicating.	Strategy forum, gap analysis, action projects, quality checkup.	Participation by all is an issue: Structure of institution is pushed to consider future, financial aid and costs reconsidered.		
Performance-based accountability measures.	Student learning and effective teaching.	Helping students learn, valuing people, measuring effectiveness.	Strategy forum, gap analysis, action projects, quality checkup.	Prohibitive costing issues: Performance is tied to student learning and assessed as potential gaps for improvement.		
Transform to a knowledge economy.	Acquisition, discovery and application of knowledge.	Accomplishing other distinctive objectives.	Action projects, systems portfolio and appraisal, quality checkup.	Broken financial-aid systems: Transformation can only come through new costing and aid systems.		
Lifelong higher education, continuous learning.	Engagement and service.	Building collaborative relationships.	Action projects, systems portfolio and appraisal, quality checkup.	Quality learning outcomes: New outcomes based on quality will change people's lives continuously.		
Commit strategic resources in key knowledge areas.	Mission and integrity, preparing for the future.	Planning continuous improvement, measuring effectiveness.	Strategy forum, quality checkup, reaffirmation of accreditation.	Institutional performance accountability: Strategic planning continuously drives resource allocation and measures of success.		
Transform to a knowledge economy.	Preparing for the future.	Measuring effectiveness, building collaborative relationships.	Strategy forum, quality checkup, reaffirmation of accreditation.	R&D for new skill sets and policies: New skills are transformational, and a knowledge-based economy requires collaborations.		
AQIP = Academic Quality Improvement Process HLC NCA = Higher Learning Commission of North Central Accreditation						

processes, the innovative AQIP approach to reaccreditation holds much promise in addressing many of the recommendations made by the Spellings report. AQIP can be one possible systematic approach to help ensure innovation and continuous quality improvement in the nation's higher education system.

Table 5 provides a matrix that combines the Spellings Commission findings and recommendations, HLC NCA criteria and AQIP's nine categories. All of this is provided in a context of relationships that must be built around quality systems and improvement strategies during a long-term process.

While it may be clear to quality professionals that these relationships and systems can be a foundation for long-term improvement in higher education, the true test must be made by academic leaders themselves. QP

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- 9. Rafael Aguayo, Dr. Deming, The American Who Taught The Japanese About

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# PDSA LEADS TO TOP ACCOLADES

# Tools, open communication and partners help school district earn a Baldrige award

#### In 50 Words Or Less

- North Carolina's Iredell-Statesville Schools earned one of three Baldrige awards granted in 2008.
- The district credits its partnerships, twoway communication and the use of quality tools—especially the plan-do-study-act cycle—as reasons for earning the award.

by Nicole Adrian, contributing editor

FORCE FIELD ANALYSIS. Two-way communication. SWOT analysis. These terms are likely familiar to quality professionals in the manufacturing, service and possibly even healthcare

fields. But to those in education? It's unlikely.

That's not the case, however, for Iredell-Statesville Schools (ISS), a K-12 public school system in southwest North Carolina. The district, situated about 40 miles north of Charlotte, earned one of three Malcolm Baldrige National Quality Awards granted in 2008. It's the first school district to receive the honor since 2005.



The residents who make up the district come from upscale homes as well as high-density rental properties. The district has about 3,400 employees, and during the 2006-2007 school year, ISS enrolled 20,902 students. That same school year, the district's budget was \$161 million, with 65% coming from state funding, 10% from federal and 25% from local and other revenue streams. The capital budget was \$13.6 million.

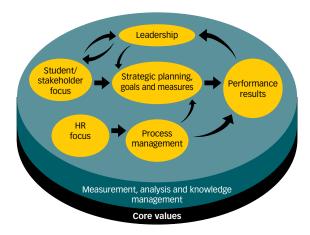
The school district includes 19 elementary schools, seven middle schools, five high schools, two early colleges and two alternative schools, plus four support facilities. The facilities range from the most modern to those in need of renovation or replacement.

ISS had been working on the Malcolm Baldrige National Quality Award criteria since 2002, when it established a Baldrige-based leadership system. During the 2002-2003 school year, senior leaders used a shared vision and values process to set the long-term direction of the district by developing its vision and mission, as well as its strategic priorities and values. The vision statement and strategic priorities established the foundation from which the senior leaders could identify short and long-term strategic objectives through the use of the strategic planning process.

In the four years prior to its Baldrige application, the district collected feedback reports from state and national awards, said Terry Holliday, former ISS superintendent. Applying for the 2008 award allowed the district to see whether its improvements and methods of doing business were paying off.

"I think it was a long journey just to improve our

#### **Performance excellence** model / FIGURE 1



school system," said Holliday, who had been the ISS superintendent for seven years. In August, he became Kentucky's Education Commissioner. "The actual award application is about the feedback. The feedback has been phenomenal on improving the results in the school system."

Receiving the award is recognition for all the hard work ISS staff has been doing, Holliday said. "But it also means more that we have more children successful today than we did seven years ago," he added.

#### Many factors

Numerous factors contributed to ISS receiving the Baldrige award. Holliday believes one is that ISS is a lowfunded school system with exceptional academic results.

"We're in the bottom 10 in North Carolina (for funding), but our results in academic performance per student come out in the top 10 in the state," he said. "We're effective and efficient, and that's what it's about."

The ISS dropout rates have seriously declined during the last few years, while SAT scores have increased. "We've gone from having one of the highest dropout rates to having one of the lowest," Holliday said. "SAT scores have gone from being well below state and national averages to being the seventh best in North Carolina."

The school district closely follows a performance excellence model in everything it does, including its drive to continuously improve key learning-centered and work processes (see Figure 1). School improvement planning (SIP) is a state requirement, and the district's board of education mandates the systemic and systematic use of the performance excellence model.

Holliday brought the model to ISS in 2002, based on his previous work with the Southern Regional Educational Board and the South Carolina Total Quality in Education Initiative. Holliday's cabinet met weekly to guide the system in the implementation of the strategic plan.

The model ensures the development and deployment of programs and services that meet current and future stakeholder needs and requirements. Additionally, the model helps build and maintain the relationships that attract and retain students and stakeholders, as well as improve loyalty to the district and its mission.

The district's strategic plan and performance excellence model focus heavily on customer satisfaction,

# "The feedback has been phenomenal on improving the results in the school system."

with particular emphasis placed on student performance, as well as effective and efficient operation and communication.

#### A PDSA cycle for everything

In just about every plan the district implements, the superintendent, administrators, teachers and board use the plan-do-study-act cycle (PDSA) to encourage innovation. "That's how we get results," Holliday said. "Everyone is always working on a PDSA. It's built into all strategic plans."

To improve key processes, the district uses a PDSA approach based on a six-step improvement model:

- 1. Validate the need for improvement.
- 2. Clarify purpose, goals and measures (plan).
- 3. Adopt and deploy an approach to continual improvement.
- 4. Translate the approach to aligned action (do).
- 5. Analyze results (study).
- 6. Make improvements (act).

Because it's such an important tool for the district, Holliday personally delivered PDSA and Baldrige training throughout the district. The district's senior leaders serve as PDSA champions for process improvements in their departments or divisions.

Even students have hands-on experience working with the quality tool via an iPod PDSA, which resulted in piloting iPods and MacBooks for use in the classroom. Students and teachers participated in the podcasting exercise to improve student achievement. After the pilot concluded, an additional PDSA cycle was used to determine whether districtwide deployment should be considered.

Another quality tool students are familiar with is the student data notebook, which ISS students use to monitor their progress. All students in grades K-12 have the notebooks, Holliday said. They were piloted seven years ago and were implemented across the district about three years ago.

Many other quality tools are incorporated into the district's everyday work, including:

· Plus/delta: Teachers use this tool to figure out

- what teaching strategies work and what needs to be improved.
- Force-field analysis: Aids in the decision-making process.
- Issue bin (parking lot): Used to encourage communication and to collect data from all stakeholders to improve the level of service within the district.
- Professional learning communities (PLCs): Teamwork and committees form the basis of what the district accomplishes through these communities.
- SWOT (strengths, weaknesses, opportunities and threats) analysis: Performance projections are based on SWOT analysis of key performance measures and indicators.
- · Gap analysis: Standard reporting templates with standard questions are used to conduct gap analysis to identify weaknesses in results.

During the 2005-2006 school year, the executive cabinet dedicated resources to establish a quality team and a chief quality officer who reports directly to the superintendent. The quality team tracks and reports districtwide progress against the integrated Baldrige deployment plan, the district strategic plan, department improvement plans, school improvement plans and professional development and education plans.

#### Lending a hand

District administrators attribute some of the district's successes to its numerous partnerships. The district's key partners and collaborators are active contributors in helping ISS achieve its mission and goals. Partners participate on school and district improvement teams, advisory committees and specific task forces. Their feedback and recommendations are used by the district as input into the strategic planning and improvement processes.

Partners and suppliers work side by side with district staff to continuously improve key work processes using PDSA cycle to develop innovative organizational processes.

ISS partners include:

- Boys and Girls Club.
- University of North Carolina-Charlotte.
- Gardner-Webb University.
- Mitchell Community College.
- Statesville Housing Authority.
- Iredell County Partnership for Young Children.
- Faith-based community.

The district's No. 1 partners are those that are faithbased, Holliday said. During the 2003-2004 school year, the district implemented a faith-based community initiative that has grown to include more than 80 church partners in the county.

"They provide in-school tutoring, lunches, meals for teachers and care for kids who are underprivileged, with coats, gloves and school uniforms," Holliday said. "The faith-based community has wrapped its arms around the kids who are less fortunate."

The faith-based partnerships also involve student and faculty support for local families and senior citizens in need of assistance. All schools and departments have programs that support key communities.

ISS partnered with Statesville Housing Authority for about \$10 million in grants, Holliday said, for programs such as summer school, enrichment programs, after-school care and parent training.

Additionally, the partnership with Mitchell Community College means students can graduate from high school and earn a two-year degree at no cost to parents, Holliday said. "It's cost effective, and it provides students with more opportunity than they can get in a traditional setting," he added. "It's innovation; Baldrige is all about innovation."

#### Closing the gaps

It's no secret that school districts across the country are working on closing achievement and learning gaps. ISS is no different. "This year, we're looking at an 11 to 12% reduction in our funding," Holliday said. "If we can't figure out how to do more with less, it will have an impact on our improvement and our achievement."

The district's success in differentiating itself from the competition now and in the future rests with its ability to close achievement gaps and to establish effective and efficient support processes by creating an aligned and integrated approach to management.

The district developed a learning triangle—a model to raise achievement and close gaps (see Figure 2). Its purpose is to illustrate the integration of key work processes and the collective knowledge, competencies and skills of employees who make up the district's

The model, which is deployed districtwide, demonstrates the integration of student support services and the financial and administrative departments. It is the principal's role, along with help from assistant principals and instructional facilitators, to prevent variability in the implementation of curriculum, instruction and assessment that may lead to variations in student learning and success.

Baldrige and quality tools have helped ISS close the achievement gap and make inroads to navigating the budget crunch. "Baldrige helps us figure it out," Holliday said. "Using PDSA and quality tools, we continue to find efficiencies. We saved more than \$50,000 in overtime costs improving the process and process management."

#### **Two-way communication**

Open communication is also important to ISS, Holliday said. "If we don't communicate the facts, people will make them up," he added. "(This past year) we were rezoning our school district to redraw attendance

#### The learning triangle / FIGURE 2



plan-do-study-act core competency, aligned strategic

plans, systems check, quality reports, integrated information and knowledge management.

boundaries, and we were able to use communication and survey processes to heavily involve parents."

ISS has implemented a two-way communication model (see Figure 3) that ensures cooperation, effective communication and skill sharing among all faculty and staff. Additionally, the model encourages feedback from all stakeholders concerning strategic priorities and the strategic planning process.

Holliday met with each school and department twice each year to discuss the progress of the school system and how staff members are involved in achieving the vision and mission of the school system. Senior leaders encourage frank discussion through the twoway communication model.

The district has numerous means of communication through which staff, parents, community members and students are kept informed. These include:

- The superintendent's blog.
- Podcasting.
- PowerPoint presentations.
- The district's website (http://iss.schoolwires.com/ iss/site/default.asp).
- Newsletters.
- Electronic feedback surveys.

Holliday said communicating through the district's website is especially important now, as North Carolina is going through a major budget crisis. Through the website, he's been able to keep ISS staff and parents up to date on budget issues.

Additionally, the district regularly distributes a community update newsletter to promote stakeholder awareness of district goals and achievements, and also to update the community on the progress and future of school construction. The newsletter features a feedback mechanism that enables stakeholders to weigh in on district issues.

#### Looking ahead

Even though the district has made significant improvement in areas such as SAT scores and graduation rates, its drive for continuous improvement hasn't diminished. ISS is making significant progress toward achieving its vision to become a top 10 school district in North Carolina. The

#### Two-way communication model / FIGURE 3

Senior leadership board of education

Includes meetings, meeting notes meeting highlights, e-mails, newsletters, website, articles and blogs.



#### Staff and stakeholders

Includes employees, parents, community, students, partners, suppliers and advisory groups.

Modes of communcation include advisory groups, task forces, e-mails, phone calls, surveys, issue bin and plus/delta.

district is also achieving leadership results by leveraging what it does well and building on those proficiencies.

ISS uses the Baldrige Criteria for Performance Excellence as a basis for assessing the organization and identifying key areas of competency. That approach has yielded education programs and services that meet the needs of the students and stakeholders, as well as effective and efficient district operations.

The feedback ISS received from the Baldrige examiners provided a vital look at where the district can improve. These areas for improvement represent hurdles to overcome as the district builds core competencies to be deployed through action plans at all levels.

Continuous improvement at ISS is an enduring priority. Two important areas the district plans to focus on are student reading and graduation rates. "We continue to work on early grades' reading to make sure every child is reading at their grade level by the end of third grade," Holliday said. "We continue to work on the district's graduation rate. We're the 10th best in North Carolina—well above state averages. But we want the highest graduation rate in North Carolina." QP

This article is based on Iredell-Statesville Schools' Baldrige National Quality Program application. The entire application is available at www.baldrige. nist.gov/PDF files/2008 Iredell Statesville Application Summary.pdf (case

#### FIND A LOCAL QUALITY AWARD

A comprehensive list of quality awards and programs can be found at www.qualityprogress.com under the Tools & Resources tab. The list includes state, national and international awards.

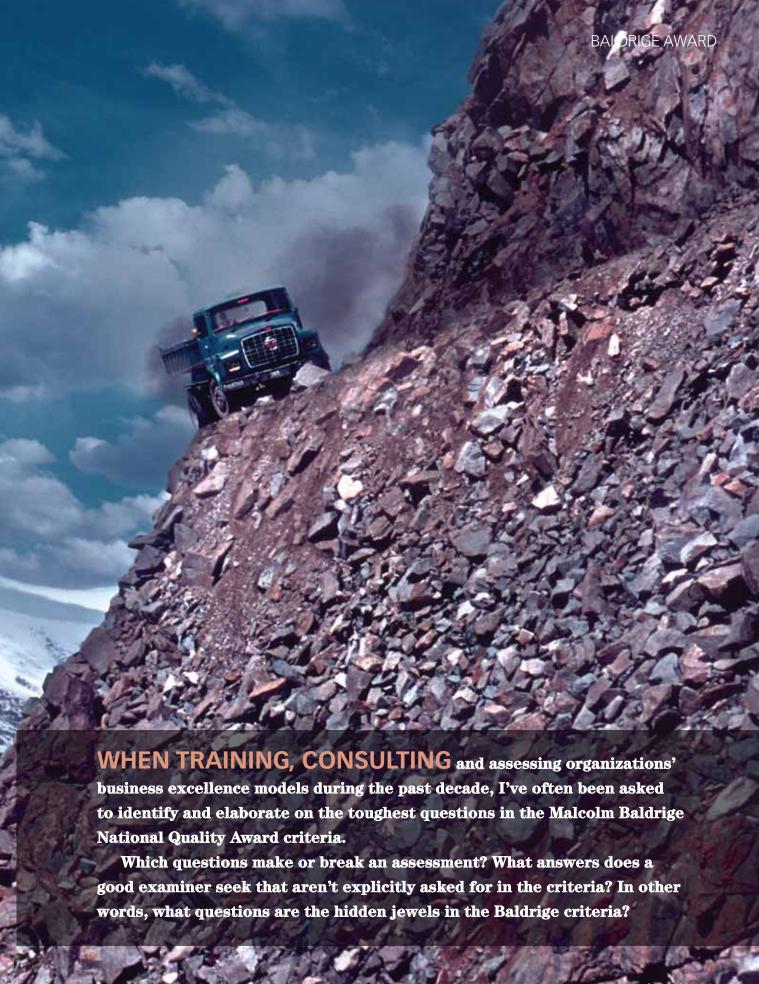
# Danger Zones

The **10 toughest aspects** of the Baldrige criteria

#### In 50 Words Or Less

- The rigorous Baldrige criteria force organizations to deal with difficult questions about their operations.
- Most organizations avoid these questions, only to struggle with their improvement efforts.
- Answering the questions adequately and appropriately can be the key to reaching higher levels of business excellence.

by Anshuman Tiwari



In my training programs, I have often presented the Baldrige criteria as a set of questions most management teams, given a choice, will not ask themselves. Most teams conduct self-assessments by relying on a list of their favorite questions. The problem is that over a period of time, team members can figure out what the boss will ask in the review, and they're smart enough to prepare answers to those questions.



The Baldrige criteria disrupt this game by asking a wide range of questions. This tends to prevent complacency because it forces organizations to confront the questions they otherwise would prefer to avoid.

But what makes a question tough? I have found there are some questions that cause organizations to trip up because they don't have convincing answers. Most of the time, the intent of the question is not clear to them. Complicating matters is that some examiners struggle to clarify the questions.

These questions are hidden within the criteria and can go unnoticed when preparing an application. By hidden, I mean the intent of the question is not clear immediately. And even when the questions are clear, their requirements are so advanced and difficult to achieve that most companies stay away from them.

What are these tough questions hidden in the Baldrige criteria? Here is a list of my 10 favorites based on the 2008 version of the criteria.1

#### 1. Succession planning

Bob Galvin of Motorola is credited with having said, "The most important job of a CEO is to find the next CEO." If you have been reading management and leadership books for the last decade or so, you will likely have noted the importance placed on CEO succession.

It all started with Jack Welch searching for the next CEO of General Electric (GE) among three senior managers who reported to him. In hindsight, the public nature of the search was a masterstroke. Welch knew the two who were not selected would leave GE, and the media attention helped ensure they would lead other reputed and successful companies.

A question in item 1.1 of the criteria, "Senior Leadership," asks: "How do senior leaders personally participate in succession planning and the development of future organizational leaders?"

When the criteria seek to uncover personal involvement, hiding beneath the surface is the opportunity to discuss personal interest in team development and succession planning. Interest in the development of those who report directly to the CEO is often left to the discretion of the CEO. Many leaders prefer to focus on their own development to be ready for roles that may emerge in the future. The criteria, however, imply that leaders at top organizations think beyond their own careers.

In a recent discussion, the head of HR for a global IT company offered an interesting twist on the topic, arguing it was time to focus on developing the employees who report to the person who reports to the CEO (we'll call them the second line of reports). Further, a manager or leader would be naturally inclined to develop the second line compared to taking interest in the first line. Think about it. He or she is less threatened by the second layer than the first.

#### 2. Identify customers, markets

In most self-assessment gap analysis workshops I have conducted, I have found the toughest questions to answer are: "Who is your customer? How do you know?"

The first question in Baldrige criteria item 3.1.a.1 asks, "How do you identify customers, customer groups and market segments?"

If the question were simply "Who are your customers?" some organizations would be able to respond after some discussion. Phrasing it as a "how" question makes it more difficult, because it begs an answer that mentions a systematic process to identify customers and customer groups.

Customers can include past, current or future customers—even the competition's customers. In answering the question, it's expected of an organization to demonstrate an understanding of the difference between markets and customers.

I have been in workshops in which the first discussion involves identifying who the customer is, and mayhem follows. Confusion starts with how you define a customer. The question is no less challenging when asked about in-house services such as HR, finance or design. Even when the customer for such services is the rest of the company, when it comes to identifying the customers of those services, it's easy to stumble.

# There are questions that cause organizations to trip up because they don't have convincing answers.

Getting over this stumbling block requires tackling the question head on in your next group meeting. Simply ask: "Who is your customer?" If you have trouble reaching consensus on "who," you likely will not have a satisfactory explanation for the question of "how."

Identifying a target customer segment is achieved through careful review of vision, company strategy, product mix and reach. Moreover, this process must be repeatable and ideally should include triggers other than frequency.

#### 3. Strategy development

Hidden in the inputs required for effective strategy development is a question meant to trip up those who submit the same plan year after year: "How do you collect and analyze relevant data and information pertaining to the following factors as part of your strategic planning process?:

- Your organization's strengths, weaknesses, opportunities and threats.
- Early indications of major shifts in technology, markets, customer preferences, competition or the regulatory environment.
- Long-term organizational sustainability.
- Your ability to execute the strategic plan."

The question exposes the malady I have seen in many plans. How is the plan different from what was presented last year? Why do organizations present the same or very similar plans each year? More often than not, it's because they fail to execute the plan.

In discussing the importance of execution within a company's strategy, Larry Bossidy and Ram Charan suggest "the gap nobody knows is the gap between what a company's leaders want to achieve and the ability of their organization to achieve it." $^2$  If this failure is a habit and the gap is persistent, shouldn't it be considered while developing the new plan?

#### 4. Link objectives, challenges

The criteria ask for a list of strategic challenges in two places—in the organizational profile and in the strategic planning category. Organizations that focus only on writing the application often are tripped up by this and wind up writing different sets of challenges.

Question 2.1.b.2 addresses those identified challenges: "How do your strategic objectives address your strategic challenges and strategic advantages?"

Strategic planning is primarily about identifying strategic challenges and then planning for how to overcome them. By checking if the applicant has addressed the challenges, the criteria and the examiner come close to assessing the strategy of the applicant.

For example, consider an applicant that presents attrition of high-performing employees as a key strategic challenge. If the strategic plan does not include any response to attrition, the examiner can come to the conclusion the applicant has not developed a robust strategy.

#### 5. HR plan

The question that deals with an HR plan—my personal favorite in the criteria—is curiously placed in the stra-

tegic planning category, not in the workforce focus category.

This question suggests an HR plan is actually an output of a strategic plan and is not a separate exercise: "What are your key HR plans to accomplish your short and longerterm strategic objectives and action plans?"

If the HR function needs to be in sync with the business plan or strategy, it must be uniquely aligned to the strategy of the company. For

example, if a company strategy includes a major push in Latin America, the HR plan would be expected to address the skills needed to operate in that market—to sell, deliver and interact (language skills are particularly important in this example).

The HR plan should cover questions such as: "Do we have the necessary people in the organization? Can we develop some internally, or will we need to recruit all new hires?"



# In many ways, the future of an organization depends on effective leadership development.

#### 6. Review to improve, innovate

Almost anyone in senior management can speak to the importance of improvement. Lately, leaders have also taken to chiming in with something about innovation. These are the right terms and ideas to tout. The guestion is how to accomplish them—or even how to start.

This is the intent of a question in 4.1.b.1: "How do you translate organizational performance review findings into priorities for continuous and breakthrough improvement and into opportunities for innovation?"

Most organization-level reviews are exactly thatreviews. You conduct your review, and everyone goes home. This question in the criteria invites the possibility of a review actually having an impact.

Reviews should help identify key areas for improvement and, more important, innovation. This question focuses, as most criteria questions do, on the process of converting reviews into opportunities for improvement and innovation. How do you distill the discussion into clear talking points? How do you prioritize what is important? What criteria do you use to prioritize?

Try listing your organization's last five innovative products or services. How many of them were identified during organizational performance reviews?

#### 7. Motivation

Motivation is an overused word, probably even more well worn than strategy. Apart from leadership, which has the responsibility to create a culture and environment in which employees are motivated, the criteria do not pin responsibility on anyone.

Consider these questions from 5.1.a.1: "How do you determine the key factors that affect workforce engagement? How do you determine the key factors that affect workforce satisfaction?"

These questions highlight the need to know the motivation for each person in the organization. What works for a marketing employee won't necessarily work for one in research. Unless you know what motivates people, you don't have a realistic chance to satisfy these needs and, as a result, provide motivation.

Think about whether you know what motivates the

employees in your company or department. A blanket answer will not be adequate.

#### 8. Leadership development

In many ways, the future of an organization depends on effective leadership development. Absent that, it is possible the organization will face an acute shortage of leadership talent in the medium to long term.

Consider this question from 5.1.b.3: "How do you evaluate the effectiveness of your workforce and leadership development and learning systems?"

Part of this question asks for the effectiveness of workforce development and learning systems. This is easily answered by most organizations. But they struggle with the part about their leader development systems. This is a tough question that can conjure some really dirty looks, as if to say, "Isn't it enough we have a program for leadership development? Why do we need it to be effective?"

It's difficult to determine when a leader development program is really successful. Is it successful if you have more leaders in the pipeline? What if you don't have opportunities and the leaders leave you to join other companies? How can you measure or assess the effectiveness of a leadership development program?

Start by looking for the leadership pipeline, the number of times new leadership positions were filled from inside and the number of leaders who have been exported or left the company.

A study on www.workforce.com reports that as of October 2007, 20% of the CEOs at the largest U.S. companies once held a position at just 20 companies. A closer look at the 20 companies reveals very effective leadership development programs.3 I am not saying that exporting talent is effective. But, if for each talented employee shipped out there are three or four who stay back, that's an effective program.

#### 9. Core competencies

With the increase in outsourcing, it is vital for organizations to understand what their core competencies are. Once you know what you are good at and should be doing, you can consider which elements can be outsourced. Alternatively, you can find outsourcing partners for processes that can't be staffed based on the skills of your workforce.

This comes to the fore in a very deceptive question in 6.1.a.1: "How does your organization determine core competencies?"

It's important to note that the question does not ask you to identify what your core competencies are. Core competencies are the core of what you do-or rather, what you should do. They are the capabilities that provide you an edge in the market. They're not necessarily your core processes. For a large IT organization, a unique core competency could be the ability to hire a large talent pool each year. This may not be a process that is core to its operations, but it is still a core competency, assuming it does it well.

Rather, this tough question looks at how you identify core competencies. Try listing your organization's core competencies and the processes you followed to identify them. Can you repeat the process when the environment changes or your competencies change? How will you act when these changes occur? What was your long list of competencies? Who was involved in developing it? What were the criteria used to shorten the list?

#### 10. Best practices

Most progress comes from learning from one another. Practices tend to degenerate if they are not shared and improved upon. Most practices are actually improvements to other existing practices.

The criteria recognize this fact and include a question in 6.2.b: "How are improvements and lessons learned shared with other organizational units and processes to drive organizational learning and innovation?"

The question seeks to identify a process for sharing and learning about improvements across the organizations. Taking it a step further, the sharing of these lessons should feed into organizational learning and innovation. That can be tough to cover in one answer. Establishing the connection, however, is vital for higher levels of performance excellence, and it is a vital part of the engine for innovation.

Innovation does not happen on its own. An infrastructure and culture need to be developed for it to happen. Companies that have achieved higher levels of performance excellence are more likely to answer this question satisfactorily. Organizations can do well on this question only if they have the right infrastructure and culture in place for sharing practices.

#### Sound investment

Does spending extra time on the always tough, often hidden questions in the criteria work? Based on my experiences, absolutely.

In an organizationwide program at my company, Infosys, that uses elements of the Baldrige criteria, we focus our attention on select questions and find it helps business units:

- · Identify high-impact areas to improve upon.
- Close key gaps in Baldrige deployment.
- · Improve scores significantly, with more bang for the buck per action item.

Infosys has developed an abridged assessment process that primarily assesses business units on the previous 10 questions (and a few more). In doing so, we discovered that in a more comprehensive assessment, the key action items revolve around the issues discussed in this article. Further, when we sat down to identify key action items from a longer list, the ones discussed in this article dominated.

This article has highlighted some very tough questions from the Baldrige criteria, with the intent of focusing attention on questions and difficult issues that tend to remain hidden. My experience shows that focusing on these questions has a domino effect on the remaining requirements of the criteria.

Thoroughly addressing the tough, hidden questions you would rather avoid forces you to answer all surrounding questions in detail and compels you to take extra care with your overall application. QP

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# **Conscientious Calibrations**

#### Monitoring your measurements is good for the environment

SINCE THE 1990s, thousands of companies and organizations throughout the world have been certified to standards published by the International Organization for Standardization (ISO). Some of the compelling reasons why companies get certified include increasing quality, reducing costs, increasing efficiencies and complying with customer mandates.

By and large, the type of certification an organization pursues reflects the activities and services it provides. An organization's certification may be generic in nature, covering a broad range of business activities, or it may be very specific, focusing on a particular activity, such as providing a testing service that requires regulatory compliance.

#### In search of ISO

The ISO 9000 series are the standards of choice for organizations looking for accreditation. The ISO 9000 family covers quality management systems and includes ISO 9001:2008 Quality management systems—Requirements and ISO 9004:2000 Quality management systems—Guidelines for performance improvements.

A company or organization can publicly state it is ISO 9001 certified if it has been audited and certified by an independent accredited assessing body recognized by industry as having authority to grant certification.

It must be noted that certification to an ISO standard does not guarantee non-defective products or elimination of substandard service. Instead, it ensures industry-accepted processes and practices are being applied and evidence of compliance is deemed applicable and sufficient.

Section 7.6 of ISO 9001, "Control of Mea-

suring and Monitoring Devices," addresses inspection, measurement and test equipment (IM&TE) calibration requirements to help ensure an organization's measurement capability is consistent with monitoring and measurement requirements. It also provides evidence of product conformity.

Section 7.6 goes on to state that to ensure valid results, it is necessary to:

- · Calibrate or verify the devices at specified intervals or prior to use.
- Calibrate devices to national or international standards.
- Adjust or readjust devices as necessary.
- · Identify devices to determine calibration status.
- Safeguard devices from improper adjustments.
- Protect devices from damage and dete-

The standard also says "the validity of prior results must be assessed and recorded if the device is found to not conform to requirements. Records of the calibration and verification results must be maintained."1

#### **Greening calibration**

It is no wonder that when the question arises as to why an organization needs to have its IM&TE calibrated, the most common response involves ISO 9001 compliance.

But, recently, we became aware of an ISO published standard our company was certified to that contains calibration requirements for monitoring and measurement equipment and that shares many characteristics with ISO 9001—ISO 14001:2004 Environmental Management Systems— Requirements with guidance for use.

ISO 14001 helps an organization identify the environmental impact of activities,

products or services; continually improve its environmental performance; and implement a systematic approach to set and achieve environmental objectives.2 As it turns out, ISO 14001 certification is an important part of our company's green strategies and initiatives.

But what is required of a company or organization to be ISO 14001 certified? Essentially, it requires an environmentally friendly policy to be in place with assurance that this policy is fully supported by senior management and abided by the rank and file.

#### What is required

In our efforts to learn more about ISO 14001, we quickly became aware that a legal copy of an ISO published standard can set you back \$100 or more. Not wanting to pony up that kind of dough, we continued our search until we came across a detailed preview of ISO 14001, in which we learned that Section 4.5, "Checking Requirements," addresses IM&TE requirements as follows:3

#### 4.5.1 Establish monitoring and measurement capabilities.

- Establish procedures to monitor and measure the operational characteristics that could have a significant impact on the environment.
- Implement your organization's environmental monitoring and measuring procedures.
- Maintain your organization's environmental monitoring and measuring procedures.
- Use calibrated or verified environmental monitoring and measuring equipment.
- Maintain your organization's environmental monitoring and measuring equipment.

# Why do I need to get my equipment calibrated? Because it's good for the planet.

Keep a record of your environmental monitoring and measuring activities. The fourth bullet of Section 4.5.1 clearly specifies that environmental monitoring and measurement equipment shall be calibrated or verified. Similar to the reasoning behind the calibration requirements of Section 7.6 of ISO 9001, Section 4.5.1 of ISO 14001 helps to ensure the validity and acceptance of measurement results.

We made it a point to share this infor-

mation with other calibration practitioners within our group who quickly surmised another logical discussion point to better answer an age-old customer question: Why do I need to get my IM&TE calibrated? Because it's good for the planet. QP

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#### GREEN LIGHT

Go ahead and let the QP community know what your organization is doing to be environmentally responsible by e-mailing editor@asq.org.



# Out of Quality, Out of Business

#### Shifting the perception of quality from nonessential to essential

**BEING LEAN** used to be associated with poverty and starvation. Today, being lean refers to profitability and fitness, especially in business. Cutting corporate fat, or nonessentials, has become as important for organizational health as slimming down is for personal health.

Unfortunately, quality seems to get tossed into the corporate fat vat more often than it should. How could quality have shifted from being essential to nonessential, and how can we shift the perception about quality back to one of being essential again?

that quality is nonessential or even wasteful. Here are five major flaws:

1. Confusing detection with prevention. Quality control and quality assurance are definitely not the same things, although they can be easily misunderstood. Quality control is about detecting mistakes after they have been made. This is also known as inspection. Quality assurance is about preventing mistakes from happening. This is also known as quality engineering or quality management.

When people unfamiliar with these differences say quality is nonessential,

> they are talking only about quality control. Unfortunately, this may be all it takes for the top management of a company to decide to eliminate all quality professionals from the workplace, including those who prevent quality mistakes.



tion for fact. Quality assurance professionals ensure quality has been designed into a product or process using the statistical tools mentioned earlier. Without this information, decision makers may believe quality has been designed into products or processes when it has not. Without quality control, quality mistakes will also not be detected.

3. Focusing on the short term without the long term. Liability associated with knowing about quality problems has made it impractical for top managers to

seek information about quality problems.1 Their most effective short-term strategy might be to avoid information about quality problems while others in the organization work to solve them.

Unfortunately, problems seldom go away when ignored and, without quality assurance professionals to identify the problems and champion their solutions, the problems will likely grow in the long term.

4. Confusing bad quality with good quality. The absence of quality may have become confused with the presence of quality. Bad quality leaves more of a lasting impression than good quality. Bad things are wasteful. If some quality is bad, it might be tempting to say quality is wasteful.

5. Mistaking excellence for quality. Excellence and quality are not interchangeable words. According to Robert Pirsig, quality came from the Greek word arete, which means excellence with virtue.2 Excellence without virtue is, therefore, not quality. Pirsig also said quality is the result of care.3

Those who stop using quality in their language may instead start using excellence. Excellence, unfortunately, does not require virtue or care. Just as a process can be perfectly in control but totally incapable, an organization can be excellent at providing a product or service about which nobody cares.

#### Restoring quality as essential

Quality has always been a selling point. In fact, quality sells itself. If we want to reestablish how essential quality is, we need to demonstrate that business cannot go on without it.

Marketing professionals use statistical



#### How quality turns nonessential

Designing quality into products and processes—a lean approach—can justify elimination of quality inspection. Statistical tools such as design for manufacturing, process capability optimization and statistical process control, along with process automation, can reduce human errors, avoid rework and scrap expenses, and stop costly warranty returns or field repairs.

In principle, becoming lean sounds sensible. In practice, there can be major flaws, beginning with the misperception

# **Good quality** sells your company's products and services.

analyses to determine what customers want. Quality professionals use statistical analyses to ensure customers get what they want. Sales professionals present the key features of products and services customers care to buy. Quality professionals ensure the key selling features of products and services are cared about by those who provide them.

Capitalize on similarities between marketing, sales and quality professionals. Synergy describes a situation whereby a group working together can produce a better single result than the combined independent results of the same individuals working alone.

Here are several ideas about how quality professionals can develop synergies with marketing and sales professionals:

- 1. Interface with prospective customers about quality requirements.
- 2. Attend customer-related events on behalf of your company to demonstrate your organization's commitment to quality. Enlist help from sales or marketing to develop your presentation.
- 3. Publicize your organization's qualityrelated achievements by sending press releases to popular industry and trade publications.
- 4. Report quality performance related to dollars shipped, sales booked and customer satisfaction.
- 5. Make quality-related presentations on behalf of your company to industry, professional or community organizations.

- 6. Include your title and company name in your profile and become active in business-related, internet-based social networks, such as LinkedIn.4
- 7. Participate in expert industry surveys by respected independent research agencies on behalf of your organization.

8. Share copies of materials from your

sales and marketing-related efforts with your organization's top management. Quality does sell. Bad quality sells other companies' products and services. Good quality sells your company's products and services. Great quality sells greatly. The bottom line is, when it comes to selling what your company has to offer, if your company is out of quality, your company is out of business. I'd say that

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#### **HOW ARE YOU KEEPING QUALITY ESSENTIAL?**

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# A Remedy Using Residuals

### Develop a univariate technique to control two process variables

**IT IS COMMON** in industrial processes for input variables to be closely associated with output variables. You may frequently encounter two process variables tied together.

For example, consider temperature and pressure. As the temperature increases, so does the pressure. Consider fuel use and steam production. An increase in steam production requires an increase in fuel use to produce more steam.

To statistically control two closely associated process variables, two distinct approaches can be used. One approach is to control the two variables (together) through multivariate statistical process control; however, not everyone is familiar with multivariate techniques. As an alternative, you can develop a univariate control procedure based on monitoring one of the variables after removing the effect of the other. This technique involves monitoring the residuals and has many applications in statistical process control.

#### **Residual error**

Consider a processing industry that monitors the amount of fuel used to produce steam. A natural gas-fired boiler converts water into steam for use in the process. The water is brought into the boiler and heated by natural gas under pressure to produce high-temperature and high-pressure steam that is distributed as an energy source throughout the plant. The unit of measure for the natural gas is in standard cubic feet of gas per hour (scfh), and the unit of measure for steam produced is pounds per hour (lbs/hr).

To increase steam production, more natural gas must be used in firing the boiler. Likewise, to decrease the amount of steam being produced, less natural gas is used to fire the boiler. This demand factor produces a swing in fuel use that invalidates the use of most control procedures because it increases the variation and produces extended runs (for example, consecutive observations above or below the fuel-use mean). This is evident in the

Shewhart control chart of fuel use for a natural gas boiler in Figure 1. The 109 observations were obtained when the boiler performance was deemed excellent.

Plotting moving averages will lessen the size of these fuel-use swings and will considerably reduce the estimated standard deviation. Consider the moving-average control chart in Figure 2 for the boiler data.

You can develop a univariate control procedure **based**on monitoring one of the variables after removing the effect of the other.

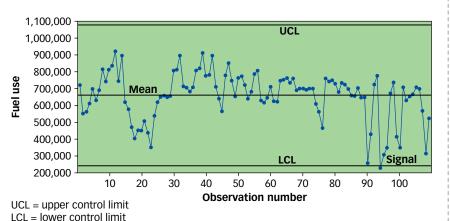
The moving averages are computed from the original fuel-use data using a time span of two. Thus, each point in the chart represents the average of two consecutive points.

Observe that there are numerous moving averages in the chart outside the upper control limit (UCL) and lower control limit (LCL), yet these values were obtained during a time period in which boiler performance was excellent.

An investigation of the points outside the control limits in Figure 2 shows the moving averages that signaled were either very large values (indicating a time period with too much fuel use) or very small values (indicating a time period with too little fuel use). In other words, the control procedure specifies a moving average as being atypical if it is not in the middle of the pack. The largeness or smallness of fuel use alone does not, however, constitute an upset condition in the system. It takes a large amount of fuel to produce a large amount of steam.

To set a clearer picture of the process, you must examine the relationship be-

# Shewhart control chart of fuel use / FIGURE 1



tween fuel use and steam production. This is depicted in the scatterplot in Figure 3 for the sample of data used to construct the control chart given in Figure 1. The computed correlation between fuel use and steam production in this dataset is 0.989, indicating a very strong linear relationship exists between them.

The relationship between the two variables also can be studied by fitting a regression line to fuel use based on steam production. The straight-line regression equation is given by:

Predicted fuel = a + b (steam), in which a is the estimated intercept and b is the estimated slope of the line. A residual, which is the error in the regression fit, is defined as the difference between the observed fuel and the predicted fuel use for a given steam value. The two estimated regression coefficients are computed from the data using the method of least squares to minimize the sum of the squared residuals. Using the data in Figure 3, the regression equation is calculated to be:

Fuel = -18,028.7 + 1.21994 (steam). It is represented by the line plotted in Figure 3.

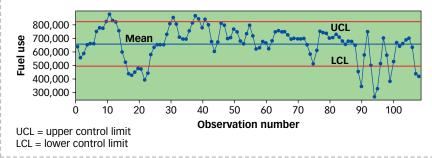
The above regression equation has numerous uses, including predicting the value of fuel for a given value of steam. For example, consider the circled point in the upper-right corner of Figure 3. The coordinates of this point are: fuel use = 850,740scfh and steam production = 732,298 lbs/ hr. Using the regression equation, fuel use can be predicted by substituting the steam production value of 732,298 and solving the equation to obtain:

> Fuel = -18,029 + 1.21994 (732,298) =875,331.

For this observation, the corresponding residual (observed fuel - predicted fuel) is given by:

Residual = 850,740 - 875,331 = -24,591. This appears to be a large number. When you consider the variation, however, you will see a different picture.

#### **Moving-average chart** for fuel use / FIGURE 2



#### Control based on residuals

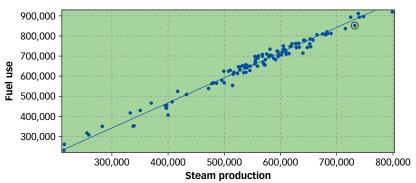
The size of a residual can be judged most easily by examining its corresponding studentized residual, which is obtained by dividing the residual error by its estimated standard deviation. For example, the value of the estimated standard deviation for the above residual is 20,954, producing a studentized residual of -24,291/20,954 =-1.174.

In general, a studentized residual can be treated as an observation from an approximate standard normal distribution—for example, a normal variable with a mean of zero and a variance of 1. Because standard normal variables occur between ± 3 approximately 99.73% of the time, this fact can be used to establish a control chart based on the residual values and with control limits set at ±3.

Using the previous fuel-use data, a control procedure was developed for the corresponding studentized residuals obtained from the plotted regression equation given in Figure 3. The results are in Figure 4 (p. 54). Only one point (No. 18) is designated as being out of control (below the LCL). Contrast this result with the many signals obtained in the moving-average chart in Figure 2, which did not adjust fuel for the effects of the steam.

For situations similar to the earlier example, a regression equation with multiple variables can be constructed from a historical data set (HDS) obtained under good operational conditions to predict an important process variable (criterion variable). Given a good fit to the data and no changes in the process, the regression equation should accurately predict the

#### Scatterplot of fuel use and steam production / FIGURE 3



value of the criterion variable from the other process variables.

The residual is a measure of the goodness of the prediction. Small errors in the residuals from this multiple regression equation would imply the process is conforming to the relationships established in the HDS. Large errors would indicate something is out of control.

For most control procedures, you assume the observations are independent. Many times in the process industry, this condition is not satisfied because the data are time dependent or autocorrelated.2 This means that an observation taken at time t is related to the previous observation made at time (t-1).

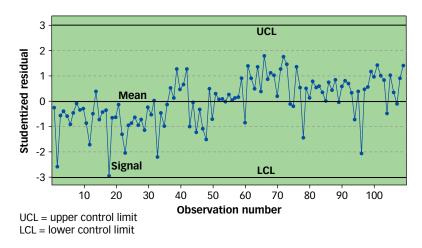
When autocorrelation is present, it is difficult to construct a control procedure on a variable due to the time effect. It is easy to construct a control procedure based on the residuals, however, in which the effect of the time variable has been removed. In this case, the underlying regression model takes a slightly different form and is referred to as an autoregressive model of order one.3 The resulting prediction equation is:

(Observation at time t) = c + d (observation at time (t-1),

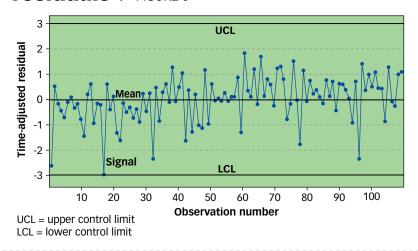
in which c and d are the estimated coefficients. The time-adjusted residuals from this fitted equation could then be plotted in a control chart.

For example, if we apply run rules (rules for detecting signals due to the length of the number of successive observations above and below the mean of zero) to the control chart in Figure 4, there would be a number of signals. This indicates the corresponding studentized residuals in the plot are autocorrelated. When you fit an autoregressive model to these studentized residuals, however, and then compute the time-adjusted studentized residuals using an autoregressive model, you obtain the time-adjusted residual plot in Figure 5.

#### **Control chart for studentized** residuals / FIGURE 4



#### **Control chart for time-adjusted** residuals / FIGURE 5



This plot does not contain all of the runs observed in Figure 4 and is free of much of the effects of the time dependency. In addition, the same observation that produced a signal in Figure 4 continues to produce a signal in Figure 5. QP



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# ASQ's **Annual Quality** Resource Guide

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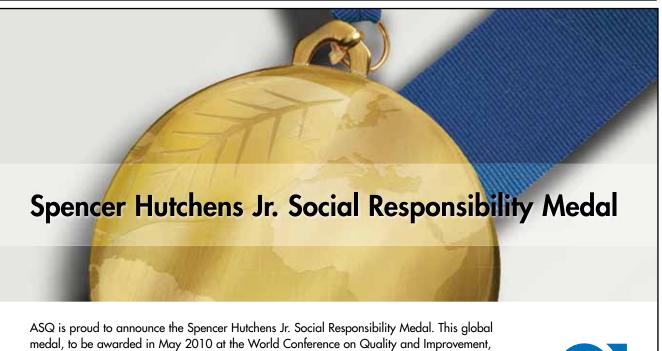
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# The Right Approach

#### An effective QMS audit requires a process-based strategy

**THE PROCESS** approach is at the heart of a quality management system (QMS) defined by ISO 9001. And, as everyone knows, it's necessary to have the old ticker checked out from time to time. That's where the plan-do-check-act (PDCA) cycle can be useful as the primary tool employed during a process audit.

But what is a process? In this context, it is a transformation of inputs to outputs that is constrained by controls and limited resources (see Figure 1).

Consider the manufacture of printed circuit boards. The process transforms raw materials, such as components and raw circuit boards, into printed circuit boards. The process is constrained by controls, such as temperature of the solder bath, speed of the manufacturing line, testing sequence, component insertion and resources that include components, circuit boards, trained personnel and manufacturing equipment.

ISO 9001 contains eight clauses, the last five of which define an effective QMS:

- Clause 4, Quality Management System: describes the basic structure of an effective QMS.
- Clause 5, Management Responsibility: indicates the management and oversight of the QMS.
- Clause 6, Resource Management: describes the control of resources and

- includes competence, awareness and training of personnel.
- Clause 7, Product Realization: identifies inputs to the product realization process, such as customer requirements, and the outputs, which are the end results of the product realization process.
- Clause 8, Measurement Analysis and Improvement: contains the method for turning data into information and actions. As part of clause 8, the improvement process includes preventive and corrective actions and concludes with management review in clause 5.

The process approach is defined in subclause 0.2 of ISO 9001 and is expanded in subclause 4.1, which requires identification of all processes and their applications; determination of their sequences and interactions; identification of criteria and methods to ensure their effectiveness; provision of supporting resources and information; monitoring, measurement and analysis of each process; and implementation of actions to achieve results and improvement.

In my experiences, a QMS has eight basic processes:

- 1. Management of the quality system.
- 2. Top management involvement.
- 3. Customer focus.
- 4. The improvement process.
- 5. Design and development.
- 6. Supplier management.
- 7. Product provision (including control of outsourced processes).
- 8. Resource management.

#### **Definition of a Drocess** / Figure 1



#### **Auditing a process-based QMS**

What is different about auditing a processbased QMS? In the past, the audit scope

was determined by the elements or clauses of the standard, and audits tended to center around yes-or-no checklists. ISO 9001:1994 was checklist-oriented and included 20 elements.

When I used ISO 9001:1994 to audit in the 1990s, however, I used a processbased method because it was closer to the way an organization operated. With the release of ISO 9001:2000, the orientation was officially changed to a process approach.

Several preliminary steps should be taken prior to auditing the processes. Start by developing a business process overview, understanding the organization's goals and business objectives, and conducting a detailed audit of the quality

Then, accomplish the following process-oriented activities: identify the organization's major quality-affecting processes, examine links between processes. determine whether processes are integrated to form a system, establish whether the eight basic processes are covered and perform a preliminary analysis of the system's processes.

Analyzing the processes consists of: identifying an owner for each process; defining the inputs, outputs and constraints (controls and resource limitations) of each process; determining the activities of each process in terms of PDCA; and developing a checklist for each process.

This information is needed to understand the operation of the system. It's best to use open-ended questions or directions; for example, "Describe the activities of the management review."

The final preliminary step is to develop

the three-year audit schedule. Many of the basic processes contain sub-processes that can be audited separately or included in the audit of the basic process.

Tables 1 and 2 are examples of a three-year audit schedule for a company that manufactures communications equipment. "R" indicates a process audit conducted during each visit, while the "S" followed by a number indicates an audit conducted during the visit indicated by the number.

#### **Auditor's role**

Process auditing starts by looking at how the processes function and how they link elements of various clauses. Many processes are cross-functional or involve several departments. The auditor should use PDCA to identify the parts of the standard necessary for the function of each process and should build the audit around open-ended questions, which reveal more about each process.

The interviews should start with the process owner-the person who can provide the best information about the operation of the process. Other key personnel should be interviewed to get a complete picture. If questions arise, start the discussion with the appropriate clauses of the standard. Always refer to the exact wording, and clarify if necessary.

The auditor should obtain objective evidence by performing a walkthrough review of the steps of each process. When a finding is identified, the auditor should sit down with the process owner and other implementers to describe the finding. Always refer to the wording of the standard.

The auditor can also identify opportunities for improvement. These are not findings-they are suggestions for improvement based on the standard. For example, I've suggested that the management review should include financial management personnel. This is not a

#### Management processes / TABLE 1

Management processes and subprocesses	Quality management	Vice president operations	Human resources
Management of the quality system	R	R	
- Document review	R		
- Document control	R		
- Control of records	R		
- Information management	R	R	
Top management involvement	R	R	
- Management review	R	R	
Customer focus	R	R	
- Returns and repairs	R	R	
Resource management	S2		S2
- Training			S2
- Infrastructure	S2		S2
- Work environment	S2		S2

#### **Production processes** / TABLE 2

Production processes and subprocesses	Quality management	Product engineering	Manufacturing
Design and development	S4	S4	S4
Supplier management	S5	<b>S</b> 5	<b>S</b> 5
Product provision	S1	S1	S1
- Orders and quotes	S1		
- Receiving inspection	S1		
- Final inspection			S1
- Inventory control	S1		
- Shipping	S1	S1	
The improvement process	S3		
- Internal audits	S3		
- Analysis and use of data	S3		
- Corrective action	S3		
- Preventive action	S3		
- Nonconforming product	S3		

requirement of the standard, but it will reveal links to the financial aspects of the organization.

#### Step by step

The following is an example of a process audit in which the PDCA cycle is employed to outline the audit procedure used for an improvement process. The numbers in parentheses are the associated clauses of ISO 9001:2008.

The "plan" step starts by reviewing top management responsibilities in clause 5. The first questions are, "What is the quality policy?" (5.3) and "How was it

transmitted throughout the organization?" Also, part of clause 5 is the determination of measurable quality objectives (5.4.1) and QMS planning (5.4.2).

Four related questions applicable during this stage are:

- How are objectives set?
- Have objectives been established for the various functions and levels throughout the organization?
- Does each quality objective (5.4.1) align with the quality policy (5.3)?
- Does the QMS planning meet the requirements of subclause 4.1? This stage also contains planning of

#### STANDARDS OUTLOOK

product realization (7.1) and planning of monitoring, analysis and improvement (8.1).

Planning of product realization includes determining quality objectives and requirements for the product; establishing the processes, documentation and records needed; and defining the elements of the realization process. Planning of measurement, analysis and improvement is meant to demonstrate conformity to product requirements, ensure conformity of the QMS and continually improve the effectiveness of the QMS.

Once the review of the planning is completed, the auditor can start looking at the "do" element. For the improvement process, this is centered on the improvement loop in subclause 8.5.1, which requires improvement of the effectiveness of the QMS through the use of quality policy (5.3), quality objectives (5.4.1), audit results (8.2.2), analysis of data (8.4), corrective actions (8.5.2), preventive actions (8.5.3) and management review (5.6).

The key to determining the effectiveness of the improvement loop is a review of the inputs and outputs of the management review function. What are the results of management review over time? How do they demonstrate the improved effectiveness of the QMS?

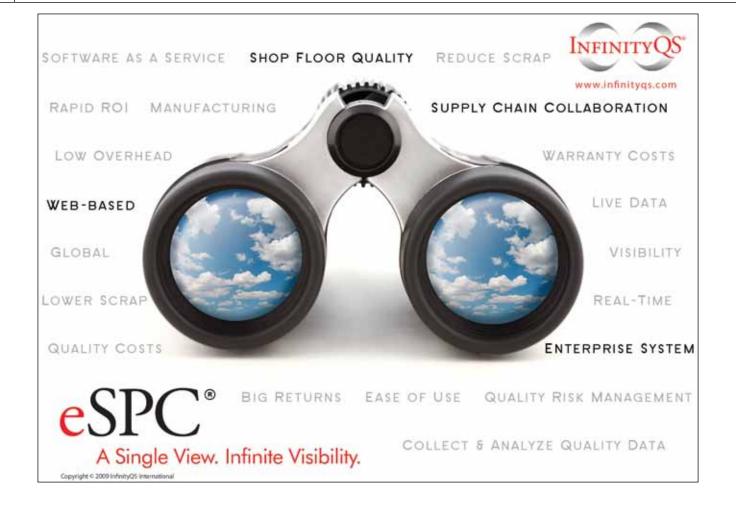
The "check" element looks at how data are gathered and turned into information. Data have no value until they become information. The data come from internal and external audits (8.2.2), monitoring and measuring of processes (8.2.3) and products (8.2.4), control of nonconforming product (8.3), customer satisfaction measurements (8.2.1) and supplier results (7.4). The analysis of the data, including trends, should lead to corrective (8.5.2) or preventive actions (8.5.3).

Finally, the "act" element describes the actions taken to improve the effectiveness of the QMS. The auditor should look at the corrective (8.5.2) and preventive (8.5.3) actions that were implemented. Were they effective? What improvements were observed?

The results should be documented as part of the management review (5.6). The

#### PROCESS SERVER

Is PDCA the best tool to use when performing a process-centric audit, or have you found others to be more effective? Share your experiences with us by e-mailing editor@asq.org.



result of the management review should be improvement of the QMS and its processes, improvement of product with respect to customer requirements and identification of added resources needed.

As part of the "act" stage, the auditor should audit top management by asking the following questions:

- What are the results of the latest management review?
- Does management examine measurements of customer satisfaction, product conformity and process performance?
- Do the management-review minutes include a review of changes that could affect the quality policy and objectives?
- What is the measure of the effectiveness of the QMS?
- Does management make decisions and create actions to improve the effectiveness of the QMS?

• How often do you or your direct reports attend the meetings?

#### An effective ending

Eleven clauses, including the improvement loop (8.5.1), require continual improvement of the effectiveness of the QMS. My experience is that most organizations do not define effectiveness well. One example of a satisfactory measurement of effectiveness is a balanced scorecard based on measurements of the key measurable objectives.

Because organizations operate via processes, the approach to internal audits has changed from element or clause-based to process-based. ISO 9001 defined the process approach (4.1) in response to this realization. The PDCA tool will help you reach the end of the audit, at which time a sound judgment can be made about the effectiveness of your QMS. QP

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SANDFORD LIEBESMAN is president of Sandford Quality Consulting in Morristown, NJ, following more than 30 vears of experience in quality at Bell Laboratories, Lucent Technologies and Bellcore (Telcordia). He is an author of TL 9000, Release 3.0: A Guide to Measuring Excellence in Telecom-

munications, second edition, and Using ISO 9000 to Improve Business Processes, Liebesman, a fellow of ASO and chairman of the Electronics and Communications Division, is a member of ISO technical committee 176 and the ANSI Z-1 committee on quality assurance. He is an RABQSA-certified ISO 9000 and TL 9000 lead auditor





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Look for the ISO 26000 - Guidance on Social Responsibility international standard, coming in the fall of 2010.

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The VPM comes preloaded with tolerance settings based on 15 internationally recognized standards. Users select the appropriate standard for the application, and the VPM logs those events while ignoring the rest. Technicians can also set their own custom thresholds to meet specific needs.

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#### OEM pressure sensors A

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#### Web-based enterprise system

EtQ has announced enhanced features in the latest release of its web-based enterprise system for quality, compliance and environmental health and safety management. Reliance 6.2 incorporates enhanced

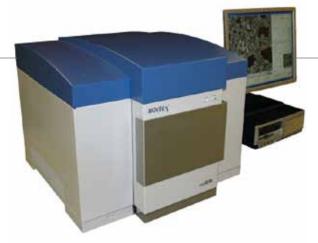
features and utilities, including automation, integration and reporting.

Enhancements to the latest release

- · Searching and filtering capabilities give the user the ability to retrieve past search strings.
- Enterprise configuration center enables a centralized resource for managing multiple facilities.
- · Customer complaints module allows users to track all aspects of their customer data.
- Connection profiles is a graphical, web-based administration tool enabling integration between EtQ Reliance and third-party business systems.
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#### Scanning electron microscope A

Novelx's mySEM is a bench-top scanning electron microscope for imaging and characterizing nanoscale objects and materials. It's compact and installs into available lab space or closer to production lines. The my-SEM is designed for low-voltage operation. It's used for the imaging of energy sensitive nanomaterials, biomaterials, polymers, thin films and membranes.

Several imaging techniques are available with the mySEM to enhance surface contrast and allow nanoscale features to be observed. The mySEM eliminates charging of non-conductive samples without the need to coat samples, which can mask many nanoscale features, or to operate at increased pressure, which can degrade resolution.

Industrial applications include the characterization of nanomaterials at corporate product development labs, the failure analysis of nanoscale defects and the quality assurance of nanomaterial-based products closer to the production line.

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#### Variable speed pump controller

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for heating, ventilation and air conditioning, and pressure booster applications.

The 502 integrated pump controller and adjustable frequency drive features control of up to four parallel pumps and four analog inputs for a combination of zone sensors, flow sensors and suction sensors. Customized algorithms to handle the entire range of pumping applications, including secondary, tertiary, hot water, chilled water and pressure boosting are also standard.

The 502 program safeguards against

damaging hydraulic conditions, such as pump-flow surges and system overpressurization. The 502 contributes to Leadership in Environmental and Energy Design certification and may also qualify for economic stimulus rebate or local power company incentives.

Call: 847-983-5811: visit: www.bellgossett.com.

#### Reference temperature calibrator >

Ametek Calibration Instruments has introduced the Jofra RTC-156, a block reference temperature calibrator featuring a dynamic load compensation (DLC) system for temperature uniformity in the insert, no matter the number or size

of the sensors immersed. The RTC-156 also has sensors for plug-and-play connectivity, a full-color video graphics array display and a USB connection for communications and software downloads.

The RTC-156 performs calibrations over a wide range of temperatures, from -30 C° up to 155 C°. Heating and cooling speeds also have been increased 20% versus comparable calibrators.

Three models are available: RTC-A reference temperature calibrator; RTC-B reference temperature calibrator with input for reference sensor, DLC sensor and sensors-under-test; and RTC-C reference temperature calibrator with input for reference sensor and DLC sensor. Ametek's Jofracal proprietary software package comes standard on all models.

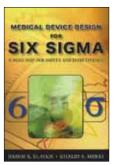
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# REVIEWS

#### **Medical Device Design for Six** Sigma: A Road Map for Safety and Effectiveness

Basem S. El-Haik and Khalid S. Mekki, Wiley Interscience, 2008, 528 pp., \$148.50 (book).



The title of this volume does not reflect the amount of material El-Haik and Mekki cover. The first four chapters provide grounding in the evolution of Six Sigma, global

perspectives on medical device regulations, how to define quality in terms of medical devices and a thorough review of the basic statistical methods needed to understand the technical chapters that follow.

The authors have chosen to focus on the U.S. Food and Drug Administration (FDA) and the design controls related to FDA regulations. The book is exhaustive in describing the process of medical device design, starting with a description of the roles and responsibilities in deploying a Six Sigma medical device design team and discussing strategic and tactical methods used.

The middle chapters of the book focus on the project roadmap and phases of design for Six Sigma (DFSS), first from a high-level overview, proceeding to specific phases and then the seven lifecycle development stages. The reader moves to quality function deployment and how it is used to transfer customer needs into the design. This is important because the authors discuss sustainability issues and how to prevent problems from arising before the design becomes operational.

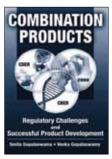
The last third of the book moves the reader through the most important aspects of risk management and how to translate the information in the book to a generic design template for continued robust design development and design verification before launching a product.

Finally, design review in light of federal regulations is discussed, and a case study is presented. An all-encompassing handbook for integrating Six Sigma and medical device design, this book would be a great addition to the bookshelves of technical staff in the medical device industry.

> Reviewed by I. Elaine Allen Babson College Wesllesley, MA

#### **Combination Products: Regula**tory Challenges and Successful **Product Development**

Smita Gopalaswamy and Venky Gopalaswamy, CRC Press, 2008, 264 pp., \$139.95 (book).



This book is an excellent summary and source of information for addressing the myriad issues involved in combination product (CP) development, regulation,

quality control and pre and post launch. A CP is the integration of at least two FDA-regulated components: drugs, medical devices or biologics.

The authors provide practical and easy-to-understand product development approaches that can be used regardless of level of expertise. This book will be useful

to anyone considering marketing any type of FDA-regulated product.

Each development scenario goes through the six domains of the lifecycle: innovation, customer needs, product function, design, processing and postmarketing with the appropriate modifications for the product type. A 360-degree viewpoint is used, and few aspects are not mentioned for consideration. Discussion of requirements is thorough and as direct as possible given the multiple product possibilities.

Particularly noteworthy are the voice of the customer analysis and DFSS cascade. Regulatory expectations are provided for each step for the United States, European Union, Canada, Japan, China and India, with guidance to the involved agencies' departments and their interactions.

The table of contents, bibliography and index are well organized and make finding specific topics simple. Numerous tables summarize huge volumes of information in an easily understood and practical manner.

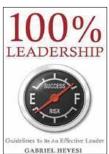
The authors have done a superb job of distilling their considerable years of experience and consulting work into an easy-toread format. If there is anything to object to in this book, it is that while there are many examples given, the authors will never be able to cover each and every reader's specific issues.

Each person responsible for a domain in the CP lifecycle should be required to read and have a copy of this book. It will definitely increase efficiency and eliminate a lot of wasted time spent searching for answers or direction.

> Reviewed by Marc A. Feldman Solvay Chemicals Houston

#### **100% Leadership: Guidelines** To Be An Effective Leader

Gabriel Hevesi, with editors Tracy S. Epley and Collin R. Mcloughlin, Enna Inc., 2008, 150 pp., \$21.99 (book).



Hevesi, a former managing partner of Brazil-based management consulting firm Target Ltd., draws on his 50-plus years of front-line business management experience in

three countries to provide yet another guide to leadership that joins the already burgeoning library of works on this topic.

Hevesi organizes his material into 16 succinct, tersely cogent chapters on common leadership issues, such as communication, team building, planning and risk taking, efficiency, decision making and global business. His intent is to make the information useful, and he includes opposing systems, theories and opinions to provoke readers into thinking about the material and adjusting it to fit their own situations and help them solve their own problems.

Hevesi's many years of first-hand responsibility in leadership positions help connect these ideas with readers who may have grown tired of the management-consultant psychobabble that, unfortunately, fills our shelves.

His sound ideas are well organized, and his concern for others bearing the burdens of leadership is genuinely evident. I recommend this book for anyone newly appointed to the role of management in any organization.

> Reviewed by Dale Farris Groves, TX

#### **Achieving Class A Business Excellence: An Executive's Perspective**

Dennis Groves, Kevin Herbert and Jim Correll, 2008, John Wiley & Sons, 385 pp., \$45 (book).



Greg Sanders is our hero in this fictitious story of a journey to lead a company using the book The Oliver Wight Class A Checklist for Business Excellence.

Sanders is brought in to save a chronically ill cosmetic product division, which is failing in its customer service.

The whole story is a skillful description of the problems an executive encounters and how to deal with them while also trying to achieve class A status.

The class A concepts are introduced through coaching lectures and personal guidance by the character Roxanne Barnes, a consultant brought in to help this company.

Just like all fairy tales, Sanders guides the division to achieve class A status and is promoted to CEO.

The book is written from a top executive's perspective, providing a solid roadmap on how to use integrated business management throughout conversion processes. The class A concepts provide another approach with the required strategy, information and tools to achieve class A status, filling in the gap Six Sigma does not adequately address. I recommend this book for all senior managers and Six Sigma practitioners.

> Reviewed by Shin Ta Liu Lynx Systems San Diego

#### RECENT RELEASES

#### HALT, HASS, and HASA Explained: Accelerated Reliability **Techniques**

Harry W. McLean, ASO Quality Press, 2009, 208 pp., \$65 list, \$39 member (revised edition, book).

Solutions to the Healthcare **Quality Crisis: Cases and Examples of Lean Six Sigma** in Healthcare

Soren Bisgaard (editor), ASQ Quality Press, 2009, 208 pp., \$40 list, \$24 member (book).

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- 13-15 Lean Product Development. Schaumburg, IL. Visit the Society of Manufacturing Engineers' website at www.sme. org.

- 13-16 Global Lean, Six Sigma and **Business Improvement Summit and** Awards. Orlando, FL. Call Worldwide Conventions and Business Forums at 800-959-6549 or visit www.wcbf.com/quality/5099.
- 15 ASQ Education Course. ISO 22000:2005 Food Safety Management System Requirements: An Overview-Virtual Course.
- 15-16 ASQ Conference. 18th Annual Audit Conference. Tucson, AZ. Visit the Audit Division's website at www.asg.org/ audit/interaction/conferences-audit.html.
- 23 ASQ Conference. Silicon Valley Quality Conference. Santa Clara, CA. Visit www.asq-silicon-valley.org.
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- 21-23 15th International Symposium on Quality Function Deployment. Monterrey, Mexico. Visit Latin American Quality Function Deployment's website at www.gfdlat.com/isgfd09.
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# Testing, Testing, 1, 2, 3

#### Verify the manual, as well as the product

**JUST AS IT** is important that a product function properly, the product manual must also work. Owners or product users must be able to easily find information they need to use an item effectively.

To achieve this objective, the manual's content must be clear and its organization beyond reproach. Unfortunately, product manual writers and product users do not always think the same way.

Proper content and organization might seem like a given, but there are often inherent differences between the mind-set of the writer and that of the reader. These differences can stand in the way of creating a truly useful document and are likely to affect the manual's organization more than its content. Manuals are usually written by someone who is an expert in the way the product works, while users are often novices

Expert and novice differences in thinking have been the focus of an impressive body of research that began around 1965.<sup>1,2</sup> In applying this research to product development, we could conclude that someone with an expert's knowledge of a particular product would think about that product in terms of patterns, integrated components and abstract relationships. The novice user of the product, on the other hand, would reason about it in terms of individual components that are concrete and visible.

#### **Shedding some light**

As an example of these differences, I wanted the interior overhead light of my new sport utility vehicle to come on when I opened the door. The overhead light section of the owner's manual indicated that the three-position switch ("off," "door"

and "on") needed to be in the "door" position, which it was. What this section of the manual did not say was that a control on the front instrument panel must be set in a particular position for the overhead light to be triggered by the opening of a door.

I learned of this requirement only after calling the dealership. The control setting was indeed mentioned in the owners' manual, but it appeared in the instrument panel section. This placement probably

jectives and plan. The novices should use the manual to guide them in the product's intended function, solve problems that are encountered and answer questions.

The novices could be representative users of the product within the company, or they could be potential customers, perhaps in the form of a focus group. Another approach would be forming a test group within the company whose mission and skill is that of product manual testing.

# Manual writers and product users do not always think the same way.

made perfect sense to the expert who wrote the manual and understood the relationship between these two components. It didn't, however, make sense to me, the novice who was trying to get the light to come on and who didn't know of this relationship. I only thought to look it up in the overhead light section of the manual.

This is an example of a product with excellent quality and a manual with all the necessary information. The issue is where that information is located in the manual.

#### **Testing, 1, 2, 3**

The product manual, then, should be tested, along with the product. This should be performed by a combined effort of experts who thoroughly understand the product and novices who do not. The expertspreferably not the same ones who wrote the manual-should establish the test ob-

In general, almost any form of documentation intended for non-experts could benefit from this approach. This is consistent with a true customer-centered design process, as it forces the writer to focus on the thought process of the customer, especially with respect to the organization of the document. **OP** 

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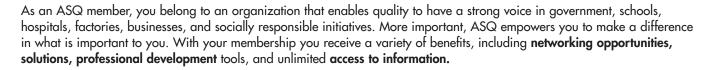








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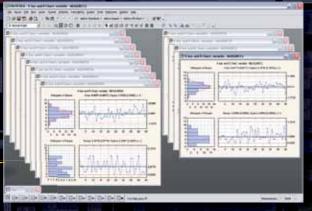


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