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ISO 9001:2015

VOLUME 47/NUMBER 9

QP

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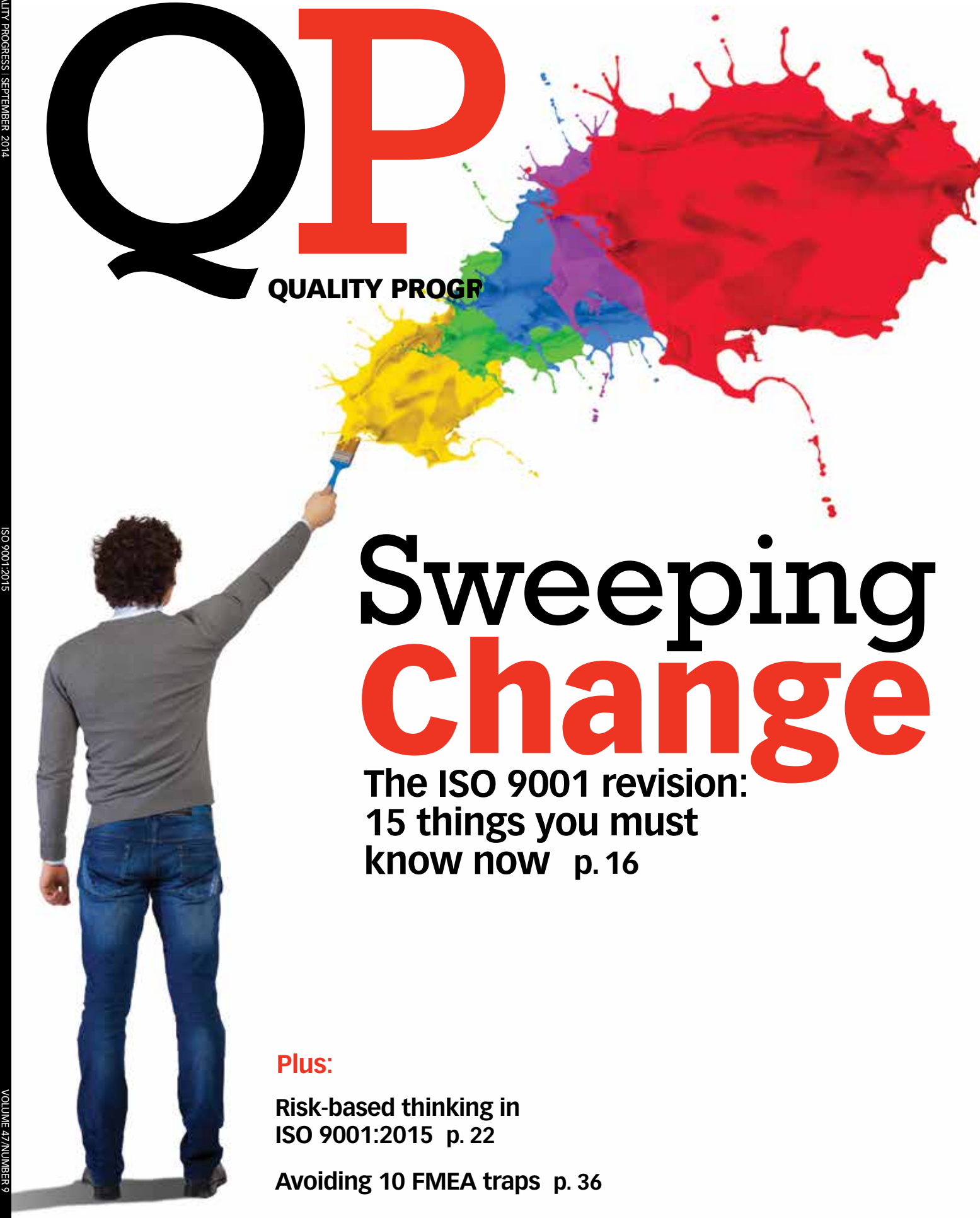

Sweeping Change

The ISO 9001 revision: 15 things you must know now p. 16

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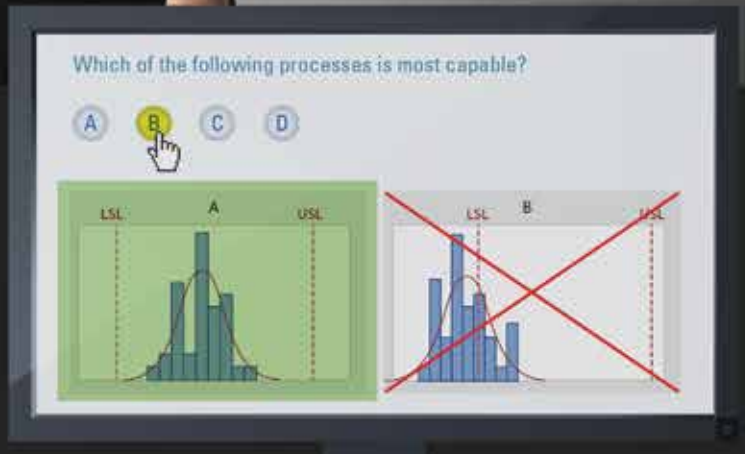

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  Watch a video interview featuring Paul Palmes, author of "A New Look" (pp. 16-21), discussing the ISO 9001 revision and key points organizations must consider as the draft international standard version progresses through the development process.
- **Risk Exercises**
  Find additional figures and tables you can use to enhance your organization's risk management approach, just one consideration for organizations as the ISO 9001 revision nears completion ("Brought Into Focus," pp. 22-29).
- **Eye Opener**
  View a video interview with Donna Thomas, author of "Onward and Upward" (pp. 30-34), as she talks more about Xerox and how the organization used ISO 9001:2008 to transform its quality management system.
- **Daily Dose**
  Check *Quality News Today* for the latest quality-related headlines.

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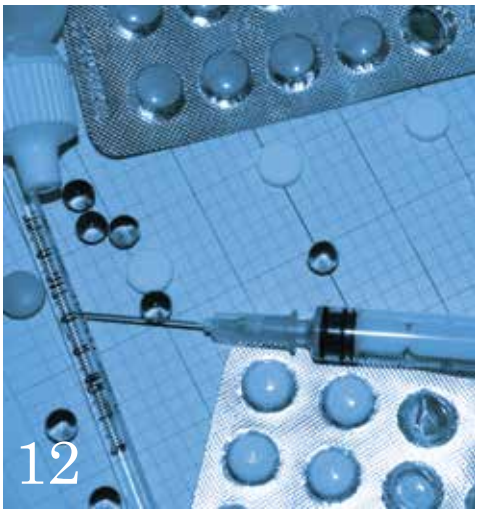

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- DECISIONS, DECISIONS
The top five ASQ certifications and why you should consider achieving one or more.

- GET READY
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Prep Schooled

New ISO 9001 presents significant change

THE IMPENDING RELEASE of a new version of ISO 9001 always provokes some level of trepidation, but this one in particular, ISO 9001:2015, due out late next year, has really got people on the edge of their seats, itching to know how it will affect their organizations' operations given the significant changes being made to it.

This revision—currently at draft international standard stage—includes major definitional shifts, and other additions and deletions. In anticipation of the release, QP is geared up to give you all the information you need to be in-the-know and fully prepared.

This month's issue focuses on standards and auditing, led off by the cover story, "A New Look," p. 16, which offers 15 key things you need to know now related to the revision. Use this guide as you navigate your way to the eventual release, and prepare your organization for what's to come.

The word "risk" has been introduced into ISO 9001 in this revision. Author Sandford Liebesman explains how and where in "Brought Into Focus," p. 22, and provides expert advice for helping your organization identify and mitigate risk. Included are some helpful tools to aid in your efforts.

The Innovation Imperative column, "Embracing Change," p. 44, delves into how—and where—innovation fits within the standard, and details where it should mesh within specific clauses.

Another area of concern has been the removal of documentation requirements in the drafts of ISO 9001 and ISO 14001; this is addressed in the Standards Outlook column, "Missing in Action," p. 52.

Looking for a one-stop-shop to learn more and stay informed about the standard's progression? Visit http://asq.org/standards-iso-9001-2015.html. This content clearinghouse will help keep you up-to-speed with video, articles, webcasts and other resources.

Finally, in August, QP Assistant Editor Amanda Hankel traveled to Washington, D.C., to interview a host of subject matter experts convened for an important standards meeting. She returned with 25 video interviews answering a range of questions about the standard, its development, its influence in industry and other hot topics. Look for portions to roll out in upcoming episodes of ASQ TV and elsewhere. QP

Seiche Sanders
Editor

Don't forget to watch the new episode

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ISO 9001 revision explained

In response to "A Step Forward" (March 2014, pp. 38-43): Excellent article on the changes to the ISO 9001 standard. Preventive action has always been a difficult topic to implement and audit. I felt the author's justification of its exclusion from the 2015 revision was well thought out.

Ram Veeraraghavan
Singapore

Career advice taken

In response to "Making Connections," (July 2014, pp. 24-27): All your advice is timely. Especially, "Ask for recommendations on LinkedIn"—so helpful!

Karen Phelps Perkins
Virginia Beach, VA

Preparing for IoT

Mark Edmund's article on the Internet of Things (IoT) ("Full Steam Ahead" August 2014, pp. 12-13) was spot on. On the dark side, logistics wins wars and I feel we are ill-prepared for the next one.

John Friedrich
Amesbury, MA

Expertly answered

In response to July 2014 "Expert Answers: Understanding medians" (pp. 8-9): Good answers. Thanks. This will be valuable to other quality professionals, as well.

In fact, I am cross referencing this Expert Answer in the next revision of the *Certified Six Sigma Green Belt Handbook* (Quality Press, 2008).

Govind Ramu
San Jose, CA

Classic resources

Readers of the Back to Basics article "Curve Your Enthusiasm," (June 2014, p. 72) may be interested in some vintage acceptance sampling references that deal with sampling requirements. They might help facilitate answers to daily questions about particular sampling plans.

In particular, Table 1 in reference 1 would even suggest meeting particular quality requirements. The references are:

1. Robert L. Kirkpatrick, "Binomial Sampling Plans Indexed By AQL and LTPD," *Industrial Quality Control*, Vol. 22, No. 6, pp. 290-292.
2. W.R. Pabst, D.B. Owen, Harold F. Dodge and Robert L. Kirkpatrick, "Letters to the Editor About Reference 1," *Industrial Quality Control*, Vol. 23, No. 1, pp. 28-32.
3. Frank E. Grubbs, "On Designing Single Sampling Inspection Plans," *Annals of Mathematical Statistics*, Vol. 10, No. 3, pp. 242-256.

The Back to Basics article, in choosing a plan "designed to allow lots that are 8% nonconforming to be accepted no more than 10% of the time," suggested the sampling plan of n = 75 and c = 2.

Alternative suggestions from reference 1, Table 1, are: n = 28 and c = 0; n = 48 and c = 1; n = 65 and c = 2. You may not like the c = 0 plan with its severity at the beginning of the operating characteristic curve with its small 0.2% nonconforming necessary to get a 95% chance of acceptance. At any rate, they would be considerations.

Robert L. Kirkpatrick
Shawnee, KS

Tune In

The latest episode of ASQ TV focuses on creating a culture of quality. In the episode: Learn the distinction between culture and compliance, review key culture findings from a global study and look at ways to "millennialize" your workplace.

Watch for another episode available Sept. 16 on government.

Visit **http://videos.asq.org** to access the full video library.

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- **Culture of quality white paper**
  Did the August QP cover story, "Clues About Culture" (pp. 18-23) pique your interest to learn more about creating and sustaining a culture of quality in your organization? Be sure to check out the white paper, "Culture of Quality: Accelerating Growth and Performance in the Enterprise," at www.cultureofquality.org.

- **Get published in Logon**
  Have something to say about a recent article in QP? Send letters to the editor to editor@asq.org, or comment on the article's webpage. Your comment could appear in an upcoming issue of QP.

- **Ask the experts**
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QUICK POLL RESULTS

Each month at www.qualityprogress.com, visitors can take an informal survey. Here are the numbers from last month's Quick Poll:

What do you think is the most important component of a culture of quality?

- Leadership. 53.5%
- Clearly articulated vision and values. 26.7%
- Meeting customer requirements. 17.8%
- Promoting innovation and risk taking. 1.7%

Visit www.qualityprogress.com for the latest question:

What anticipated change in ISO 9001:2015 will affect your organization the most?

- A focus on risk-based thinking.
- New clause structure.
- More abstract requirements.
- More prescriptive requirements for top managers.

QualityNewsTODAY

Recent headlines from ASQ's global news service

(All URLs case sensitive)

U.S. Government Drops Hospital-Mistake Reports
The federal government quietly stopped publicly reporting when hospitals leave foreign objects in patients' bodies or make a host of other life-threatening mistakes. The change means people are out of luck if they want to search which hospitals cause high rates of problems such as air embolisms—air bubbles that can kill patients when they enter veins and hearts—or giving people the wrong blood type. (http://bit.ly/hospitalmistakes)

Automation Can Improve Safety
If some of the workshops had been upgraded with totally automated assembly lines or robots, the blast that killed 75 people at Kunshan Zhongrong Metal Products in East China's Jiangsu province would never had happened, according to Zhou Jianghua, sales manager at Kawasaki Robotics (Tianjin) Co. Ltd. Shanghai branch. (http://bit.ly/automationimprovessafety)

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EXPERTANSWE

Leadership, culture and quality

Q: What's an effective approach for providing leadership and management for the quality function, and sustaining the quality philosophy and lean culture for the division at the plant level?

David Stuckey
Fort Worth, TX

A: Your question essentially deals with the art and science of change management. Changing and sustaining a culture—whether it is a lean culture, quality culture, safety culture, innovation culture or customer intimacy culture—is challenging. It is particularly difficult, however, at the plant level because plants are often remote from the parent company and generally focus on only a part of the value stream, such as a specific function, component or product.

Recognizing the symptoms of a deteriorating culture are just as important as determining how to create a lasting culture. Classic symptoms of decay include lack of employee engagement, uncompleted projects, excessive emphasis on cost cutting, high employee turnover and lack of respect for co-workers and customers. Extreme examples include subversive behavior, such as misrepresenting information (for example, the Veterans Administration Affairs crisis in which patient appointment wait times were falsified to meet the 14-day specification) or the failure to act even when lives are at stake (for example, General Motors' flawed ignition switch on the Chevrolet Volt was a known safety hazard for more than 10 years before a recall was issued).

THE CORE components of change helped teams in Atlanta and Delhi, India, work together.

While effective change management techniques vary, I can draw from my own experience creating and sustaining a quality culture as an example. In 2013, Cbeyond Communications, a $500 million, publicly held telecommunications firm based in Atlanta, partnered with Tech Mahindra, an IT and telecom company based in India, to perform critical telephone porting, circuit provisioning and service order activities.

As director of process excellence and the program leader, I knew this was going to be challenging given the sensitive nature of the initiative, scope of the work, distance (Atlanta is 8,000 miles from Delhi), difference in hours of operation (Delhi is 9.5 hours ahead of Atlanta), as well as language and cultural differences. We could not afford to create an "us (Cbeyond employees) vs. them (Tech Mahindra employees)" environment.

Our first step was to effectively make the case for change—in other words, provide context to our internal employees and the Indian outsourced employees. They had to know the "why." The case for change could not be fragile. It had to be clear and direct with leadership out in front. And, it had to be communicated in an open and consistent manner.

For Cbeyond, the partnership was a strategic decision to free our employees to deliver newer products.

Although requirements for change vary, at a minimum they should include the following core components (Figure 1):

- **Vision:** What future success looks like—not next quarter or next year, but three to five years from now. Vision should be grand in scope. A vision is a picture of where you want to be. If you can see it, you can be it.
- **Goals:** Goals are the steps toward your vision. How do you achieve a vision? One step at a time. Goals are like the rungs of a ladder, the footsteps of a journey. Having goals makes accomplishment more likely. Goals should be specific, measurable, attainable, relevant and timely (SMART).
- **Planning:** A means of efficiently fulfilling goals. Some goals can be achieved in a short amount of time. Others are long-term goals that might require a number of smaller steps. Organizing goals and capturing the details is part of planning.

You need all three components for change to be successful. If the vision is missing, chaos and confusion will ensue. Fear and anxiety will thrive in an atmosphere in which

Core components for change / FIGURE 1

RS

The hardest part about any quality culture **is making it sustainable.**

employees are not given the proper context from leaders on why they are embarking on a quality program. Without SMART goals, change will be slow or may not occur. In the absence of planning, expect false starts, frustration and aggravation.

Strong leadership is the glue that holds all three components together. Leadership embodies many characteristics, including the ability to develop people rather than just manage them; innovating instead of administering; thinking long term instead of short term; looking at the horizon, not just the bottom line; and asking "what and why" instead of "how and when." To me, leadership is as simple as raising your hand. Volunteers make great leaders because they know there is a need for change. They are willing to take a risk, and they want to have an impact on the organization.

The hardest part about any quality culture is making it sustainable. It requires relentless discipline, steady communication and regular recognition. What was our formula for sustaining the quality culture in our Indian office 8,000 miles away? The same formula we used in Atlanta. We continued conducting our daily meetings, real-time coaching and corrections, regular root cause analysis and start-stop-continue exercises. Recognition of achievements was frequent and communicated throughout Tech Mahindra and Cbeyond (see the team in the photo). There was no secret to our success. It was based on a solid foundation of leadership, vision, goals and planning.

Peter J. Sherman, CMBB, CQE, CSCP
Partner, Riverwood Associates
Atlanta

Truth about traceability

Q: What is the real meaning of traceability in calibration validation?

Dinesh Chandra
Raigarh, Chhattisgarh, India

A: This is a simple question loaded with a lot of complexity. First, consider the definition of traceability as defined in the ISO Guide 99:2007. Metrological traceability is defined as "property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty."[1]

To validate the calibration of a unit, you have to look for the following:

- Is the standard used suitable? Is the calibration status valid and not expired?
- Is the standard itself traceable? That is, it has an accredited calibration with measurement uncertainty data provided, or you can trace the calibration hierarchy all the way to a National Metrology Institute of the country that is recognized under the International Committee of Weights and Measures Mutual Recognition Arrangement.
- Is the uncertainty of the standard used at least four times less than the tolerance of the unit?
- Is the resolution of the standard used at least 10 times better? For example, to calibrate a unit with 0.1 resolution, a standard with at least 0.01 unit resolution should be used.
- Is the measurement uncertainty for the unit being calibrated properly calculated and reported on the calibration certificate?
- When making a compliance decision to a specification for the unit being calibrated, is the uncertainty of the calibration process taken into account?
- Does the calibration report meet the appropriate requirements of ISO/IEC 17025, clause 5.10?[2]

If the answers to all of the above are yes, the metrological traceability has been validated for the calibration.

Dilip A. Shah
President
$E = mc^3$ Solutions
Medina, OH

REFERENCES

1. International Organization for Standardization and International Electrotechnical Commission, *ISO/IEC Guide 99:2007—International vocabulary of metrology—Basic and general concepts and associated terms.*
2. International Organization for Standardization and International Electrotechnical Commission, *ISO/IEC 17025—General requirements for the competence of testing and calibration laboratories, Clause 5.10—Reporting the results.*

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.

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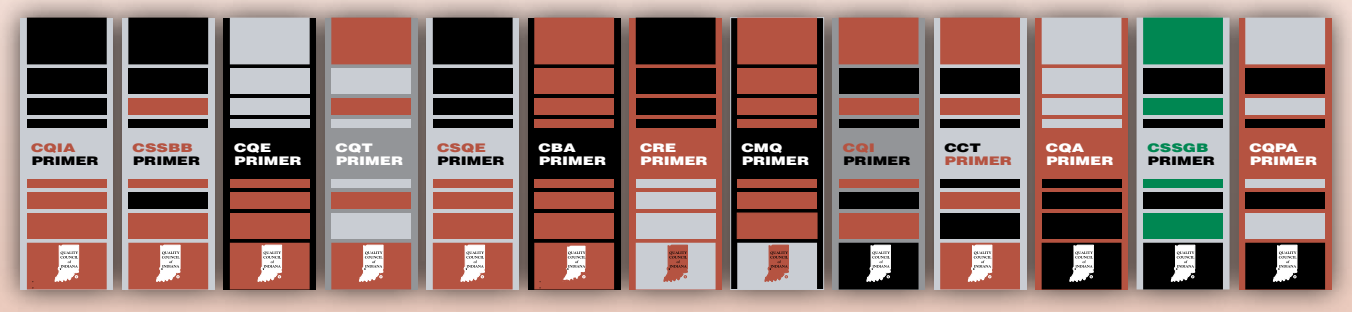

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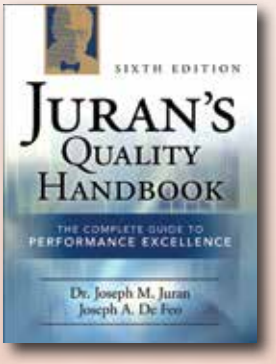

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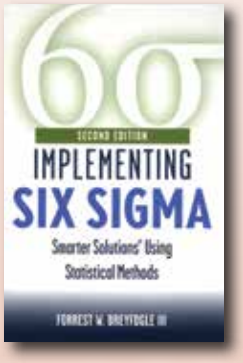


Implementing Six Sigma

by Forrest W. Breyfogle, III
A great CSSBB reference

The Quality Technician's Handbook

by Gary K. Griffith
Great for CQT and CQI exams.

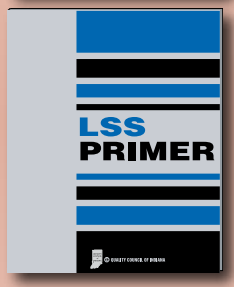
Spanish Green Belt

The Spanish version of the CSSGB Primer.

Quality Dictionary

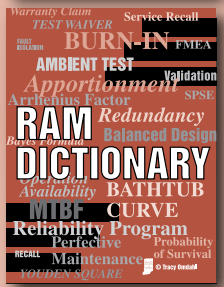
by Tracy Omdahl

More than 2500 definitions. Great for any ASQ certification.



LSS Primer

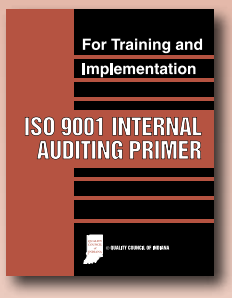
The Lean Six Sigma Primer is written to a QCI BoK. There are more case studies and lean content than in any other QCI products. 400 questions are included. A solution text is also available.



RAM Dictionary

by Tracy Omdahl

Contains 2800 definitions. Helpful for Reliability and Quality Engineers.



ISO 9001 Internal Auditing Primer

by Greg Wies & Bert Scali

A convenient book for training internal auditors to the ISO 9001 expectations.

An instructor CD is available.

ISO Primer

by Bensley & Wortman

Presents a thorough treatment of the ISO implementation and documentation process. There are generic manuals on the CD.

Reliability & Maintenance Analyst CD

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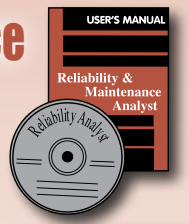


Measurement Analyst CD

Performs all measurements required in the AIAG manual. Contains ANOVA methods and excellent graphs.

Site and global license available!!!

Used by Chrysler, ITT, FedEx, Ford, TRW, GM, HP, U.S. Postal Service

Quality System Handbook

by Edenborough

Details the selection, organization, and writing of quality documents. The disk contains procedures and work instructions.

HEALTHCARE

Antibiotics Overdose

Overprescribed antibiotics under CDC's microscope

As Ebola ravaged areas in West Africa this summer, medical experts around the world tried to calm fears that the deadly virus would spread to other countries.

An Ebola outbreak is unlikely in places like the United States, Japan or Switzerland that have strong healthcare response capabilities.[1] There is, however, another global health threat sickening two million people each year in the United States alone and killing at least 23,000 of them—antibiotic-resistant bacteria known as superbugs.

Infectious disease experts point to the overuse and misuse of antibiotics as the major cause of superbugs. The Centers for Disease Control and Prevention (CDC) warns that immediate action must be taken before life-saving antibiotics are no longer effective. Last year, the CDC reported about half of antibiotics prescribed by doctors in the United States went to people who didn't actually need them.[2] Overuse and misuse of health treatments and services are two problems affecting healthcare quality and cost.

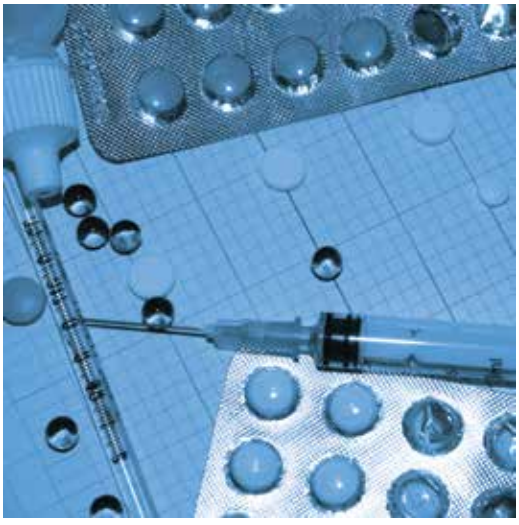
At a July press conference, CDC Director Thomas Frieden said the agency will isolate superbugs in medical facilities and eliminate them through more thorough tracking systems and tougher safety methods.

"We always want to be part of the solution, but sometimes in health we're part of the problem," Frieden said.[3]

Too much of a good thing?

While antibiotics should be used to treat bacterial infections, they are not effective against viral infections responsible for the common cold, most sore throats and the flu, according to the CDC.[4]

A July 2014 *Medscape* survey of doctors showed physicians commonly prescribe



antibiotics when they are unsure of an infection's cause. Medical providers, on average, reported prescribing unnecessary antibiotics 20% of the time.[5]

Doctors reported increased pressure to meet patients' expectations, and that their pay and performance may be linked to patient satisfaction. Though the extent is unknown, some clinicians said patients expect and demand antibiotics.

"It is very hard to get a patient out the door of the ED [emergency department] without a prescription for an antibiotic," said an emergency medicine clinician surveyed.

Another emergency medicine practitioner said, "Prescribing unnecessary antibiotics is quicker than taking the time to explain properly, and customers who don't get antibiotics are much more likely to complain. Good medicine is taking a back seat to the 'customer is always right' mentality now prevalent in healthcare."

Several clinicians revealed they lost their jobs following complaints from patients who didn't receive antibiotics.

One clinician responded, "I am in the waning days of employment at a privately owned urgent care center. One of the reasons cited for my departure was my reluctance to provide antibiotics 'on demand.' I was told that I was not responsible for antibiotic overuse and resistance. Needless to say, I am leaving, in no small part due to the emphasis on patient satisfaction over standards of care in this and other matters."

Post-antibiotic world

Antibiotic resistance costs the U.S. healthcare system $20 billion a year and it becomes more difficult to stop the longer it persists, Frieden said.[6]

"We talk about the pre-antibiotic era and the antibiotic era; if we're not careful we will soon be in the post-antibiotic era," he said. "And, in fact, for some patients and some pathogens we're already there."[7]

The World Health Organization recently reviewed how well antibiotics performed in 114 countries. In some places, antibiotics no longer work for half of all people being treated for common diseases.[8]

"Antibiotics are a natural resource, just like fossil fuels," said Ramanan Laxminarayan, a director at the Public Health Foundation in India. "Finding new ones will be hard and expensive. Penicillin costs pennies. Newer antibiotics may cost hundreds or even thousands of dollars."[9]

Restore development pipeline

It would seem another alternative solution is to create stronger antibiotics. But many drug makers are reluctant to develop new antibiotics.[10]

"From a strictly business standpoint, the terrible thing about antibiotics is they cure people," Frieden said. "That's not a model for a highly lucrative pharmaceutical product—you want a product that has to be taken for a long, long time."[11]

During the 1970s, drug developers focused on noninfectious health problems, such as cancer and heart disease. In the past 30 years, no new types of antibiotics have been developed.

Systems to reduce misuse

In July, the CDC launched a new system that allows hospitals to track the antibiotics dispensed and obtain real-time patterns of antibiotic resistance so doctors can determine which antibiotics are most likely to work.[12]

Superbug squashers

As the healthcare system works to change its antibiotics-prescribing practices, researchers around the world are developing alternative methods to fight superbugs:

- A ward at Glasgow Royal Infirmary's intensive care unit in Scotland is piloting the use of high-intensity narrow

(continues on p. 15)

Who's Who in Q

NAME: Beth Cudney.

RESIDENCE: St. Louis.

EDUCATION: Doctorate in engineering management from Missouri University of Science and Technology in Rolla.

INTRODUCTION TO QUALITY: Cudney's father was an industrial engineer, and she learned a lot about the impact of quality and quality engineering by watching him and listening to him talk about his work. Her first job out of college was as a quality engineer for the Spicer Axle Division of Dana Corp.

CURRENT JOB: Associate professor in the engineering management and systems engineering department at Missouri University of Science and Technology. Her research focuses on quality engineering, pattern recognition and healthcare systems.

OTHER NOTEWORTHY JOBS: Cudney served as a Six Sigma Black Belt and manufacturing manager at Jacobs Vehicle Systems, headquartered in Bloomfield, CT, where she led numerous lean implementations and *kaizen* events. She also developed a graduate-level Six Sigma course as an adjunct professor at the University of Hartford in West Hartford, CT. Doing this training and teaching led to her desire to become a professor and lead research in quality engineering.

ASQ ACTIVITIES: Cudney serves as editor of *Quality Approaches in Higher Education*, an online journal published by ASQ's Education Division. She was the 2007 recipient of ASQ's Feigenbaum Medal. Cudney also holds eight ASQ certifications.

ACTIVITIES/ACHIEVEMENTS: Cudney is president of the American Society for Engineering Management (ASEM). She is the past president of the Rotary Club of Rolla and has received the following honors: the Society of Manufacturing Engineer's Outstanding Young Manufacturing Engineer Award, ASEM's Outstanding Dissertation Award and the Institute of Industrial Engineer's Lean Teaching Award. She is also a member of the International Academy for Quality.

PUBLISHED WORKS: Cudney has written four books on topics such as lean, *hoshin kanri* and Six Sigma. She also has contributed eight chapters to other books, authored 39 journal articles and written 68 conference papers.

RECENT HONORS: Cudney was part of the 2013 class of ASQ fellows.

PERSONAL: Married 16 years to Brian. They have two children.

FAVORITE WAYS TO RELAX: Spending time with family and watching the children's activities.

QUALITY QUOTE: Quality is not a destination; it is a continuous journey to meeting and exceeding ever-changing customer requirements.

HEALTHCARE

STUDY: MEDICATION SAFETY IMPROVES

While medication safety has improved, hospital-acquired infection rates are still troublesome, a new study of U.S. hospitals concluded.

The report from the healthcare watchdog group, Leapfrog, says the use of computerized physician order entry, an approach proven to reduce medication errors, has climbed. Some problems with performance of the systems persist, however, such as failure to alert potentially fatal medication errors.

Other findings from the Leapfrog report included:

- Dramatic improvement in areas of maternity care, especially in reducing early elective deliveries, with the average rate of early elective deliveries declining from 11.2% in 2012 to 4.6% in 2013.
- Better compliance with intensive-care unit physician staffing standards, shown to decrease mortality by as much as 40%. Notably, 41.7% of reporting hospitals fully meet this standard in 2013, compared to 39% in 2012.

For more from the report, visit http://tinyurl.com/nmbqlmd.

SHORTRUNS

ISO 45001, which sets requirements for occupational health and safety management systems, has now reached committee draft stage. This draft standard, inspired by OHSAS 18001, is designed to help organizations ensure the health and safety of the people who work for them. For more information, visit http://tinyurl.com/k4ac4g8.

THE GOVERNMENT OF Prime Minister Narendra Modi in India proposed a sweeping change to ensure product quality and that substandard goods be automatically withdrawn from the marketplace, according to a recent report in the *Economic Times,* an Indian newspaper. The proposed change would allow the Bureau of Indian Standards to evolve as a national standards body for goods and services, with an emphasis on self-certification and market surveillance instead of inspection. To read the full story, visit http://tinyurl.com/pnhdh56.

NOMINATIONS FOR THE 2015 Harry S. Hertz Leadership Award are now being accepted by the Baldrige Foundation. The award is named for the long-time director of the Baldrige Performance Excellence Program, who retired in 2013. A description of the award, the award criteria and nomination process, and names of members of the selection committee can be found at http://tinyurl.com/pcx6tt5.

BALDRIGE

NEW FOUNDATION LEADER NAMED

Al Faber, president and CEO of the Partnership for Excellence in Columbus, OH, has been named the president and CEO of the Baldrige Foundation.

Faber will assume overall responsibility for the operation of the Baldrige Foundation, including all philanthropic, strategic and day-to-day functions. The foundation's mission is to ensure the long-term financial growth and viability of the Baldrige Performance Excellence Program and to support organizational performance excellence in the United States and throughout the world.

The foundation's board unanimously approved the appointment of Faber to the board and to his role as president and CEO.

Mr. Pareto Head

BY MIKE CROSSEN

Superbugs *(continued from p. 13)*

spectrum light to kill superbugs. The light is powerful enough to kill superbugs and poses no health risk to patients.[13]

- An engineering team at the University of California in San Diego is developing biocompatible, biodegradable nanosponges that soak up superbug toxins in the bloodstream.[14]
- Microbiologists at Victoria University of Wellington, New Zealand, are bio-synthesizing antibiotics. The microbiologists are rearranging the enzymes that comprise a specific antibiotic so the resistant bacteria won't recognize it.

Biotechnologist David Ackerley, who oversees the research at Victoria University, likened the war against superbugs to an arms race that requires the constant development of new ammunition and weapons.

"If you've got rifles and your opponent suddenly develops tanks, you're going to need armor-penetrating bullets," he said.[15]

—Compiled by Megan Schmidt, contributing editor

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OBITUARY

MONRÉAL, FORMER ASQ BOARD MEMBER, DIES

Elías Monréal, an ASQ senior member and a former member of ASQ's Board of Directors, died in late July. He was 41.

An ASQ member since 2000, Monréal served on the board from 2011-2013. He also served as ASQ Tucson-Old Pueblo Section chair, vice chair of the Section Affairs Council, Region 7 director and ASQ's Measurement Quality Division membership chair. In addition, Monréal spent four terms as an examiner for the Arizona Quality Alliance's state quality award.

Monréal, who worked as a quality engineer at Industrial Tool, Die and Engineering in Tucson, AZ, had been selected as one of QP's "40 New Voices of Quality" (http://tinyurl.com/op73rb9) in a 2011 feature on up-and-coming individuals who would help shape the future of the profession.

Visit http://tinyurl.com/qjpl6oh for a full obituary.

ETHICS

PANEL DISCIPLINES EXAM PROCTOR

ASQ's Certification Board Ethics Subcommittee has disciplined an exam proctor who violated the nondisclosure agreement (NDA) the individual had signed.

In April, the subcommittee considered the case of the person who was performing duties as an ASQ exam proctor during the same period of time the person was teaching both ASQ certification refresher courses and refresher courses for alternative certifications that mirrored ASQ certifications. This action is in direct violation of the NDA signed by proctors, the subcommittee concluded.

As a result, the subcommittee barred the person from proctoring ASQ exam administrations permanently. The individual's extant ASQ certifications also have been canceled, and the person is not allowed to sit for ASQ certification exams for five years.

ASQNEWS

UPDATED CASE STUDY ASQ's Knowledge Center has updated a case study on the Wisconsin school district that received a Malcolm Baldrige National Quality Award last year. The case study, originally published in 2008, describes the Pewaukee School District and its 10-year journey, which culminated in the Baldrige honor in 2013. Visit http://tinyurl.com/p3pl6us to read the entire case study.

MEDAL RECIPIENT Manu Vora, an ASQ fellow, was named this year's recipient of the Harrington/Ishikawa Medal, which recognizes individuals who contribute to the advancement of quality in the Asia-Pacific region. The Asia Pacific Quality Organization will present the medal to Vora at its conference in November in Kuala Lumpur, Malaysia.

A NEW Look

15 things you must know about the upcoming ISO 9001 revision

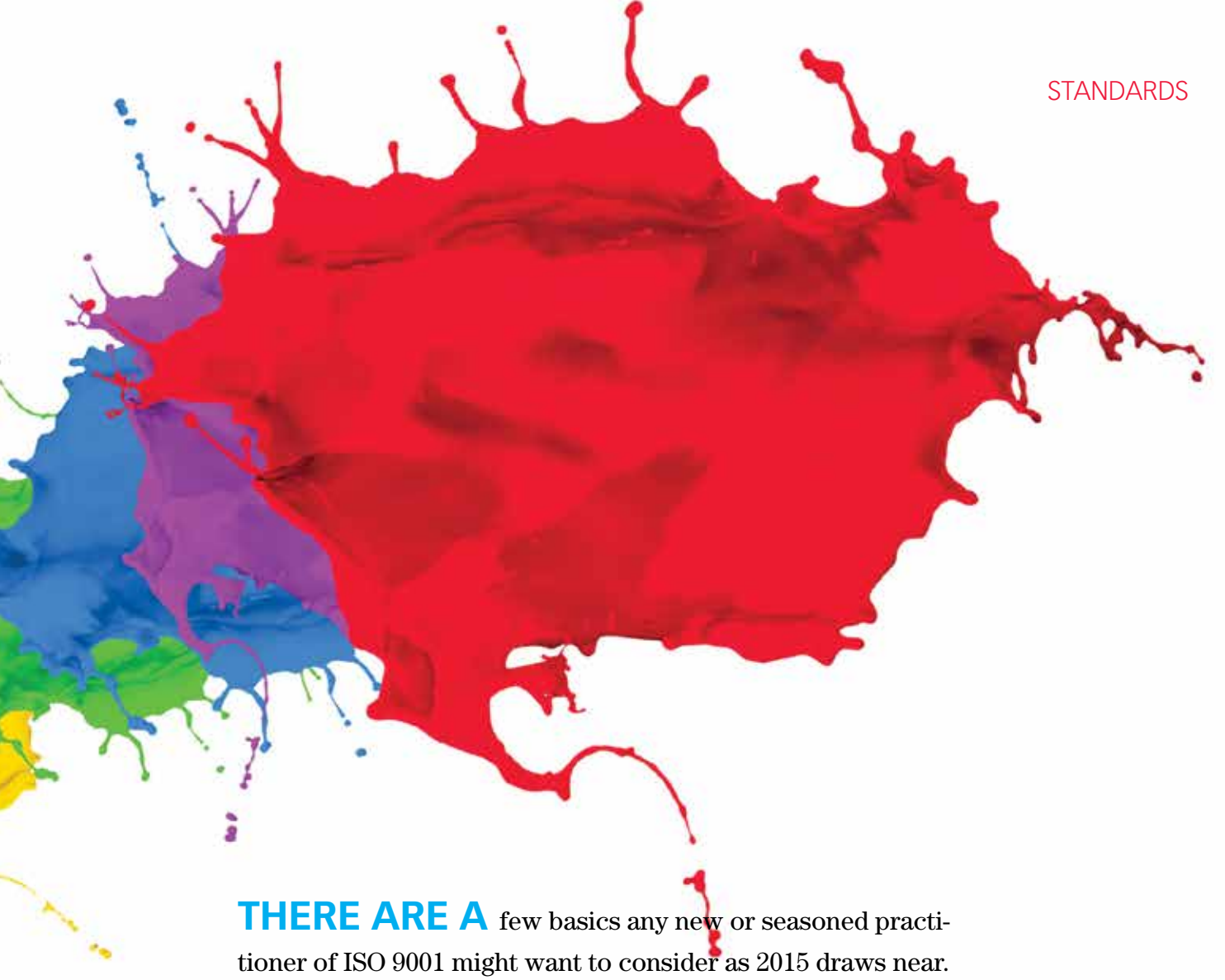
by Paul Palmes

In 50 Words Or Less

- A revised version of the quality management standard ISO 9001 is expected to be published in 2015.
- You can prepare for the standard's significant changes by considering these 15 concepts and issues related to the revision while the draft international standard version continues to progress through the development process.

Timeline for ISO 9001:2015

JUNE 2013: Committee draft published; countries participating in the development process form national positions on the draft.



THERE ARE A few basics any new or seasoned practitioner of ISO 9001 might want to consider as 2015 draws near.

The release in May of the ISO 9001 draft international standard (ISO/DIS 9001:2015) finally opened the door to comment from around the world on what will be a series of changes that surpass those in the 2000 revision—the last release considered significant.

Here are 15 concepts and issues that either spurred development or will drive major change as a result of ISO 9001:2015's release:

MAY 2014: Draft international standard available (public comments period for U.S. stakeholders ended July 15).

MID-2015: Expected publication of final draft international standard (FDIS)

LATE-2015: Publication of the international standard as ISO 9001:2015.

Visit ASQ's Standards Central website at http://asq.org/standards-iso-9001-2015.html for more information about the development of ISO 9001:2015 and links to articles, books, video and other resources about the upcoming revision.

1. Periodic review

ISO 9001 was initially released in 1987. The process of periodic review is embedded in all International Organization for Standardization (ISO) management systems standards and requires that member bodies (country committees) examine the relevance of a given standard every five years.

The choices are to continue publication without revision, revise or discontinue issuance. The obvious benefit is to ensure relevance, and in the case of ISO 9001, relevance is of utmost importance. With more than 1 million registered users, content improvement with special attention to trends within international trade and how modern business operates are of paramount importance.

"Electronic exchange," is an excellent example: When ISO 9001 was first issued in 1987, computers were in their relative infancy compared to today's reliance on personal computers and their use in data management and records. Until the issuance of ISO 9001:2015 and its normative reference, ISO 9000:2015, documents and records were traditionally thought to be hard copy.

The revised ISO 9001 will refer to format (language, software version, graphics and media, whether paper or electronic), in the now all-inclusive phrase "control of documented information." Separate references and clauses related to documents and records are gone.

Periodic review also revealed the service industry's long-standing claim that the standard is mostly written with manufacturing organizations in mind. As a result, ISO 9001:2015 will no longer use the term "product," but instead says "products and services" throughout the document. It's a major change, and one that goes to the heart of an aging misconception.

Subcommittee 1 (SC1) representatives who develop and maintain ISO 9000 worked alongside those of subcommittee 2 (SC2), working group 24 (WG), which is chartered to write the contents of ISO 9001 to further expand and clarify the output of a process to include services, software and other products. This is a major improvement, and expectations are high with regard to its acceptance within the user community.

2. User survey

Changes in ISO 9001:2015 are also the byproduct of a further ISO requirement to survey the user base to determine needed areas of improvement. It took years to amass the results of thousands of respondents, and you may have contributed to the input. The net result was a series of recommendations that eventually found their way to the design specification for the writing group to follow.

A look back shows that the release of ISO 9001:2008 was little more than clarification of several elements within the last major shift in the standard with the release of the 2000 revision. It, too, credited much of its content to a prior user survey. The bottom line is that the 2015 edition will be the result of far more than a few individuals' thoughts. Instead, it will stand atop a foundation of actual users' concerns and technical input.

3. Sector-specific input

Another important input to the 2015 revision came from groups that use ISO 9001 as the foundation for their standards. The telecommunications standard, TL9000, aerospace's AS9100 and medical devices' ISO 13485 are examples. Representatives of each of these and other standards have routinely attended drafting committee meetings and offered comments throughout the ISO 9001 life cycle.

The addition of the concept of risk ("risk-based approach") within the 2015 version is often credited to several sector-specific concerns voiced in recent years. Users of these similar sector-specific standards have significant interest in the outcome of any revision to ISO 9001 simply because when it changes, they are subject to adoption or abandonment of their foundational content.

As of this writing, strong opposition has been lodged by several sector-specific groups, primarily regarding what has become known as the new high-level structure.

4. High-level structure

The technical management board (TMB) within ISO central and the joint technical coordination group (JTCG) have determined that all management systems standards follow a new format, called the "high-level structure," as defined in Annex SL (previously Guide 83). With the addition of several new elements, or clauses, the impact of this new structure will be significant to many current users of the standard.

Initially, much attention was devoted to challenging the mandate and perhaps submitting a request to deviate from adopting the new approach. Two efforts took place simultaneously: one to petition for release

from the high-level structure and the other to go forward with the rearrangement of 2008 content within the newly defined clause structure.

The ISO/DIS 9001:2015 clearly settles the dispute and places ISO 9001 within what will become a unified and consistent family of management standards. Voting, by the way, started on July 10 and ends on Oct. 10. Comments, many of which will undoubtedly question the use of the high-level structure, are expected to be numerous. Note, however, the definitive text within Annex A, clause 1, of the ISO/DIS 9001:2015 makes clear that wholesale documentation restructuring is not a requirement:

- The clause structure and some of the terminology of this international standard, in comparison with ISO 9001:2008, have been changed to improve alignment with other management systems standards.
- The consequent changes in the structure and terminology do not need to be reflected in the documentation of an organization's quality management system (QMS).
- The structure of clauses is intended to provide a coherent presentation of requirements rather than a model for documenting an organization's policies, objectives and processes. There is no requirement for the structure of an organization's QMS documentation to mirror that of this international standard.

5. Be cautious

The last time ISO 9001 revised its structural components with the issuance of ISO 9001:2000, a flood of consultants' offers, articles, books and lectures preceded and followed its release. Full disclosure—I am one of several who will fall into this group—but the following message remains the same: A user's guide is being developed by members of WG24, scheduled to be available for purchase simultaneously with the release of ISO 9001:2015. If you feel as though you will need additional input, it's probably all you'll need.

For most progressive organizations, revisions and additions should be relatively straightforward. Yes, several components of the 2015 revision might be confusing. There always are questions, but the expected flood of training offers and help from your registrar and others will likely answer most concerns.

Remember, your registrar should represent more than an agency that schedules an occasional visit. Proactive registrars will recognize the need to develop a workable plan to convert their client base to the 2015 revision within the three-year requirement. Ask your auditor what is expected and when to implement. Short of actual consulting, most will be glad to help.

6. You have until 2018

Schedule revisions at your own pace because you have until 2018. Once again, work with any available guidance from your registrar. Join in the discussion with others who have gone before you, but beware of foot dragging. If the 2000 revision was any example, a flood of registrants waited until the final months to complete their work, resulting in registrar scheduling nightmares.

The adage "failure to plan is planning to fail" is fully in effect when it comes to your organization's response to ISO 9001:2015. For some organizations, the task will be little more than appending an unnecessary equivalency matrix to their quality manuals and writing a few new words to cover additional clauses. This is the group that prefers minimal investment and therefore can typically expect minimal outcomes.

If, however, you decide to use the 2015 revision to truly improve your organization, it will take time and practice to get it right. Implementation planning and goal setting using project management tools is highly recommended. There is simply no substitute for a well-designed, phased approach to implementing a standard. Its numerous interdependencies require care to implement in the proper sequence and steadily build either atop or adjacent to each step to provide mutual support and value. Just don't take too long.

Editor's note: The following are major changes within ISO/DIS 9001:2015. As mentioned in the beginning of the article, note that revisions can be expected based on comments received. Several of the elements that follow will require additional development within each organization to address overall compliance methods.

7. Context of the organization

Understanding an organization and its context, and the needs and expectations of interested parties, is central to maintaining a business. Section 4.1 of the revision requires an organization to determine "external and internal issues that are relevant to its purpose and its strategic direction."

After they are determined, the organization is to monitor those internal and external issues. The clause further requires an assessment of the organization's ability to achieve the intended results of its QMS. The tool most capable of supporting compliance to section 4.1 is a SWOT or strengths, weaknesses, opportunities, and threats analysis. Another tool, the balanced scorecard, is also a likely candidate. Both are products of business, not necessarily quality management.

At its face, "business thinking" is a welcome addition to the standard, addressing a long-standing complaint that ISO 9001 is not understood as a business system with an output of quality.

8. Leadership

Leadership and commitment to the business system is also thoroughly addressed in *Clause 5.1.1—Leadership and commitment for the quality management system*. The theme of uniting business and quality continues in this section with the addition of elements such as "ensuring that the quality policy and quality objectives are established for the QMS and are compatible with the strategic direction and the context of the organization."

If that was not a clear enough call to unite business and quality systems, the requirement that leaders "ensure the integration of the quality management system requirements into the organization's business practices" is the clarion cry to stop the practice of visualizing quality management as somehow separate from business management.

9. Planning for the QMS

Section 6.1, "actions to address risks and opportunities," is perhaps the single-most talked about addition to the standard. Section 6.1 weaves together previous elements 4.1 and 4.2, understanding the context of the organization, and the needs and expectations of interested parties by requiring that analysis of these issues become actionable risk-based plans, targets and goals.

WATCH and LEARN
At **www.qualityprogress.com**, watch a video interview featuring Paul Palmes discussing the ISO 9001 revision and key points organizations must consider as the draft international standard progresses through the development process.

The accompanying note to section 6.1.2 provides excellent guidance in this regard, saying "Options to address risks and opportunities can include: avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk or retaining risk by informed decision."

There is no mention of preventive action in ISO 9001:2015; it is expressed through the phrase "risk-based approach." Incidentally, sections 6.1.1 and 6.1.2 continue the theme of borderless business and quality system planning and management. The risk-based approach in ISO 9001:2015 is basic: After you know your challenges, develop appropriate plans and monitoring methods to mitigate the risk of inaction in these defined areas.

10. Organizational knowledge

Section 7.1.6 ushers in the discipline of knowledge management through the requirement that "the organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services." The point is that knowledge—what, how, when and often why—is required to generate consistent and conforming products.

Furthermore, the right people need access to this knowledge to create this desired outcome. Organizational knowledge management requires analysis and planning that are unique to each organization to balance the typical blend of competent people no longer requiring tools—such as work instructions—against those who do.

11. Applicability

In ISO/DIS 9001:2015, section 4.3, determining the scope of the QMS, you will no longer find references to the term "exclusions." Instead, it's up to the organization to decide which elements do not apply.

The choice to disregard a requirement is not allowed, however, if it pertains to normal operations. Furthermore, the text states, "If any requirement(s) of this international standard cannot be applied, this shall not affect the organization's ability or responsibility to ensure conformity of products and services." Once again, the issue of applicability is tied to whether your organization is capable of producing consistent, conforming product.

12. Annex C

Annex C, a formal introduction to the ISO 10000 portfolio of quality management standards, is a wonderful addition to ISO 9001. There are three SCs within ISO technical committee 176. ISO 9000 is the responsibil-

ity of SC1, ISO 9001 and ISO 9004 are the responsibility of SC2, but subcommittee 3 (SC3) is perhaps best described as having responsibility for everything else.

SC3 produces guidance documents: excellent resources for the world community to apply to its QMSs. If you are in search of moving your organization to the next level in any number of critical disciplines, the work of SC3's ISO 10000 series of documents is for you. In Annex C, ISO/DIS 9001:2015 offers a clearly stated synopsis of many of these guidance documents.

13. Annex A

Annex A, clarification of new structure, terminology and concepts, is another important and informative addition to ISO 9001. Many issues in this article are discussed in this section in well written and concise ways.

For example, "externally provided products and services" is explained as follows in section A8: "Whether the organization is purchasing from a supplier, through outsourcing or by any other means, the organization is required to take a risk-based approach to determine the types of controls appropriate to particular external providers and externally provided products and services."

The whole topic of outsourcing, especially questions regarding what goods or services are or are not outsourced, has been problematic in prior editions of ISO 9001. Given the above explanation and regardless of what is obtained through outsourcing, organizations are required to take a risk-based approach. This is a welcome, easy-to-understand stipulation and, of course, is linked closely with the concept of the risk-based approach discussed earlier.

14. Quality management principles

There are now seven quality management principles instead of the previous eight. Regardless, a disturbing few ISO 9001 practitioners have truly made these principles the foundation of their QMSs. Now is the chance to revisit the updated and revised seven principles to enable change throughout your organization at the bedrock level.

The introduction states, "The ISO portfolio of quality management system standards are based on these seven quality management principles" in much the same manner as an organization would use its mission statement to frame actions and discussions. They are a point of reference—a beacon in the storm—or perhaps a constant set of reminders of what is right and fair in promoting goodwill and best practices.

15. ISO 9000:2015

DIS/ISO 9001:2015 does not yet cite ISO 9000 as its normative reference, but it will after it's released as the final draft international standard (FDIS)—expected in the middle of next year. The ISO/DIS 9001:2015 now includes a large collection of terms and their definitions in section 3 as a convenience to the writing group.

Each definition, however, is derived verbatim from ISO 9000. As the bulk of the revision will be completed with the release of the FDIS, section 2 also will be revised to once again cite ISO 9000 as its normative reference.

The ISO/International Electrotechnical Commission (IEC) Directives, part two, section 6.2.2 states that normative references are considered to be "indispensable for the application of the document." A normative reference is, therefore, more than a casual reference to another document that may be helpful. It's no wonder ISO 9001 and ISO 9000 are often sold as a set.

Moving forward

Changes in ISO 9001:2015 are an opportunity to revisit organizational areas that have not performed well in the past. An awareness of the upcoming changes in ISO 9001:2015 will enable quality professionals to use the new standard as a vanguard to spur their organizations forward. QP

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Brought Into FOCUS

by Sandford Liebesman

In 50 Words Or Less

- For the first time, the word "risk" is being incorporated into the new version of ISO 9001.
- This may require organizations to refine methods for identifying, managing and mitigating risk.
- Using risk-based thinking and tools such as risk analysis and risk control matrixes can enhance an organization's risk management approach.

ISO 9001:2015 specifically addresses risk. Is your organization ready?

THE GLOBAL ECONOMY has provided organizations with many opportunities that didn't exist even 10 years ago, but it also presents organizations with many risks due to changes, including the internet and extensive outsourcing to countries such as China and Mexico.

To handle these changes, organizations must employ risk-based thinking, an approach that includes tools for identifying, managing and mitigating risks. One method consists of defining the organization's objectives, specifying the risk categories, identifying risks to the objectives and developing methods for managing the risks.

While this article covers the basics of a risk-based thinking method, visit this article's webpage at www.qualityprogress.com to view Online Figures 1-7, which are templates you can fill out as exercises to enhance your organization's risk approach.

Risk in ISO/DIS 9001:2015

There are many elements of risk-based thinking in the draft international standard (DIS) of ISO 9001:2015 (ISO/DIS 9001:2015) that may affect organizations as they work toward compliance to the revised standard.[1] The following excerpts and summaries describe references to risk in ISO/DIS 9001:2015.[2]

Definition. ISO/DIS 9001:2015 defines risk as the "effect of uncertainty on an expected result." The DIS does not include requirements for preventive action.

Process approach. An important element discussed in clause 4.4 of the DIS is the process approach, which requires an organization to "determine the processes needed for the quality management system (QMS)" and its application of those processes throughout the organization. This includes identifying:

- Inputs, outputs and resources.
- Sequence and interaction.
- Effective operation.
- Responsibilities and opportunities for improvement.
- Risks and the opportunities and actions needed to address them.

Customer focus. Clause 5.1.2 says top management must "demonstrate leadership and commitment with respect to customer focus by ensuring ... the risks and opportunities that can affect products, services and the ability to enhance customer satisfaction are determined and addressed."

Actions to address risks and opportunities. Clauses 6.1.1 and 6.1.2 say organizations must "determine the risks and opportunities" that must be addressed to ensure the QMS can:

- "Achieve its intended results.
- Prevent or reduce undesired effects.
- Achieve continual improvement."

Actions taken to address risks and opportunities must be proportionate to the potential effects on conformity of goods and services, and customer satisfaction. Furthermore, the organization should implement changes in a "planned and systematic manner," identifying risks and opportunities, and reviewing the potential consequences of changes. Options for addressing risk can include avoidance, eliminating the source, sharing the risk, and deciding whether to take the risk.

Post-delivery activities. According to clause 8.5.5, when applicable, an organization must determine and meet requirements for post-delivery activities associated with the nature and intended lifetime of the goods and services, accounting for:

- Risks associated with the goods and services.
- Use and lifetime.
- Customer feedback.
- Statutory and regulatory requirements.

Management review. Clause 9.3 says an organization must consider the effectiveness of the actions taken to address risks and opportunities (also see clause 6.1). This includes:

- Determining what needs to be monitored and measured so the organization can demonstrate conformity of goods and services to requirements.
- Evaluating the performance of processes (also see clause 4.4).
- Ensuring conformity and effectiveness of the QMS.
- Evaluating customer satisfaction.

Internal audit. Clause 9.2 says an organization must "plan, establish, implement and maintain an audit program," and establish the "frequency, methods, responsibilities, planning requirements and reporting." The audit program must consider the quality objectives, importance of the processes concerned, related risks and results of previous audits.

Risk-based approach. Section A4 of Annex A describes a risk-based management approach consisting of:

- Requiring the organization to understand its context consisting of internal and external issues.
- Understanding that one of the key purposes of a management system is to act as a preventive tool.
- Determining its risks and opportunities.
- Addressing the risks and opportunities identified.

Applying risk-based thinking

The four main types of risks that affect organizations could be characterized as:

1. **Organizational risk**, which occurs at the entity and activity levels.
2. **Strategic risk**, which happens when an organization's strategy or business plan is inadequate.
3. **Compliance risk**, which involves failure to comply with legal and regulatory requirements.
4. **Operational risk**, which includes seven subcat-

egories related to an organization's procedures and actions.

1. Organizational risk

Entity-level risks can be external or internal. External factors include technology, competition and legislation. Internal factors involve security, information systems, lost shipping and receiving, personnel competence and changes in responsibilities.

Activity-level risks affect individual units or functions, and include things such as information or materials not entered into the system, lost receiving reports or shipping records, poor security control, inadequate skilled labor and employee carelessness. If activity-level risks occur across the organization, they will ultimately affect entity-level risks.

2. Strategic risk

A strategic risk is a loss that might result from pursuing an unsuccessful business plan or strategy. This might be due to making poor business decisions, substandard execution of decisions, inadequate resource allocation or failure to respond to changes in the business environment.

3. Compliance risk

Compliance risk is due to legal and regulatory requirements. Environmental, health and safety requirements cause concern because of the risk of fines, shutdowns or criminal prosecution. Conformance to quality and environmental standards and specifications is also included in this category.

Environmental risks include liquid spills, gaseous emissions and incorrect disposal of solid waste, and would include events such as:

- The purchasing department's shift from a domestic to a foreign supplier.
- Not replacing a key environmental manager.
- Not developing a data safety sheet for new material.

4. Operational risk

Operational risk can be thought of as having seven subcategories:

1. Management systems risk. Management systems may be ineffective due to inefficiencies in strategies, practices and tools, data processing, call centers, contract administration, and design and development. A highly outsourced supply chain, for example, can be a major risk.

Other management system risks include incorrect revenue recognition, violation of homeland security rules, and noncompliance with environmental requirements and the Sarbanes-Oxley Act (SOX).[3] These may result in fines, shutdowns or criminal prosecution. To reduce these types of risks, an organization's top management and its board of directors must understand the management system and work to improve its effectiveness. If the following activities are ineffective, a management system can be harmed:

- HR practices.
- Management tools.
- Data processing.
- Call centers.
- Marketing.
- Contract administration.
- Customer communication.
- Design and development.

Top management and the board of directors must understand their management system and improve its effectiveness.

2. Customer satisfaction risk. Customer satisfaction risk is affected by customer communication, problems with delivery, product, design and repair, and poor response to customer feedback. To reduce this risk, data should be input into a process of analysis along with product quality data, product and process monitoring data, and inputs on supplier quality.

3. Supply chain risk. Procurement managers must be concerned with outsourced products and services, sole suppliers, timely delivery, inventory management and documentation. Communication is a key to effective supply chains. Metrics used to manage supply chain risk include delivery times, inventory levels and cost.

4. Revenue recognition risks affect profits. Managing this type of risk consists of tracing products from sales, through production, to delivery and payments receivable. Revenue recognition is affected by accounts payable, accounts receivable, revenues recorded before delivery, quotation to cash errors, spreadsheet errors and incomplete pricing information.

The quality manager has a major role in controlling the effectiveness of the revenue recognition process. There is overlap between quality and financial management systems, including product realization, costs, sales, invoices, payments, inventory management and delivery. Data from shipping are a direct input

into accounts receivables and revenue recognition. In many organizations, revenue recognition problems have a major effect on earnings and may result in a falling stock price.

There is also a risk of material misstatements due to fraudulent revenue recognition. An auditor should test the controls established to detect fraud in the revenue recognition processes.

5. Information security risks include viruses, unsecured files, inaccurate financial records and reporting, poor change control, information retrieval errors, overuse of spreadsheets, use of contractors and consultants, the introduction of new technology, industrial espionage and fraud.

ISO/IEC 27001:2005—Information technology—Security techniques—Information security management systems—Requirements[4] contains requirements for establishing, implementing, operating, monitoring, reviewing, maintaining and improving information security management.

6. Logistics risks. A major concern for organizations today is the risk caused by the threat to national security. The search for concealed weapons of mass destruction slows the shipping process. One consideration is how containers will be screened, identified and traced from the country of origin to the purchasing organization. The following factors affect logistics risk:

- Transportation of raw materials and completed products.
- Damage during shipping.
- Delays resulting in missing on-time delivery requirements.
- Delays causing understocking of materials.
- Homeland security information requirements.

New tools must be developed for screening and tracing without supply line disruption. After the product is produced, you must overcome these logistics-related challenges to ship it to the customer.

7. Natural disaster risk. In the past few years, the world has experienced a number of natural disasters. Businesses continuity (BC) requires safekeeping of information in protected storage and planning for disaster recovery.

IT plays an important role in the BC process. IT procedures should be specifically defined to assure that BC will operate in a timely and effective manner. The organization's members of IT should be part of the BC development team.

IT must provide safekeeping and protective storage of information and must manage, secure and provide safety against all disasters. The method is to regularly copy information and store it in a backup system at a secure, off-site location. Data at this location should be tested for accuracy regularly.

ISO/IEC 27001 provides controls for BC management. The following are components of a BC plan (BCP):

- Business risk and impact analysis.
- Initial response activities for a disaster event.
- Procedures for managing emergencies and business recovery processes.
- Plans for training at multiple levels.
- Procedures for keeping the BCP up-to-date.

BCPs should be exercised periodically. Some questions an organization should ask about its BCP are:

- Does a written plan exist to ensure continuation of information processes?
- Is the plan updated and tested annually? When do significant modifications to computer hardware, software or application systems occur?
- Is the back-up media tested regularly?
- Are application programs, application data and operating system software backed up periodically?
- Are copies of the plan and the back-up information retained off-site?

Risk analysis methods

Risk analysis starts with the organization determining its risk appetite and risk tolerance so all members of the organization can understand the risk philosophy. After these are decided, there are tools to determine the risk levels and manage the identified risks. One key tool is the organization's controls. These are especially important for compliance to SOX. Compliance includes financial controls at the entity and activity levels.

Risk appetite and risk tolerance

Risk appetite is the amount of risk on a broad level an entity is willing to accept. It is the measure of the risk reward trade-off within the business. In terms of SOX compliance, risk appetite reflects the tone at the top. It is a major consideration in shaping the control environment, as outlined by the Committee of Sponsoring Organizations of the Treadway Commission.[5] Risk assessments beyond the boundaries of the risk

While risk appetite is a **broad, entity-wide concept,** **risk tolerance** has a narrower focus.

appetite should result in preventive actions being implemented.

Risk appetite acts as a driver for allocation of capital to identified risks. Improving the understanding of risk appetite leads to a more efficient allocation of capital across the organization.[6] It should be a function of the capacity to bear risk. Constraints on risk appetite include the capital needed to maintain the organization's credit rating and meet regulatory capital requirements.

On the other hand, risk tolerance relates to the entity's specific objectives. It is the amount of variation relative to the objectives an entity is willing to accept. Risk tolerance varies within an organization.

While risk appetite is a broad, entity-wide concept, risk tolerance has a narrower focus. An organization may have different risk tolerances for its various operating units. When the individual risk tolerances are combined, however, they should fall within the overall risk appetite set by top management and the board.

Using controls

One important tool for managing risk is the organization's set of controls. Controls are especially important for compliance to SOX. Auditors test the controls as a key part of the compliance process. The financial and quality controls are at two levels, entity and activity, while the quality controls also appear as "shall" statements in ISO 9001 and ISO 14001. Shall statements are often accompanied by requirements to submit data. Some process performances requirements also include records of results, which can be used to identify impending risks.

Examples of entity-level controls include:

- HR policies.
- Code of conduct.
- Communication strategy.
- Accounting policies.
- Management's risk assessment process, organizational structure and contract review. Contract review requirements are related to quality requirements in ISO/DIS 9001:2015, *Clause 8.2.3—Review of requirements related to goods and services*.

Activity-level controls include reconciliation of the general ledger to a subsidiary ledger, automated data validation and edit checks, limited access to confidential information, numbered transactions prior to entry, and review and approval of paper-based information prior to input.

Quality controls at the activity level include control of production (clause 8.6.1), documented information—correction of nonconforming products and services (clause 8.8) and identification of significant environmental aspects (ISO 14001:2004, clause 4.3.1).

Risk and preventive action

Effective risk assessment activities include:

- Defining the organization's measurable objectives.
- Assuring the compatibility of the objectives.
- Identifying risks to achieving objectives.
- Judging which risks are critical. A risk analysis matrix can be used to determine criticality of the risk.
- Using risk management tools to mitigate risks, such as the objectives, risk, controls and alignment (ORCA) process, the ISO 9001 improvement process, failure mode and effects analysis (FMEA) and risk control matrix.

Risk analysis matrix

A key tool is the risk analysis matrix. For each identified risk, the consequences and likelihood of occurrence of the risk are estimated. These are then input into a risk analysis matrix, shown in Figure 1 (p. 28).

After the level of concern is determined for each risk, actions can be implemented for the extreme and high risks.[7] ISO/DIS 9001:2015 requires a procedure that implements the following:

- Take action to control and correct the nonconformity.
- Evaluate the need for action to eliminate causes.
- Implement corrective actions.
- Review effectiveness of actions.
- Make changes to the QMS, if necessary.

ORCA

Risk expert Greg Hutchins suggests considering using ORCA as an organizational risk assessment method.

"It is well accepted and adopted. It incorporates elements of other types of assessments including process, internal control and system audits." he wrote. "Also, it fits into today's corporate governance focus on risk management and operational effectiveness."[8]

ORCA requires organizations to:

- Articulate organizational objectives.
- Identify and assess risks across the entire spectrum.
- Build in balanced controls to manage organizational risks.
- Ensure alignment of objectives, risks and controls across the entire enterprise.

After the risk assessment is conducted, senior and operational management can develop strategies to manage risks and execute business decisions. Risk management strategies include avoidance, mitigation, acceptance, diversification and control.

ISO 9001 improvement process

Clause 10.2 of ISO/DIS 9001:2015 says an organization should improve its QMS by responding to:

- Results of analysis of data.
- Changes in the context of the organization.
- Changes in identified risk (clause 6.1).
- New opportunities.

FMEA

FMEA is a method for risk prioritization and taking preventive action aimed at risk reduction. FMEA is used to examine potential failures in products or processes and helps select remedial actions that reduce risks.

FMEA starts with a description of the parts of a system. Next, the consequences of each part failure are determined. A risk analysis matrix is used to evaluate the severity and likelihood of occurrence of each failure. The ability of controls to detect failures also is determined.

Actions that could eliminate or reduce the occurrence of failures or improve the ability to detect the risks are identified. Finally, the FMEA helps institute changes to processes and products, which are incorporated to avoid potential failures.

Carl S. Carlson of ReliaSoft Corp. describes an 11-step process for developing an effective FMEA process.[9] He starts with the development of strategic and resource plans and describes generic programs included in design management reviews, quality audits, supplier FMEAs, and methods of execution and follow-up of recommended actions. His final steps are to include software support, links to other processes and testing, and follow-up of field failures.

Risk control matrix

A risk control matrix is a tool to manage the risk of a specific process. Controls are set up to determine the status of the individual risks to the process. A risk control matrix gives management a picture of the most recent results of the control assessment.

The example in Figure 2 shows an analysis of the process of closing the books.[10]

Adopt a risk-based approach

ISO/DIS 9001:2015 is strongly risk oriented. Risk-based thinking within an organization must start by defining its measurable objectives. Risks are obstacles that impede progress toward achieving these objectives.

Organizations must determine their risk appetite and risk tolerance so they will have a consistent risk philosophy. They then determine risk levels by combining the likelihood of an event and its consequences in a risk analysis matrix.

In a SOX-compliant process, controls should be selected using a top-

Risk analysis matrix / FIGURE 1

	Consequences				
Likelihood	**Insignificant**	**Minor**	**Moderate**	**Major**	**Catastrophic**
Almost certain	Moderate	High	High	Extreme	Extreme
Likely	Moderate	Moderate	High	High	Extreme
Possible	Low	Moderate	Moderate	High	Extreme
Unlikely	Low	Moderate	Moderate	Moderate	High
Rare	Low	Low	Moderate	Moderate	Moderate

Adapted from:

Australian Government Department of Finance, "Qualitative Risk Analysis Matrix—Level of Risk," http://bit.ly/1o9dRjj (case sensitive).

ioMosaic Corp., "Designing an Effective Risk Management Matrix," www.iomosaic.com, 2002.

Risk control matrix / FIGURE 2

Key process number	Process	Risk number	Risk	Control objective	Control number	Control description	Control owner	Process narrative	Control category	Control type	Primary/secondary	Control frequency	Design assessment
1.1	Close the books	1	Financial statements may contain material or immaterial misstatements or omissions.	Financial statements do not contain material or immaterial misstatements or omissions.	1	Various review activities are performed throughout the close process to verify financial data. These activities include the finance department's review of intercompany account balances for discrepancies, review of currency translation adjustments, and review of prior and current year accumulated deficit balances.	J.H. Doe	A.2	Detective	Manual	Secondary	Monthly	Adequate
1.2					2	The accounting manager reviews all journal entries.	J.H. Doe	A.3	Detective	Manual	Primary	Twice weekly	Inadequate

Process: Close the books
Objective: Integrity of financial reporting
Financial reporting element: All financial reporting elements

down, risk-based approach and tested to identify deficiencies and possible material misstatements. Based on the revision to date, the new versions of ISO 9001 and ISO 14001 seem poised to provide valuable tools to organizations working to improve their risk management strategies. QP

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2. International Organization for Standardization, *ISO 9001:2015 Draft International Standard—Quality management systems—Requirements*.
3. SOX is a U.S. federal law that identifies standards for U.S. public company boards, management and public accounting firms, requiring top management to certify the accuracy of financial information. The law made penalties for fraudulent financial activity more severe and increased oversight of boards of directors and the independence of the outside auditors who review the accuracy of corporate financial statements. For more information, visit Wikipedia, "Sarbanes-Oxley Act," http://en.wikipedia.org/wiki/Sarbanes_Oxley_Act.
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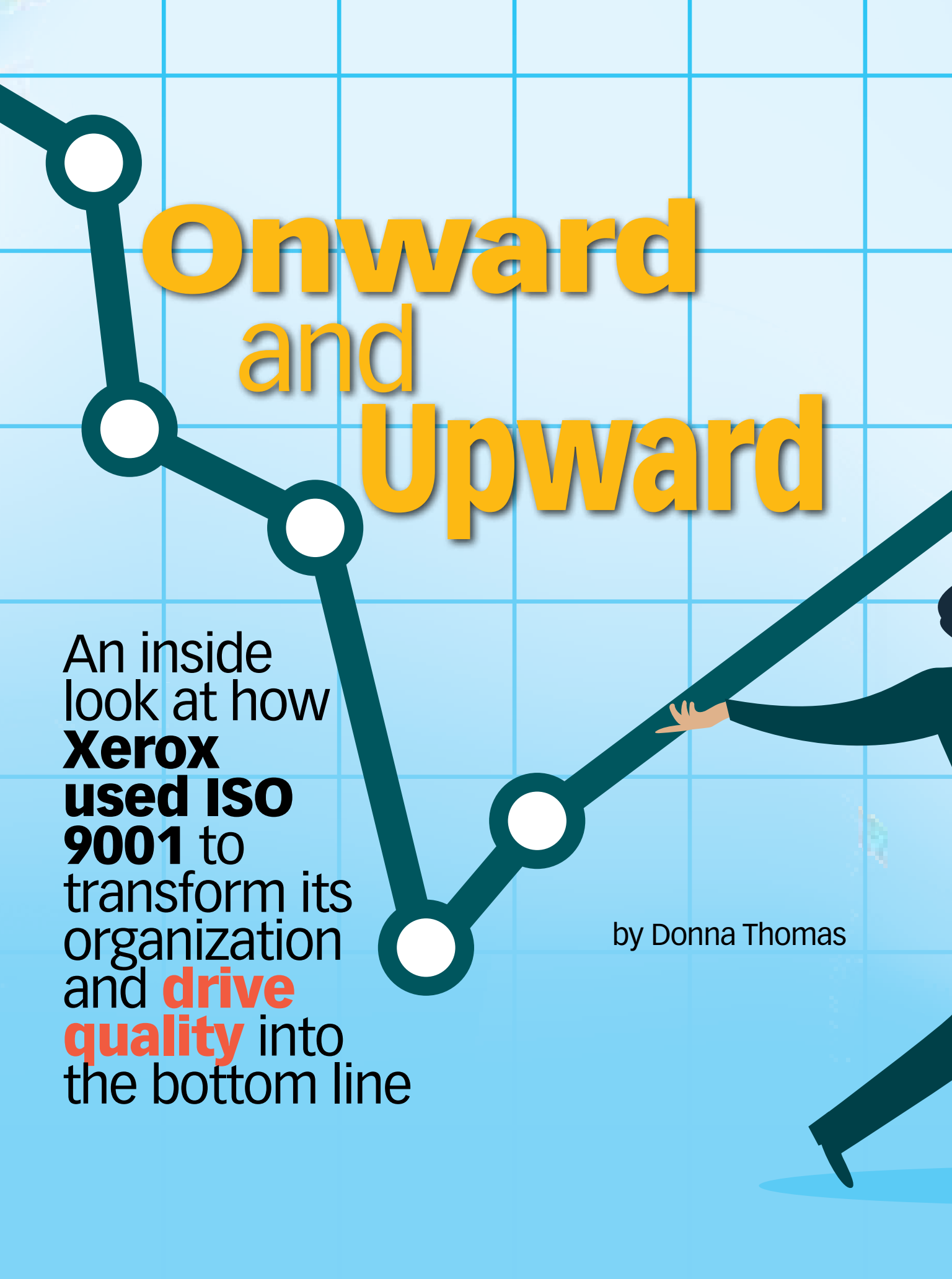
Onward and Upward

An inside look at how **Xerox used ISO 9001** to transform its organization and **drive quality** into the bottom line

by Donna Thomas



OPERATIONAL EXCELLENCE has been a long-time focus for Xerox, the international document management corporation. Before joining Xerox, our legacy organization, Affiliated Computer Services (ACS), shared that same focus. As reported by Interbrand, Xerox's global brand value is $6.7 billion,[1] a valuation that depends on continued operational excellence to sustain and grow.

As the Norwalk, CT-based corporation took on ever-more complex work for clients, we embarked on a transformation to revise our quality management system (QMS) to ensure it is efficient and effective while protecting profit margins. ISO 9001:2008 played a central role in making that transformation happen.

Organization description

The Technology Delivery Center (TDC) is an engineering-matrix organization within the government and transportation sector of Xerox Services. This organization supports multiple lines of business with project management, software design and development, hardware design and development, systems design and development, testing, quality assurance, safety and installation work. The center has multiple work site locations, the primary ones being two international and five U.S. sites.

In 50 Words Or Less

- To get a handle on variations in processes and be able to take on more complex work for clients, a Xerox business unit decided it needed to revamp its quality management system.
- ISO 9001:2008 was integral in transforming the unit and helped the document management organization grow its business profitability.

We also started conversations with executives and senior managers about what we wanted to do, gaining their endorsement of our approach to transform our QMS by first using ISO 9001:2008.

Single piece of paper

Inspired by the Xerox brand, we embraced the brand personality and the marketing slogan: We make things simple so you can focus on what you do. We examined the variations of processes across our enterprise and determined that if we characterized what we do on a single page of paper, we could abandon the mounds of paper that we previously needed to work through to understand how we perform work.

We developed a vision to create a process on a page (POP) for key performance processes. If we needed detailed instructions, we called them work instructions. If we needed templates, we created them.

Our first POP was our process revision process. Because we had a variety of processes for the different things we do—and for different locations and suborganizations—we needed to examine all of the approaches and develop a meta process for the POP that defined roles and responsibilities consistently, capturing measurable performance objectives by role and process metrics to understand whether the processes were working.

Facilitators, each either holding the certified-ISO 9001 lead auditor credential or having completed an ISO 9001 implementing and auditing class, were assigned to shepherd each POP through review and baselining.

As a large organization, we determined we had 55 key performance process areas to rationalize and streamline. Each process area was assigned to a color group—based on the colors in the Xerox brand—and each color group was associated to a particular subsection of ISO 9001. Each color group had a team lead, who also served as a member of our governance committee and our change control board.

To begin revising all of these processes, we developed a process revision checklist (PRC), which contained core questions about every aspect of the process, including what internal auditor questions would be used when we audited to the process. Each facilitator organized and held meetings with subject matter experts from each of the primary sites to get input and make action item assignments.

Every discussion was documented to ensure we accurately captured the similarities and differences in how each site or project team executed each process, and so that each could accept the POP as an accurate high-level description of the current process in use.

Depending on the complexity and scope of a process, there were up to 22 deliverables per process that were provided as part of the delivery to the governance board for approval. Each set of deliverables required a POP, training material and a completed PRC. Some of the helpful items we collected as part of each PRC included:

RAPPIN' ITS HEAD AROUND QUALITY

To keep members of Xerox's Technology Delivery Center (TDC) motivated while they were revising their quality management system—and later to celebrate when the center achieved ISO 9001:2008 certification—a college student who later joined the center wrote and performed two rap songs based on the center's quality efforts.

Roger Delacruz had been working his way through college—studying computer science at the University of Maryland, College Park—by participating in rap and hip hop contests and writing music. Donna Thomas, director of quality assurance for service delivery at Xerox, asked him to come up with the first song, "The TTC Theme Song" (http://tinyurl.com/obfzfk3).

"Everyone has hobbies on the side. Writing songs and performing rap songs is Roger's favorite pastime, and he had the unique opportunity to apply his talent in the workplace," Thomas said. "The song and the words are great, but the connections created by listening to the song are priceless."

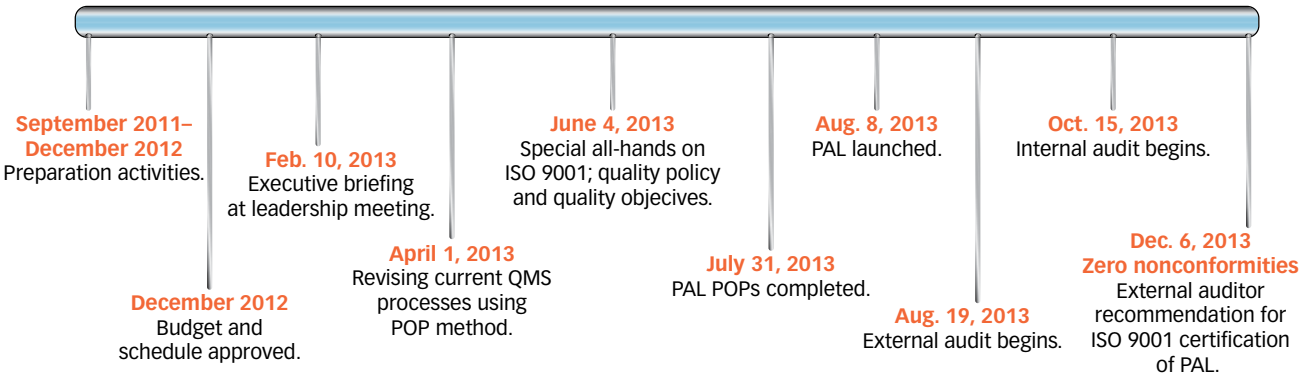
When Delacruz graduated, Thomas hired him to be a part of her team as a junior quality analyst. After the ISO 9001 certification was issued, Delacruz wrote a sequel to the first rap: "Xerox Theme Song 2" (http://tinyurl.com/pym8peb).

"Roger actually lived through revising our quality management system and the audit preparation activities," Thomas said. "Roger is witness to all of these efforts we all encountered—and that's reflected in the second song."

Note that Delacruz's lyrics mention TTC, the acronym for the Xerox unit when it was called the Transportation, Local and Central Government (TCLG) Technology Center. The songs were written before the unit's name was changed to TDC.

—QP Staff

Xerox's TDC ISO 9001 journey / FIGURE 1



PAL = process asset library
POP = process on a page
QMS = quality management system
TDC = Technology Delivery Center

- Names of the people to contact.
- Identification of existing documentation.
- Relevant facts.
- Process questions.
- Meeting and peer review records.

A core requirement to submit these assets for baselining was a compliance statement and records to show the POPs reflected what we actually do, not what we aspire to do. This ended up being important as we prepared for the external audits.

Executing the plan

Essential elements of marketing, training, business rhythms, process revision, internal audit execution and site preparation for external audit were all executed within a 12-month cycle during 2013. See Figure 1 for a summary of the TDC's ISO 9001 journey.

After POPs and related assets were approved by the governance panel, we added them to our process asset library (PAL). It is a secure-sockets layer (standard security technology) single sign-on portal in which anyone in the TDC can access the controlled assets, store records and documents, write and manage action items, review internal audit results and review key performance indicator (KPI) metrics of the health of our QMS.

While POP was being created, we worked on the infrastructure that would support us using our PAL. We also produced computer-based training materials. When the processes were approved and we started inserting them into PAL, we began preparing for external site audits and executing internal audits. Due to the size of our organization, we had a site manager at every primary location who worked with the management representative and leadership team at our sector headquarters.

Site preparation activities included preparing audit notebooks. This would appear to be antiquated, but it truly helps the flow of the external audit activities. While we did demonstrate our electronic PAL platform and its robustness, the flow of questioning by the external auditors was supported by easily showing a level of compliance in the notebooks. This was augmented by random requests for more records that looked similar to what we had in the notebooks.

Along with proof of compliance, each member of the TDC had proof of competency skill discussions with managers, along with process training and operational knowledge of his or her role's value stream as it related to the QMS.

External site audit experience

Throughout our year-long journey, we strategically and tactically planned for all audits to be conducted late in the year. We deliberately avoided telling anyone the dates or the sites where the audits were to occur so everyone would be audit-ready all the time. The lucky site manager would receive a call from the management representative a day or two before the external auditor was to arrive, announcing the selec-

tion of his or her site, the start date and the duration of the audit.

Each audit was conducted by British Standards Institution (BSI) auditors, and at the end of each audit, our results were reported back with zero nonconformities. This happened four times. To yield these results, it was evident we not only had built an effective QMS, but that it also was effective because we all were living up to what we say in our processes. The final audit report cited we had 24 best practices.

Post-audit reflections

Since the receipt of our ISO 9001 certificate, internal audits continue with the monitoring of changes due to corrective actions, preventive actions and resolution of nonconformities. We have collected lessons learned during the implementation and have prepared a tool kit to assist other areas of Xerox. Our implementation team structure remains engaged to ensure the TDC will maintain our certificate.

With a broadly used process baseline in place, we've now put focus on evaluating work that results from following the processes. This includes collecting a standard set of productivity and quality metrics on all development projects.

SEE and HEAR
At **www.qualityprogress.com**, watch a video interview with Donna Thomas as she discusses more about Xerox and how the company used ISO 9001:2008 to transform its quality management system.

We are discovering inefficiencies and opportunities that need improvement. It is a massive undertaking to collect and package the metrics for weekly management review and has led to a movement to automate the interface to our configuration management, defect tracking and time recording systems.

By leveraging our lean Six Sigma (LSS) heritage, we are driving LSS projects to improve KPI measurements that align with our corporate objectives and strategy.

We made the choice to use ISO 9001 to transform our organization. The benefits we imagined at the beginning have been realized. We have noticed improvements in the level of output, quality and client satisfaction. Our quality policy has been a key driver to being predictable on-budget, on-schedule, with full-function performance. We have been able to demonstrate this by the use of metrics, effective cross-site team performance, transparent and inclusive communications, and processes that are efficient, consistent and disciplined.

We have experienced visits and site audits from customers who also have commented on some of the items that were cited as best practices. The outcomes of our visits have been positive and rewarding because we have been audit-ready. We also have won business because ISO 9001:2008 was a stated requirement or qualification.

Growing the bottom line

The journey to ISO 9001:2008 certification of our QMS has been an important step in our quest to grow our business profitably. Leveraging the legacy of quality within Xerox and ACS, the TDC was able to simplify our processes so that they are easy to follow—no matter where our resources are located.

All employees understand their roles and are accountable to contributing through understanding the bigger picture of how we operate and who depends on them for the expected outcome. Detailed on-demand, computer-based training enables each person to ensure that he or she understands the processes, and we have records of employee training along with competency and skills.

With the centralized platform of our PAL, all details of the QMS and related records are accessible anywhere in the world. Using ISO 9001 helped us revisit our QMSs across all of our primary sites, which we were able to consolidate and streamline into a common approach for one team—the TDC.

Simply by using this approach, we improved consistent performance and outcomes, and we were better able to estimate, plan and execute work. Continual improvement is essential to keeping our QMS evergreen, and that is a challenge to all organizations that are ISO 9001:2008 certified.

We have top-down leadership and focus in driving quality, process excellence and continual improvement into the bottom line. QP

REFERENCE

1. Interbrand, "Best Global Brands 2013," www.interbrand.com/it/best-global-brands/2013/xerox.

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Which FMEA Mistakes Are *You* Making?

Turn 10 common **FMEA missteps** into an effective audit process

by Carl S. Carlson

In 50 Words Or Less

- Failure mode and effects analysis (FMEA) can achieve safe, reliable and economical products and processes.
- Certain FMEA mistakes are repeated, however, with many organizations getting little value for the time and resources expended.
- Focusing on achieving quality objectives and using an FMEA audit process will greatly enhance the tool's effectiveness.

"Experience is the name everyone gives to their mistakes."[1]
—Oscar Wilde

FAILURE MODE AND EFFECTS analysis (FMEA) can be used to anticipate and prevent problems, reduce costs, shorten product development times, and achieve safe and reliable products and processes. It must, however, be performed on the correct parts, by the correct team, during the correct timeframe and with the correct procedure.

Frankly, there are mixed results with FMEA applications. Consider these questions: Why is there so much variation in applying

a tool that has been around for decades? What can be done to help achieve uniformly successful results?

Six important elements are critical to uniform success in applying FMEA:

1. Understanding the fundamentals, definitions and procedures of FMEAs.
2. Selecting the right FMEA projects.
3. Preparation steps for each FMEA project.
4. Applying lessons learned and quality objectives.
5. Providing excellent facilitation.
6. Implementing an effective organization-wide FMEA process.

This article focuses on the fourth element.

There is a maxim that says, "Good judgment comes from experience and experience comes from poor judgment." This article presents lessons learned from experience with more than 2,000 FMEAs in more than 100 organizations and can serve as the foundation for an effective FMEA audit process.

Readers will learn the top 10 FMEA mistakes and their associated design and process FMEA quality objectives (Table 1, p. 38). You will learn how to avoid these FMEA pitfalls and how to audit FMEAs[2] against quality objectives (read the sidebars "FMEA Defined," p. 39, "Using Quality Objectives," p. 40, and "FMEA Audit Procedure," p. 41.

Mistake No. 1: design/process improvements

A review of FMEA applications across industries shows some FMEAs drive ineffective actions or no action at all. Some design FMEAs drive mostly testing, while some process FMEAs drive mostly controls. FMEA's failure to drive product or process improvements is mistake No. 1.

Associated quality objective

The FMEA drives design improvements (design FMEA) or manufacturing or assembly process improvements (process FMEA) as the primary objective.

Effective application: The quality and reliability fields have many tools to choose from in driving design or process improvements. The key is using the recommended actions worksheet column of the FMEA to identify and execute tools that can optimize designs and processes. This is one of the reasons quality or reliability engineers should participate in FMEAs.

How to audit: Review the FMEA recommended actions and observe whether most of them drive design improvements (for a system or design FMEA) or process improvements (for a process FMEA). Talk with team members to ensure their focus was on improving the design or process.

Mistake No. 2: high-risk failure modes

Although organizations define risk using different criteria, failure to address all high-risk failure modes can result in potentially catastrophic problems or lower customer satisfaction. Failure of FMEA to address all high-risk failure modes is mistake No. 2.

Associated quality objective

The FMEA addresses all high-risk failure modes, with effective and executable action plans.

Effective application: The team first addresses all high-severity issues, regardless of risk priority number (RPN). After high-severity issues are addressed, the team can prioritize and address high-RPN issues (or high severity x occurrence if severity and occurrence are used rather than RPN). The key is effective actions that reduce or eliminate risk. Most high-risk problems require multiple corrective actions.

How to audit: Review high-severity and high-RPN issues to determine whether the corresponding recommended actions are adequate to reduce risk to an acceptable level. Talk with the team members to ensure they are satisfied that all high risks were addressed and no important concerns were left unaddressed.

Mistake No. 3: design verification or process control plans

Some organizations miss the opportunity to improve their design verification plan (DVP) or process control plan (PCP) based on the failure modes or causes from the FMEA. The result is inadequate product testing or PCPs. Failure of the FMEA to improve test and control plans is mistake No. 3.

Associated quality objective

The DVP considers the failure modes from the design FMEA. The PCP considers the failure modes from the process FMEA.

FMEA quality objectives / TABLE 1

1. **Design/process improvements.** The failure mode and effects analysis (FMEA) drives design improvements (design FMEA) or manufacturing or assembly process improvements (process FMEA) as the primary objective.
2. **High-risk failure modes.** The FMEA addresses all high-risk failure modes, with effective and executable action plans.
3. **Design verification or process control plans.** The design verification plan considers the failure modes from the design FMEA. The process control plan considers the failure modes from the process FMEA.
4. **Interfaces.** The scope of the design FMEA includes interface failure modes in both FMEA block diagram and analysis. The scope of the process FMEA includes inter-operation failure modes, such as transfer devices, as well as incoming parts and shipping, in both process flow diagram and analysis.
5. **Lessons learned.** The FMEA considers all major lessons learned (from in-service warranties, customer service databases, recall campaigns, prior manufacturing or assembly problems and others) as inputs to failure mode identification.
6. **Level of detail.** The FMEA provides the correct level of detail to get to root causes and effective actions.
7. **Timing.** The FMEA is completed during the window of opportunity from where it can most effectively affect the product design or manufacturing process.
8. **Team.** The right people, adequately trained in the procedure, participate on the FMEA team throughout the analysis.
9. **Documentation.** The FMEA document is completely filled out by the book, including "action taken" and final risk assessment.
10. **Time use.** Time spent by members of the FMEA team is an effective and efficient use of time with a value added result.

Effective application: The FMEA team will often discover failure modes or causes that were not part of the design controls, process controls or corresponding procedures. The key is to ensure the DVP or PCP is affected by the results of the FMEA. This can be done by including test or control personnel on the FMEA team, and through well-written recommended actions.

How to audit: Review the recommended actions to determine whether there are improvements to the DVPs, PCPs or corresponding procedures based on risk associated with current design or process controls. Talk with the team members to determine whether they had adequate representation from test or controls groups, benefited from their input, and whether test and control procedures were improved.

Mistake No. 4: interfaces

Empirical data show at least 50% of field problems can occur at interfaces between parts and subsystems or between the system and environment. Similarly, many manufacturing or assembly problems occur at the interface between operations or beyond operations, such as while transporting materials, receiving incoming parts or shipping. Some practitioners miss these interfaces. Not including interfaces in design or process FMEAs is mistake No. 4.

Associated quality objective

The scope of the design FMEA includes interface failure modes in both FMEA block diagram and analysis. The scope of the process FMEA includes inter-operation failure modes, such as transfer devices, and incoming parts and shipping, in both process flow diagram and analysis.[3]

Effective application: Product design interfaces can include physical connections, material exchanges, energy transfers or data exchanges. The FMEA block diagram should clearly show the interfaces that are part of the design FMEA scope. Similarly, the process flow diagram should show inter-operation connections and exchanges, such as with materials transport, and receipt of incoming parts and shipping.

How to audit: Review items, functions, failure modes and other portions of the FMEA to ensure interface issues were addressed within the design FMEA scope. Ensure connections and exchanges between operations were addressed within the process FMEA scope. Review the FMEA block diagram and process flow diagram to verify. Ask the team how it determined no interface issues were missed.

FMEA DEFINED

Failure mode and effects analysis (FMEA) is a method designed to:

- Identify and fully understand potential failure modes and their causes, and the effects of failure on the system or end users, for a given product or process.
- Assess the risk associated with the identified failure modes, effects and causes, and prioritize issues for corrective action.
- Identify and carry out corrective actions to address the most serious concerns.

FMEA is an engineering analysis done by a cross-functional team of subject matter experts that thoroughly analyzes product designs or manufacturing processes, early in the product development process. Its purpose is to find and correct weaknesses before the product gets into the hands of the customer. The primary objective of an FMEA is to improve the design of the product or process being analyzed.

Design FMEA focuses on design-related deficiencies, with emphasis on improving the design and ensuring product operation is safe and reliable during the useful life of the equipment.

Process FMEA focuses on manufacturing or assembly-related deficiencies, emphasizing how the manufacturing process can be improved to ensure that a product is built to design requirements safely with minimal downtime, scrap and rework. *—C.S.C.*

Mistake No. 5: lessons learned

Some organizations do not provide links between FMEAs and field data (in design FMEAs) or manufacturing data (in process FMEAs). It takes concerted effort to integrate problem resolution databases with the FMEA. A lack of integration can cause serious problems to be repeated. Disconnect between the FMEA and information from the field or plant is mistake No. 5.

Associated quality objective

The FMEA considers all major lessons learned (from in-service warranties, customer service databases, recall campaigns, prior manufacturing or assembly problems and others) as inputs to failure mode identification.

Effective application: Field and manufacturing failure databases often have noise. Effort is needed to filter the correct input information to FMEAs. New FMEAs should be seeded with potential field and manufacturing problems, and should show how the problems will be avoided in the new or modified design or process. Hold FMEA teams accountable to ensure

known problems are not repeated.

How to audit: Review failure modes and causes to ensure they contain supplemental field failure data (for system and design FMEAs) and manufacturing failure data (for process FMEAs). Talk with the FMEA team to ensure the FMEA benefited from lessons learned and that high-risk issues will not recur.

Mistake No. 6: level of detail

Some FMEAs are too detailed in their analysis, which makes it difficult to focus on areas of higher risk. Some FMEAs aren't detailed enough, which makes it difficult to determine the root cause and effective corrective actions. Having the wrong level of detail in the analysis is mistake No. 6.

Associated quality objective

The FMEA provides the correct level of detail to get to root causes and effective actions.

Effective application: Good FMEA facilitation keeps a team focused on areas of risk that lead to root causes and effective corrective actions. FMEA discussions should be limited to areas of concern noted by at least one member of a properly constituted FMEA team. Avoid lengthy discussions about low-risk issues. The higher the risk, the more important and in-depth the discussion should be. Low-risk issues should receive less, but appropriate, discussion.

How to audit: Verify that the level of detail on high-risk issues is adequate to fully understand root causes and develop effective corrective actions. Review the different worksheet columns of the FMEA to ensure the overall level of detail is proper and adequate.

Too much detail may appear in the form of endless pages of FMEAs covering issues no one on the team is concerned about. Too little detail shows up as underdefined functions, failure modes, effects, causes or controls, or as areas of unaddressed concern from one or more FMEA team members. Talk with the FMEA team members to determine how they addressed the level of detail and ensured all concerns were included in the scope of the FMEA project.

Mistake No. 7: timing

Many organizations conduct FMEAs late, and this reduces their effectiveness. FMEAs should be completed according to design or process freeze dates in line with the product development process. Performing FMEAs late is mistake No. 7.

Associated quality objective

The FMEA is completed during the window of opportunity from where it can most effectively affect the product design or manufacturing process.

Effective application: The key to completing FMEAs on time is to start the FMEAs on time. Design or process FMEAs should begin soon after the design or process concept is determined and be completed before design or process freeze dates. Starting and completing FMEAs on schedule requires proactive management support throughout the FMEA process.

How to audit: Review the timing of the FMEA against the product development process timeline. Verify the FMEA was started and completed in the proper timeframe to maximize the value of the FMEA results.

Mistake No. 8: team

Some FMEA teams do not have the right experts on their core teams. Some FMEA team members just sit in their chairs if they show up at all and don't contribute to team synergy. FMEAs having inadequate team composition and participation is mistake No. 8.

Associated quality objective

The right people, adequately trained in the procedure, participate on the FMEA team throughout the analysis.

Effective application: People have blind spots. A well-defined, cross-functional team minimizes errors due to blind spots. FMEA analysis requires SMEs from a variety of disciplines to ensure all necessary inputs are incorporated into the exercise. The cross-talk and synergy among SMEs that occurs during FMEA meetings is essential, because well-defined groups can discover what individuals miss. Attendance is influenced by management support. A team size of four to eight people works best.

How to audit: Review the FMEA team member ros-

USING QUALITY OBJECTIVES

Failure mode and effects analysis (FMEA) quality objectives should be integrated into FMEA team training and reviewed at each stage of FMEA project completion. They can be used to assess the quality and effectiveness of original equipment manufacturer and supplier FMEAs. FMEAs should not be considered complete until all of the quality objectives are met. They are important ingredients for an FMEA quality audit process and are essential to ensuring effective FMEAs. —*C.S.C.*

ter to ensure there was adequate representation from the various disciplines based on the type of FMEA and the project scope. Check FMEA team meeting records to ensure attendance was adequate at each meeting. Talk with individual team members to learn whether their input was elicited in decisions.

Mistake No. 9: documentation

There are hundreds of ways to do FMEAs wrong. Some organizations do not encourage or control proper FMEA methods. Or, they copy old FMEAs and don't adequately address changes, such as new technology or new applications. Training, coaching and reviews are necessary for success. Use of improper FMEA procedures is mistake No. 9.

Associated quality objective

The FMEA document is completely filled out by the book, including action taken and final risk assessment.

Effective application: The FMEA team must have a solid understanding of FMEA fundamentals, definitions and concepts. There is no substitute for properly applying FMEA fundamentals. This is a broad quality objective to ensure the FMEA worksheet is filled out completely and properly.

How to audit: Verify that the FMEA worksheet columns were correctly filled out and that FMEA procedure was properly followed. Talk with the FMEA team members to ensure they rigorously followed FMEA guidelines and practices.

Mistake No. 10: time use

Some organizations mandate FMEAs, but that doesn't ensure the time spent on them is productive. Prework must be completed, meetings must be productive and high-risk issues must be resolved. Ask the FMEA team whether their time was well spent, and take action to address shortcomings. Inefficient use of time is mistake No. 10.

Associated quality objective

Time spent by members of the FMEA team is an effective and efficient use of time with a value-added result.

Effective application: If this quality objective is met, future FMEA meetings will be well attended and supported by SMEs and management. Conversely, if subject matter expert time is wasted, it will be difficult to generate attendance at future meetings.

How to audit: Talk with the FMEA team to learn whether each member believes his or her time was well spent and whether a value-added result was achieved. If not, find out why.

FMEA AUDIT PROCEDURE

Failure mode and effects analysis (FMEA) quality audits are in-person audits of completed or nearly completed FMEAs, performed with the FMEA facilitator and core team present. Perform the audit on a prescheduled or random basis. The auditor must be skilled and experienced with the content and quality of good FMEAs. The auditor can be from management or be an FMEA expert.

Each of the 10 FMEA quality objectives has a corresponding "how to audit" recommendation. In a nutshell, an FMEA SME or manager reviews the FMEA results with the FMEA team against each of the FMEA quality objectives, one by one, using the audit recommendation. Each quality objective is evaluated for how well it is achieved. This evaluation can be assigned a variable representation, such as high (3), medium (2) or low (1), or another scale. The numerical output represents the quality of the FMEA.

Allocate one hour for the audit, or about five minutes per FMEA quality objective. In addition to the numerical output, the results of the audit provide valuable information to improve future FMEAs. The focus is on improving the FMEA process, not on the person or team doing the FMEA. The auditor is looking for specific process-related issues that underlie deficiencies in achieving the quality objectives, such as lack of training, procedures, facilitation skills, standards, resources or support. Action items from the FMEA quality audit should be documented and pursued to improve the overall FMEA process. Do not expect to achieve all 10 FMEA quality objectives instantly. Rather, work to maintain steady improvement. —*C.S.C.*

Increase FMEA value

FMEA has the potential to be a powerful reliability tool to reduce product design and manufacturing risk in a cost-effective manner. Yet in practice, FMEA does not always live up to its potential. Using an audit process based on the FMEA quality objectives will increase the value of FMEAs in your organization. QP

REFERENCE AND NOTES

1. Oscar Wilde, Act III, *Lady Windermere's Fan*, 1892.
2. For more information about FMEA auditing, including examples from an FMEA audit, view a webinar from the ASQ Reliability Division, "How to Audit FMEAs Using Quality Objectives," https://asq.org/reliability/110170/web.html?shl=110170.
3. An FMEA block diagram is a visual depiction of the entire system or design to clearly show the boundaries of the FMEA analysis (what is included and not included), the interfaces between items and other information that can help depict the scope of the FMEA. Definitions for basic FMEA terms used in this article are available at www.effectivefmeas.com/uploads/Glossary_of_FMEA_Terms.pdf. (case sensitive).

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Making the Jump

Should you quit your day job and become a consultant?

MOST KIDS DREAM about becoming a famous athlete, a movie or rock star, or perhaps even an astronaut. In my case, I considered becoming a professional cartoonist. Like many dreams, that one came and went. I eventually earned three degrees in engineering. After obtaining sufficient education, experience and confidence, I went out on my own as a management consultant specializing in statistical data analysis, customer satisfaction and continuous quality improvement.

At some point in your career, you may aspire to become a full-time management consultant, just as I did. Avoid making a hasty decision, and ask yourself:

- Do I have the right credentials to make the move?
- When and how should I make the move?
- Should I start part-time?
- What should my specialty be?
- Who are my potential clients?
- How do I attract clients?
- How will potential clients find me?
- Who are my competitors?
- What do my competitors charge for their services?
- Am I willing and able to travel?
- How and where should I market my services?
- Should I focus on one or more particular industries?
- Should I obtain relevant certifications?
- Should I join an existing consulting firm or create my own?

Now, I'll offer my thoughts on some of the top concerns for aspiring consultants based on my experience.

Credentials

Credentials are what potential clients look at first. Your experience should include industries and functions that assure potential clients you have a full understanding of their situations. Your certifications should indicate your skills and knowledge. Your education should first reflect your highest degree, followed by lesser degrees. Potential clients also will want assurance that there will be good chemistry between you and their organization.

Economics

Timing is critically important when making the move to full-time management consultant. The status of the economy, especially in your specialty businesses and industries, must be considered, particularly if you're starting with minimum capital and a short list of potential clients.

Part time vs. full time

If you prefer to operate solo, the probability for long-term success increases if you begin consulting on a part-time basis while you're still employed full time. This is how I began my consulting career and built a client base without sacrificing my income. In fact, this modus operandi helped me acquire sufficient savings to protect my family's lifestyle when I became a full-time consultant. When you're just starting, one or more of your potential clients will ask you if you've done similar work for other organizations. Anticipating this, I provided pro bono assistance to nonprofits such as Goodwill Industries. The only request I made of these organizations was that they agree to become a reference.

Consulting specialties

The number of consulting specialties seems endless. What you know best and are known for is probably the best place to start, whether it's auditing, healthcare, customer service or lean Six Sigma. You can expand your range of services after starting, just as I did.

Clients

At the outset of your management consulting career, the number and type of your potential clients are theoretically unlimited. Being realistic, however, there will be some important restrictions—some self-imposed. Restrictions include factors such as your areas of specialization, tolerance for travel, your reputation, your preferences regarding types of clients (size: large, medium or small; ownership: public vs. private; age: old vs. new; and others).

Whether you're starting solo or working with others, you must let your world of potential clients know that your consulting services are available for hire. There are many ways to attract potential clients. The following are just a few ideas that have worked for me:

- Write articles for publication in profes-

sional magazines and journals relevant to your target client base.
- Write and publish professional books and have them reviewed in the same professional journals.
- Deliver presentations to chapter and national meetings of professional societies such as ASQ, the Institute of Industrial Engineers or the American Society of Safety Engineers.
- Deliver webinars and webcasts under the auspices of the same professional societies.
- Network by attending chapter and national meetings of the same professional societies.

The reasoning behind these ideas is repetition: The more your name is seen and heard by your potential clients, the more likely it will be recognized, remembered and recalled when a person with your skills, experience and education is needed. It's not much different than marketing products and services.

Marketing

You must have a professional website that details previous projects and what you can do for potential clients. I'm sure mine isn't perfect, but visit www.revellesolutions.com for some ideas to include. Many management consultants promote their availability in classified ads in journals. I've never used this tactic, but I assume some consultants find them worthwhile based on the continued appearance of some ads.

When you're having your business cards designed, make good use of the back side to let potential clients know about your skills, education and experience. Using social media sites such as LinkedIn is another way to establish lines of communication and spread the word regarding your management consultancy.

Competition

When you're running a race, it's clear who the competition is. When you're competing for a consultant job, it's not always clear. Only twice in all my years of consulting have I learned who my competitors were, by accident. Your competition could be working solo or might be part of a consulting organization. Whichever the case, don't depend on knowing who your competition is to give you a competitive advantage.

When you're a consultant, discovering what your competitors charge for their services is not like comparison shopping for groceries. Consultants don't openly advertise so everyone can compare prices. This is one of the most difficult, if not impossible, challenges you'll face. Gaining this information is unlikely, unless you have a knowledgeable friend on the inside of a competitor or clients willing to divulge this information.

Travel

Are you willing or able to be away from home much of the time? Are you willing to drive or fly from your home territory to serve clients hundreds, or even thousands, of miles away? Are you willing to put up with the security restrictions and inconveniences associated with travel? As a long-time management consultant, I quickly determined that my tolerance for travel was limited.

Presentation

After contact is made between you and a potential client, it's time for you to become the right person for whatever jobs the client's contact person describes. You must be alert and engaging. Listen for key words or phrases that clarify the client's major concerns. Demonstrate your ability to get along with individuals at a variety of organizational levels. Indicate how you've successfully resolved similar problems in the past. If it's necessary to demonstrate concepts using graphics on a flipchart or white board, be sure to obtain prior permission from the client's contact person.

You may believe you have the capability to identify all of your client's problems and quickly solve them. I recommend, however, that you focus efforts on whatever problem the potential client believes is most important. There's nothing more irritating to clients than summarily dismissing their assessments of their processes. If you believe clients are off base in their understanding of what must be done, present your best explanation of the situation and what you believe should be done to rectify it without stepping on toes.

Certifications

Clients want their management consultants to have appropriate credentials. If your educational achievements are limited to a bachelor's or master's degree, acquiring certifications is a good idea. If you hold a doctorate, certification can still be an attractive feature on your résumé. As a management consultant, consider obtaining a certified management consultant designation through the Institute of Management Consultants.

Solo vs. team

Decide whether to work alone, form a consultancy with others or join an existing consulting organization. There are advantages and disadvantages to each option.

Ask for advice

I hope this food for thought helps you start thinking about whether you want to make your dream of management consulting a reality. You'll be the final decision maker, but it might be a good idea to discuss your thoughts with someone who has been down this path before. They will no doubt help you cut through the clutter and find the best solution for your future. QP

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Embracing Change

Embedding innovation into your QMS via ISO 9001:2015

TWO YEARS ago, I described in this column how you can use ISO 9001 as the basis for innovation management.[1] Many people were surprised because there is a tendency to think that a quality management system (QMS) based on ISO 9001 is inflexible. That is far from true, and I have previously quoted the agile manifesto[2] as an excellent frame of mind to have when developing your QMS.

The International Organization for Standardization (ISO), however, is aggressively pursuing innovation with the formation last year of Technical Committee (TC) 279 on innovation management, on which I serve. Our first meeting was held in December 2013 and three working groups (WG) have been formed:

- WG1 is developing the new innovation management standard, initially as a guidance standard before becoming a requirements document.
- WG2 is developing terms and definitions.
- WG3 is developing innovation tools.

The next meeting of TC279 will be in October in Buenos Aires.

Last year, I introduced you to ISO 10018 on people involvement and showed how it can be a great asset in drawing knowledge from people—the fuel of your innovation process.[3] I was convener of ISO 10018 and I am delighted to see so much of its thinking now embraced by the revised version of ISO 9001. In the meantime, the revised ISO 9001 provides some great opportunities for innovators, but you must look carefully for those opportunities.

ISO 9001 changes

ISO 9001:2015 is at the draft international standard (DIS) stage. The structure of the standard is set. That means the clauses and subclauses are set, but the text within the clauses will be revised in the light of the comments received from around the world.

At a high level, there are some great improvements. The archaic term "management responsibility" has finally gone and it's replaced with "leadership" (section 5) and planning (section 6). This is the language of business. "Resources" is retitled "support" (section 7) and the term "production realization" has been replaced with "operations" (section 8), which again reflects the language of business. The improvement section is also split in two and becomes performance evaluation (section 9) and improvement (section 10). This follows a structure adopted by ISO for all management system standards. I applaud this move forward; it means whether your management system is for quality, environment, or health and safety, it will have the same structure.

There also are some major shifts in thinking behind the standard and that provides the agility that is so important for innovation. Risk is a significant introduction. The old standard implied risk, the new standard states it emphatically. What greater risk for an organization than to have a mature or declining offering? Enter the innovator!

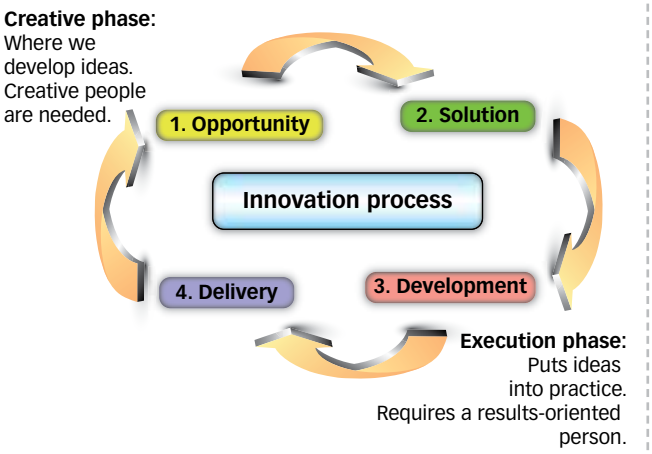
Documentation of mandatory procedures has been eliminated, and the standard has shifted to ensure that processes and hence the system is in control. Some people say this means no quality manual is required. If you can find a better tool against which to evaluate the effectiveness of your QMS, then you can do so.

Innovation in ISO 9001

To refresh your memory, Figure 1 shows the steps of the innovation process.

Getting into specific clauses of the new standard, the first requirements appear in *Section 4—Context of the organization*. Context is about the internal and external factors that affect the organization—and of course for the innovator, that means external change. External change is the driver for innovation. In *Clause 4.2—Needs and expectations of interested parties*, this is where the innovator will address future needs. This is how you maintain future direction. This leads into *Clause 4.3—Scope*, which should include future offerings as well as today's offerings. *Clause 4.4—Processes* is where you

Innovation process / FIGURE 1



include your innovation process.

The quality management principles are in Annex B of the standard and *B3—Leadership* tasks organizations to set direction and objectives. One of your objectives should be innovation and your direction should be looking to the future. In *Section 5—Leadership*, clause 5.1 addresses strategic direction and *Clause 5.1.2—Customer focus* requires enhancement of customer satisfaction, and we, of course, address that by meeting unmet customer needs. This is reinforced in *Clause 5.2—Policy* by including future needs of your customer. *Clause 5.3—Responsibility* does not mention the title management representative, but it still requires someone to report on QMS performance. Clause 5.3 is where you will include your innovation champion.

Section 6—Planning is where risk is introduced and organizations are asked to plan it into the context of the organization to prevent future undesired effects. What is more undesired than to have no offering in the marketplace? Again, enter the innovator. Organizations are asked to address risk, and clearly, innovation is one of the primary activities for addressing future risk. In setting objectives (clause 6.2), the development of future offerings is a key objective. *Clause 6.3—Planning of change* means that, to quote Charles Darwin, "The species which will survive is that which responds to change."[4] An organization's change process must include the ability to respond to external change.

Section 7—Support shows *Clause 7.1.2—People* and *Clause 7.1.6—Knowledge* as high-value clauses for the innovator. Clause 7.1.2 draws in ISO 10018, which is explained more fully in Annex C of ISO 9001. *Clause 7.1.6—Organizational knowledge* (also see Annex A7) is the fuel of the innovation process and includes the phrase "access the necessary additional knowledge." This is a key element of your innovation process and especially addresses the creative steps.

Clause 7.2—Competence reminds users to know their innovation competencies. You can do this by going to www.petermerrill.com/self-assessment to identify your competence inventory. Then you need to fill the competence gaps.

Section 8—Operations is quite similar in structure to its predecessor, section 7 of ISO 9001:2008, but there are improvements in flow. *Clause 8.2—Determination of requirements* is improved with customer communication coming first in clause 8.2.1. There will be customer needs that do not become agreed requirements in *Clause 8.2.3—Review of requirements*. You should understand that if you identify a need in clause 8.2 that you cannot meet due to your own lack of capability, that is an innovation trigger. In this clause, the standard also asks us to obtain customer views and perceptions—another trigger for innovation.

Clause 8.3—Design and development has improved a lot with much better flow. However, work is still needed on clause 8.3.1, which addresses the applicability of design. The flow is now *Clause 8.3.2—Planning*, *Clause 8.3.3—Input*, *Clause 8.3.4—Control* and *Clause 8.3.5—Output*, which makes far more sense.

Clause 8.4 used to be purchasing and is now about "external providers," and for the innovator, this is one of the highest risk areas. A new offering means a new supplier or subcontractor. Clause 8.4.2 addresses control of these providers, and there are important words that say "outsourced processes are within the scope of the QMS," so risk must be managed here.

Clause 8.5 is about delivery, and this is often where innovators stumble. This is where you include your piloting process and clause 8.5.1 addresses validation of processes for your new offering. Don't overlook *Clause 8.5.5—Post delivery*, where you evaluate issues with the user that you may have missed.

Finally, section 8 of the old standard is split into *Section 9—Performance Evaluation* and *Section 10—Improvement*. *Clause 9.1—Monitoring and measurement* must include measurement of innovation, and I have written about this previously in QP.[5] Clause 9.1 includes customer satisfaction measurement, which is often done poorly by a lot of organizations. The standard asks you to find views and opinions, as stated in clause 8.2. Don't ask questions like: "Are you satisfied?" Instead, find opportunities by asking: "Where do you waste time?" or "Where do you have difficulty?"

Clause 9.1.3 tells you whether needs have been met and points to those future opportunities. *Clause 9.2—Internal audit* also will point you to internal process opportunities for innovation. *Clause 9.3—Management review* says to not just look at history, but look to the future and address changes. Clause 9.3.2 says to identify innovation opportunities.

Section 10—Improvement importantly points to the fact that improvement can be achieved through creativity and innovation.

I have sprinted the ISO 9001 marathon in this column, but my aim was to outline how you can embed innovation into your QMS as you transition to the revised standard. You can do this by creating an agile QMS, which is what the revised standard is calling for. QP

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BY DILIP SHAH

Measuring Proficiency

Evaluating laboratory measurement performance

PROFICIENCY TESTING (PT) is defined as the "evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons" by the ISO/IEC 17043 standard.

PT is often misunderstood when laboratories seeking initial ISO/IEC 17025 accreditation hear about it. Many think that its purpose is to test their employees' skills. While proficiency is indirectly a result of the employees' skills, training and other factors, PT assesses an individual laboratory's measurement performance against the industry measurement performance. It identifies areas for improvement in measurement and techniques. It may identify best practices by comparing other laboratories in the same field of calibration or testing.

For the customers of laboratory services, PT:

1. Establishes confidence and is a demonstration of accreditation.
2. Helps the customer decide whether the laboratory meets its measurement, calibration and testing requirements.
3. Acts as a measure for ensuring that the laboratory will continuously and consistently meet its quality requirements.

Continued, planned participation in PT is also a requirement by accrediting bodies for a laboratory to maintain accreditation. An example is clause 5.9.1(b) of ISO 17025, which requires laboratories to participate in PT or interlaboratory comparison schemes. There are many different PT schemes that a laboratory can participate in to assure the quality of its calibration and tests. One of the schemes for participation is outlined in Figure 1.

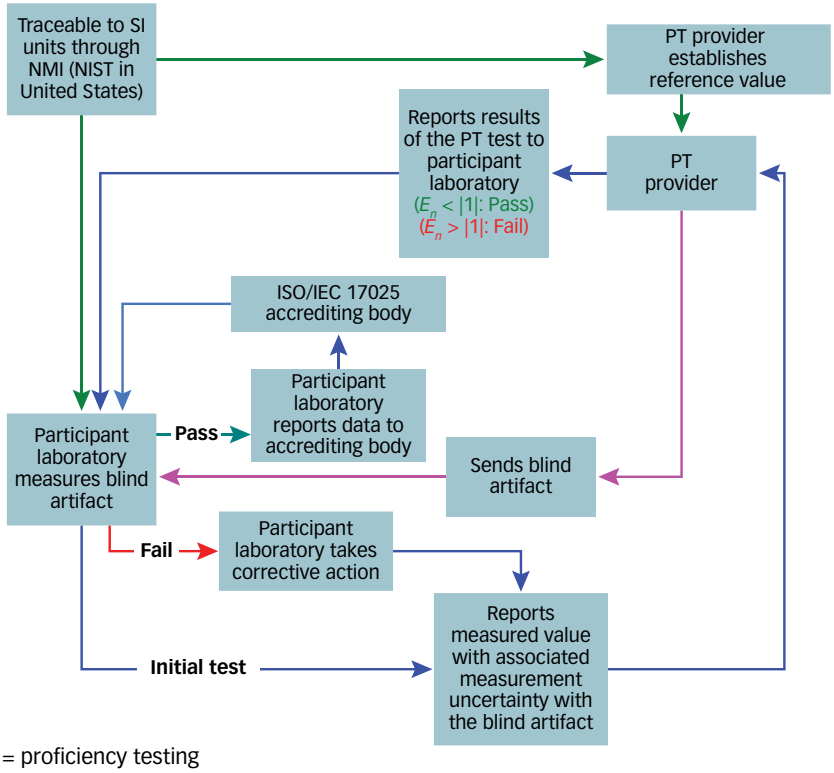
Acceptance of PT data is based on several factors. Statistical tests are one method to determine compliance and to form the basis for things such as data outliers. ISO/IEC 17043 Appendix B provides a limited discussion on statistical methods. It is important that a PT provider has a good statistical support base to ensure that the correct, unbiased assumption about data is made and reported.

At a minimum, the following statistical parameters should be considered when determining whether PT data are acceptable:

- Mean.
- Standard deviation.
- Range (range can be a good estimator of variability).
- Statistical significance using z, t or F tests.
- Measurement uncertainty.

The laboratory is asked to report its measurement result and the associated measurement uncertainty when participating in a commercial PT program. The PT provider issues a report with a calculated E_n number, which is based on

PT scheme example / FIGURE 1



PT = proficiency testing
NMI = National Metrology Institute
SI = known in English as the International System of Units
NIST = National Institute of Standards and Technology

Laboratories should ensure their measurement **processes are in statistical control** before participating in the proficiency testing program.

Laboratories should ensure their measurement processes are in statistical control before participating in the PT program. Using Shewhart X-bar and R control charts in the laboratory calibration and maintenance program is one way to do this in a preventive manner. Process control should cover operator training, controlled procedures and measuring equipment repeatability and reproducibility studies.

These are good laboratory practices that not only help affirm the PT measurement results, but ensure confidence when reporting results for the customer or if there is doubt on any measurement reported.

From the PT provider's perspective, it is critical that the confidentiality of the laboratories be maintained when the PT data are reported publicly. The PT provider also should ensure and maintain neutrality and report data in an unbiased manner.

A reputable and technically knowledgeable PT provider will engage the laboratories on their reported measurement results to understand their technique and provide feedback in improving the technique for future participation without influencing the results in any way. QP

the following formula and criteria for acceptance:

$$E_n = \frac{x - X}{\sqrt{U^2_{LAB} + U^2_{ref}}}$$

$|E_n| \leq 1 = Satisfactory$

$|E_n| > 1 = Unsatisfactory$

in which x is the participant laboratory's measured result; X is the assigned value by a reference laboratory; U^2_{LAB} is the uncertainty of the participant's result (k = 2); and U^2_{ref} is the uncertainty of the reference laboratory's assigned value (k = 2).

Development of measurement uncertainty budgets and measurement uncertainty analysis of the measurement process is another important consideration when reporting the measurement data for PT.

Many laboratories fail the PT test participation (E_n value >1) because they may have made an error in calculating measurement uncertainty when they report the measurement results to their PT providers. These are some of the common errors that a participating laboratory may make when reporting the measurement uncertainty (U^2_{LAB} in the E_n equation):

- The specification of the blind artifact that the laboratory is measuring is taken into account.
- The uncertainty units are not in the same unit as that of the artifact value measured (such as reported in percentage, parts per million or milligrams instead of grams).
- The laboratory forgets to convert all uncertainty contributors to one standard deviation before combining with the root sum square method.
- The laboratory reports the measurement uncertainty that is in the laboratory's scope of accreditation (the calibration and measurement capability, or CMC value) and does not take into account the uncertainty contribution of the blind artifact.
- The laboratory forgets to report the measurement uncertainty at 95% confidence interval (usually k = 2, but may vary depending on the effective degrees of freedom and referencing the student's t-distribution).
- A single measurement is made and reported instead of making at least 10 measurements and reporting an average (and the associated repeatability standard deviation).
- The laboratory excludes the repeatability standard deviation in the uncertainty estimation (if a single measurement is made, it will not be possible to report it).

MORE MEASUREMENT ADVICE

Learn more about metrology by reading additional Measure for Measure columns by Dilip Shah and other experts. Visit www.qualityprogress.com under the Departments and Columns tab.

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 BY LANCE COLEMAN

Road Warrior

Why conferences are your secret career weapon

SINCE RETURNING to the quality field in 2010 after a more than 10-year hiatus, attending ASQ conferences and volunteering have become a huge part of my professional growth.

I remember with a smile (or grimace) the first ASQ conference I attended—the Lean and Six Sigma Conference (LSSC) in Phoenix in 2010, which is typically held in late February or early March. At the time, I was new to my employer and though local, I was without a car. To attend, I took vacation time, volunteered so that I wouldn't have to pay the full conference registration and rode the bus two hours each way on both days of the conference. Despite the inconvenience and spent vacation time, it was more than worth it.

During these past four years, I have been able to attend three LSSCs, three Audit Division Conferences, two World Conferences on Quality and Improvement (WCQI), and one Division and Section Affairs Council meeting. The learning and networking opportunities I have experienced have proven invaluable. I partly attribute my two promotions, a substantial salary increase, plus the opportunity for international travel (*Parlez-vous Français*, anyone?) in support of our corporate audit program to my conference attendance.

Some of the benefits I have received from participating in ASQ conferences, whether by attending, volunteering or presenting, include:

- **Skills development:** Acquiring new knowledge or enhancing existing skills by attending sessions and workshops. You also may learn how others successfully addressed similar problems in your workplace.
- **Industry knowledge:** Learning current best practices, trends and news that could affect your job, organization or industry.
- **Résumé building:** Being selected to present at a national or international conference is no small feat. It is a validation of your expertise and your experience, and it looks impressive on your résumé.
- **Giving back:** Conducting a session or a workshop is a great way to share success stories, to give back to your industry and get feedback from peers.
- **Networking:** Networking opportunities abound at conferences. You don't have to be a job seeker to benefit from networking. A contact I made at an ASQ conference resulted in an eventual business trip to South Africa (If you ever see me on the road, ask me about that one—it's a cool story).
- **Mentoring:** Can you think of a better place to find a mentor than at a conference? Most conference-goers are friendly and open to sharing their knowledge and experience.
- **Certification exams:** Attending an ASQ conference also comes with the convenient perk of preconference certification exams. This means you don't have to wait for the two worldwide exam sessions offered each year.
- **Sightseeing:** Although the focus of conferences should be professional development, add a couple of vacation days to the end your trip if you can and tour the city. ASQ picks conference locations in exciting cities with interesting venues. Conferences have brought me to Las Vegas, Reno, NV, Indianapolis (a surprisingly happening city), Phoenix, Tucson, AZ, Dallas and Augusta, GA. If ASQ ever offers an international conference, I suppose I will dust off my passport and head there, too.

COLEMAN (LEFT) met Noriaki Kano at the 2014 World Conference on Quality and Improvement.

Another benefit is that you never know who you'll meet at a conference. During the 2014 WCQI in Dallas, I gave a presentation based on my upcoming book, *The Customer Driven Organization: Using the Kano Model* (Productivity Press, November 2014). I was shocked and amazed to learn that Noriaki Kano himself was in the audience. I was panic stricken and

thrilled when he stood up to comment afterward. Fortunately, his comments were positive, and he graciously posed for a photo with me. How awesome is that? Only at WCQI could this have happened.

I also met many good friends at conferences or through volunteering with ASQ. They provide mentoring, collaboration, encouragement and many fond memories. Hopefully, I have done the same for them.

Make your case

My workplace encourages professional growth through college courses, training, seminars and conferences. But I acknowledge that budgets are tight and that appropriate justification for conference attendance must be presented to management. Here are a few approaches I have used to craft my own business travel proposals at the start of each year:

- Draft a formal proposal showing benefits to the organization. Identify sessions with information that could be applied upon your return and positively affect your day-to-day responsibilities. Identify sessions with information that would better enable you to support organizational goals and objectives.
- Send the program to respected peers and key management personnel to determine if there are sessions or workshops they recommend for your professional growth or to benefit the organization.
- Mitigate costs through volunteering. Volunteers are the face of the conference and typically moderate sessions or host the information booths scattered throughout the conference venue. Often, volunteering comes with reduced or free conference registration. Volunteer duties usually take two to four hours each day, and the rest of the time is yours to learn and network.
- Mitigate costs by staying at an off-site hotel and using the meals provided at the conference as your primary meal sources each day.
- Provide a key takeaways report and email relevant session slide decks from the conference to interested managers.
- Be available to handle urgent inquiries or check in at the end of each day while you're gone.

Occasionally, conference requests are denied. In those instances, I thank my boss for considering my proposal and inquire about his or her reason for refusing my request. Sometimes, I am able to address the concerns and sway the decision (for example, by taking additional cost-cutting measures if budget is a concern). The reasons also help me refine my next proposal. In either case, it is important to keep the door open for future professional development opportunities.

Attendee A-game

The rules of engagement are simple: Be friendly, be professional and be prepared. Remember that no one likes a braggart, a lush, a leech or a lech. Other tips that I have picked up for attending conferences include:

- Ask other attendees for recommendations on speakers or sessions to attend.
- Attend sessions and take good notes. Remember, you're there on business.
- Be open-minded as to which sessions you attend. I have been pleasantly surprised by taking a few chances on sessions that didn't seem relevant to my industry or direct job responsibilities. You never know which session or workshop will give you that light bulb moment.
- Attend networking sessions and other social activities. Not only are these opportunities informative, but they also are often fun.
- Don't be pushy, or reversely, too timid about being the first person to offer to exchange business cards. It's better to bring more business cards than you need so you don't find yourself without one to give when that once-in-a-lifetime contact or opportunity occurs.

No one likes **a braggart, a lush, a leech or a lech.**

When I turned 50 a couple of years ago, I started thinking more about professional legacy and giving back to a profession that has done so much for me. Participating in conferences—whether as a volunteer, presenter or simply as an engaged attendee—allows me to do that.

So, what's next for me? Three of my favorite conferences have anniversaries coming up in the next few years: LSSC (15th), WCQI (70th) and ASQ's Audit Division (25th). I hope to be there learning, networking and making new friends. What would make my time better yet would be seeing you there, too. QP

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BY CONNIE M. BORROR

The Folly of Youth

Ask the right questions up front and along the way during data analysis

WHEN I BEGAN analyzing data for various companies and researchers a long time ago, I learned an extremely valuable lesson: When given data, be sure to ask lots of questions about it before any analysis. This may seem completely obvious to readers of this column; however, I wanted to share a scenario with you based on what happened to me.

Working with two researchers, I was given a set of data similar to the following: 5.0, 4.0, 6.0, 3.0, 4.0, 6.0, 8.0, 8.0, 7.0 and 7.0.

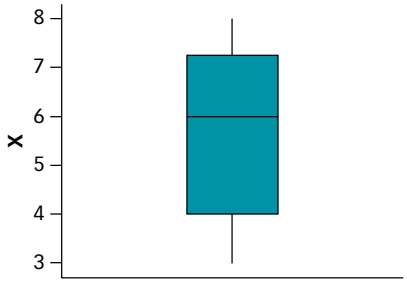
Not much data to work with, but I suppose it was what they had. The first thing I thought to do was graph the data using a histogram (Figure 1). Obviously, this was not helpful, given the data set was so small. Next, a dot plot (Figure 2) and a box plot (Figure 3) were constructed. Not so useful again, but I thought, "Well, that's about the best I can do with such a small set of data." Then some summary statistics were calculated, and a 95% confidence interval on the mean was produced (Table 1).

After I had gathered basic information, I summarized my findings in a simple short report. Being quite proud of myself, I presented the results to the researchers, thinking they would be enamored with my initial report. I could not have been more wrong. The researchers informed me the results made no sense.

As it turns out, the data given were number of outcomes, not actual measurements of an item (such as length, height and width), which is how I had treated the data. In looking at the original data again, I finally took note of the fact the decimal values were all zero. The data was really 5, 4, 6, 3, 4, 6, 8, 8, 7 and 7.

It was determined the computer package automatically reported data values with "0.0" as the convention. My thought was that some of the information in the report—such as the graphs and some summary statistics—still would be useful. I would soon realize, however, I was again incorrect.

Box plot of sample data / FIGURE 3

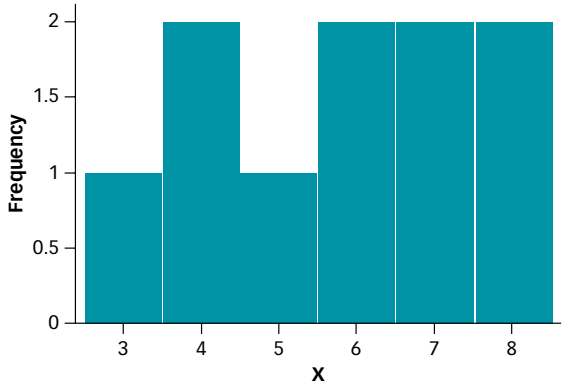


Off the mark

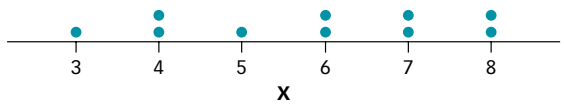
The count data given were the number of prescription errors during a 10-day period in which there were five errors on day one, four errors on day two and so on. Based on that information, looking at the raw data, it appeared as though there was an increasing trend in the number of errors over this time period. A simple time series plot of the raw data revealed the same trend (Figure 4).

As you're probably thinking, this interpretation is incorrect as well because the total number of prescriptions filled each of the 10 days varied. The correct results to analyze and interpret involve propor-

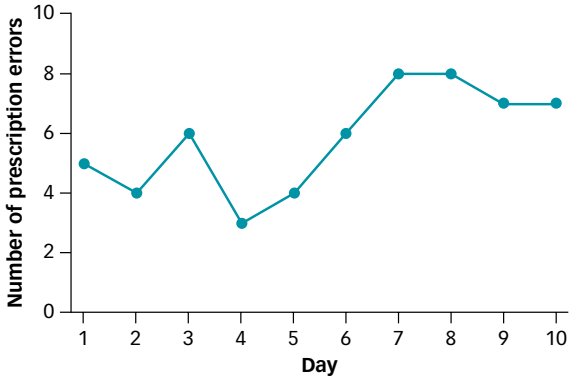
Histogram of sample data / FIGURE 1



Dot plot of sample data / FIGURE 2



Time series chart of number of prescription errors by day / FIGURE 4



tions (Table 2). Figure 5 shows proportions during the 10-day period. From this display, you see an upward trend is nonexistent. If the same number of prescriptions had been filled on each of the 10 days, Figure 4 showing the number of errors would be correct and useful, although the proportion of prescription errors may be of interest and is more often reported than the number of errors.

At this point, it seemed obvious what should have been known or communicated in the first place:

- What is the goal of this project?
- What do these data truly represent?
- Who collected the data?
- What was the operational definition of an error for a prescription?
- Was one created and used by all who collected the data?
- Were all parties involved trained using this definition?

I wanted an additional question answered: Why are the data recorded in a way to indicate the values might be continuous (that is, first looking at the data, it appears that a value of 8.2, for example, may be a possibility)?

Continuing with the analysis of the original data with the new information obtained, it would be nice to say that you have all the information you need to prepare an accurate summary report on the data at this time. You now know the data represent the number of prescription errors out of the total number of prescriptions filled. There are still some questions, however, that should be asked:

- Could a single prescription have more than one possible error?
- If so, does the number of errors represent different prescriptions in error or the total number of errors seen over all prescriptions processed that day?

For example, on day one, five errors were recorded on 320 prescriptions filled that day. Does this mean that five different prescriptions out of 320 were categorized as "error"? Or, were there only three prescriptions with errors out of 320? That is, the first prescription contained three errors, a second prescription contained one error and a third prescription contained one error—for a total of five errors? These two situations are quite different and would require different analysis. An operational definition of a prescription error would eliminate this confusion.

The scenario described still happens today at varying degrees. With better training in our universities and on the job, it is unlikely someone working on a project will run away with the data to begin analysis without understanding what the data represent or the goal of the project—like I did.

But asking the right questions up front and along the way is not just helpful, it's essential for success. QP

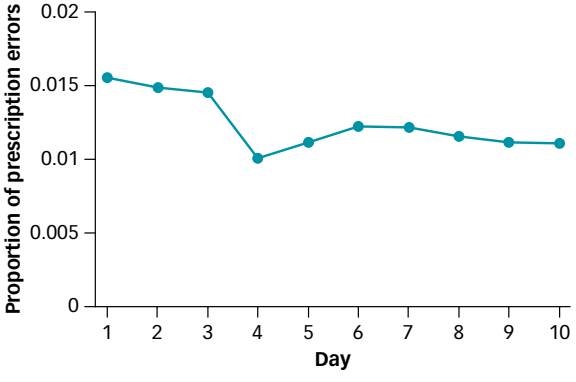
Summary information of sample data / TABLE 1

Mean	Median	Standard deviation	Minimum value	Maximum value	95% two-sided confidence interval on μ
5.8	6.0	1.751	3	8	(4.547, 7.053)

Sample data and summary information for number of prescription errors / TABLE 2

Day	Number of errors	Number of prescriptions	Proportion of prescription errors
1	5	320	0.0156
2	4	268	0.0149
3	6	412	0.0146
4	3	298	0.0101
5	4	356	0.0112
6	6	487	0.0123
7	8	658	0.0122
8	8	687	0.0116
9	7	624	0.0112
10	7	631	0.0111

Time series chart of proportion of prescription errors by day / FIGURE 5



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Missing in Action

New standards beg question, 'Where have all the documents gone?'

THERE WAS a hit song in the 1960s titled "Where Have All the Flowers Gone?"[1] Originally written in 1955 by Pete Seeger and Joe Hickerson, the song was a catchy tune sung around campfires at summer camp and also became a political ballad.

Many of those reviewing the current draft of the revisions to *ISO 9001—Quality management systems—Requirements*, and *ISO 14001—Environmental management systems—Requirement*s, are asking, "Where have all the documents gone?"

This question has been prompted by the fact that the words "document," "procedure" and "record" have all but disappeared from the draft international standard (DIS) for ISO 9001 and ISO 14001.

Does this mean documented procedures and records are no longer required?

Not exactly.

What has replaced those words is a new term—"documented information."

The use of this new term is one of many changes to International Organization for Standardization (ISO) management system standards (MSS) imposed by Annex SL, an addition to the ISO directives that mandates the use of a common high-level structure and terminology.

This new term is defined as "information required to be controlled and maintained by an organization and the medium on which it is contained."[2] It should be noted that the draft of the revised version of *ISO 9000—Quality management systems—Fundamentals and vocabulary* further defines the word "information" as "meaningful data" and "data" as "facts about an object," with an "object" being further defined as anything "perceivable or conceivable."

It is interesting to compare the definition of document that was included in the prior versions of ISO 14001 and ISO 9001 as "information and its supporting medium" to the definition of the new term being used in the DIS of both standards—"documented information."

What changed?

A new concept has been added. "Documented information" is now, by definition, limited to just the information that is "required to be controlled and maintained by an organization." As a result, other information, even if important, arguably is not documented information and, therefore, does not need to be controlled.

This raises the question of who determines what information is required to be maintained. Is it the organization? Is it the certifying body? Is it a regulator or other interested party?

Examples of the impact of this change in terminology in the draft standards include:

- Instead of requiring the organization to "ensure that its environmental policy is documented" in clause 4.2 of ISO 14001:2004, clause 5.2 of the ISO/DIS 14001:2015 states "the environmental policy shall be available as documented information."
- Currently, clause 4.2.1 of ISO 9001:2008 contains an explicit documentation requirement that includes the documents needed by the organization "to ensure the effective planning, operation and control of its processes." This has been replaced with, "The organization shall maintain documented information to the extent necessary to support the operation of processes and retain documented information to the extent necessary to have confidence that the processes are being carried out as planned," as stated in clause 4.4.

In both of these examples, the docu-

mentation requirements have become more ambiguous.

Similar changes have been made throughout ISO/DIS 9001:2015 and ISO/DIS 14001:2015. Requirements for procedures and records are gone, and requirements to maintain and retain documented information have been added.

To help organizations understand the new concepts and to make the transition to the new standards, an explanation is provided in an annex to ISO/DIS 14001:2015 that the phrase "maintain documented information" is intended to refer to documents, which include procedures, and the phrase "retain documented information" is intended to refer to records.

This means requirements for documented procedures and records are not truly gone. They are now stated as follows:

- Maintain documented information means having documented procedures.
- Retain documented information means keeping records.

In developing new documentation for their management systems and revising their existing documentation, organizations must be mindful of the impact of these changes.

Implementing the changes

So what does this mean for users of these standards?

First, rather than simply relying on the ISO standards to clearly and explicitly state what must be documented, organizations must make their own determination concerning what documented information is required. This may provide new flexibility to some organizations. They may be able to rely on other types of process controls in place of documentation, such as automated control systems.

Because the documentation requirements set out in the standards are more ambiguous, however, documentation determinations may need to be justified. Because different organizations may have different interpretations of what constitutes documented information, accreditation and certification bodies may find it more difficult to maintain consistency in their interpretation of the ISO 9001 and ISO 14001 requirements. Certification bodies may end up developing their own policies regarding the need for management system documentation.

Second, organizations will still be required to determine whether information needs to be maintained or retained; that is, whether it must be controlled as a document or record. Although explicit provisions for document control and record control have been eliminated from ISO/DIS 9001:2015 and ISO/DIS 14001:2015, the requirements previously associated with these clauses simply have been lumped together in a new *Clause 7.5.3—Control of documented information.*

It will now be up to organizations to determine which of the subclauses in clause 7.5.3 apply to what documented information and which do not.

Finally, to the extent organizations increasingly rely on computerized data rather than paper documentation, additional requirements for process validation, data integrity, confidentiality and information availability must be addressed. Satisfying these requirements will present new and often complex challenges for many organizations.

So, the documentation requirements of the ISO standards have not gone away—they have become more difficult to assess.

Long time passing

Those familiar with the lyrics of the song "Where Have All the Flowers Gone?" are aware that the answer to this question in the song is, "Long time passing."

There are those who view the elimination of explicit documentation requirements from ISO standards as a good thing—a move to update the ISO standards to make them modern. In their view, leaving the determination of which information must be maintained as documented information undefined is an improvement.

They envision a world in which information is primarily electronic data, and process control is increasingly dominated by automated computer systems; a world where the line between a process and a procedure is blurred, and the distinction between data and records is nonexistent. No more procedures in three-ring notebooks. No more paper records in filing cabinets.

Others are not so sure. They mourn the loss of clarity and certainty associated with explicit requirements in the ISO standards for documented procedures and records. They are uncertain that leaving it to organizations to determine what must be documented and recorded, and what does not, is an improvement.

They are concerned about a world in which information has no physicality and computers are in control of processes. They are concerned that just as computers can retain vast amounts of data, the same data can be deleted with a few keystrokes. They value the permanence of paper.

Only time will tell which view is right. QP

REFERENCES

1. Peter Seeger and Joe Hickerson, "Where Have All the Flowers Gone?" 1955.
2. International Organization for Standardization and International Electrotechnical Commission, ISO/IEC Directives, Part 1, Annex SL.

THEA DUNMIRE is the president of ENLAR Compliance Services, where she specializes in helping organizations implement management systems. She has participated internationally in the development of multiple International Organization for Standardization (ISO) standards. She is currently the chair of the ANSI Z1 auditing subcommittee, which focuses on alignment of auditing requirements across the ISO management system standards. Dunmire has a law degree from Syracuse University in New York.

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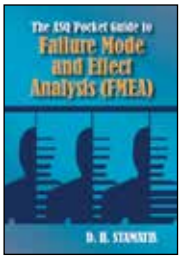

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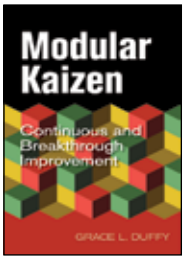

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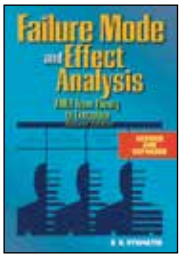

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Internal fan alternator ►

Prestolite Electric has unveiled the AVi2800 internal fan alternator for heavy truck and school bus fleet aftermarket requirements. The AVi2800 features a fan design that offers 33% less weight than any of its antecedents. This internal fan alternator also is offered with an expanded temperature rating to +125°C.

The AVi2800 includes an additional 30 amps, allowing it to provide more power at idle. Units are also remote sensing capable, ground isolated and e-coated for enhanced protection from corrosion, humidity and moisture.

The Prestolite AVi2800 internal fan alternator is ideal for high-performance aftermarket retrofit upgrades, particularly within heavy trucks or in applications

where weight reduction, higher temperature and higher power are target goals.

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Acoustic-level interface ▲

FloLevel Technologies has released a self-cleaning acoustic-level interface transmitter for Flotation Cells. This technology measures most liquid and slurry solutions—where an interface of up to two densities exists—that need to be monitored continuously.

The level interface transmitter tracks liquid-to-liquid interface, liquid-to-paste interface and liquid-to-granular interface. The pulse amplitude is great enough to cause a phenomenon called rarefaction, which causes cavitation to be produced from the array transducer diaphragms as they pulse. The cavitation bubbles oscillate in front of the diaphragm, which cause implosions that generate high energy levels.

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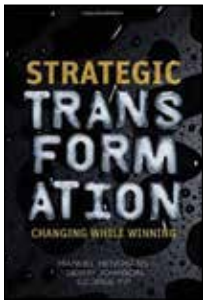
QP REVIEWS

Strategic Transformation: Changing While Winning

Manuel Hensmans, Gerry Johnson and George Yip, Palgrave McMillan, 2013, 256 pp., $36 (book).



The authors of this book are senior European professors with considerable experience in the business world and are previous bestselling authors. They combined their talents, conducted research and focused on the pattern of a hero company that turns into a zero company. Why did a successful company that is doing well not see the change coming until it was "too late." To use their words "their picture of what is happening diverges from real events."

The book is divided into three parts. Part one discusses change and identifying long-term high performers. Part two recognizes and analyzes three successful companies. This portion of the book also looks at three competitors that were not successful. Part two contains a lot of data.

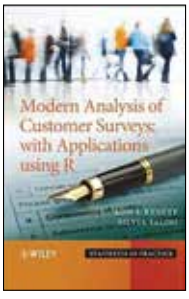
In part three, they list their view of four traditions of successful transformation: continuity, anticipation, contestation and mobility, and discuss them in detail. The last chapter provides a plan for long-term success. The authors found that as the companies matured, they tended to move away from a dominant bureaucratic leader toward coalitions of managers that banded together to get things done with alternate solutions. They found a key element to long-term success was this constructive dissent.

The book also features a large notes section that informally discusses important points and the background in each chapter. It should be read by high-level corporate executives, members of management coalitions and boards of directors that can actually change the strategic direction of currently successful companies. This book offers an abundance of helpful tips.

Bill Baker
Speed to Excellence
Santa Fe, NM

Modern Analysis of Customer Surveys: With Applications Using R

Ron Kennett and Silvia Salini, Wiley, 2012, 524 pp., $114 (book).



This book seeks to present basic and advanced methods for analyzing customer survey data. The book consists of 21 chapters and can be divided in two parts. The first nine chapters cover the basics of customer survey analysis, including sampling, surveys, measurement scales, missing data and ordinal data analysis. The last chapters cover new and advanced methods of analyzing surveys. These include Bayesian networks, fuzzy methods, principal components and decision trees.

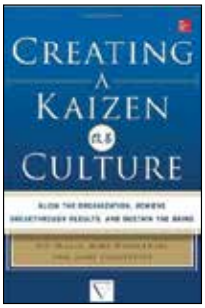
The book's scope is quite comprehensive and each chapter provides a good overview of the many topics included in the book. It was especially interesting to see topics from psychrometrics and statistical process control applied to survey analysis. The book is not meant for those who are new to the field of survey sampling or those who lack a sufficient background in statistics.

The book does include an introduction to R in the appendix. The R code for methods presented in chapters 11-21 are included on a separate website provided by Wiley. However, the number of examples given is limited and someone new to R would have difficult time learning from the book. Overall, the book would be useful for survey specialists and market researchers already familiar with R and looking for different methods of analyzing survey data.

Brian Cocolicchio
New City, NY

Creating a *Kaizen* Culture: Align the Organization, Achieve Breakthrough Results, and Sustain the Gains

Jon Miller, Mike Wroblewski and Jaime Villafuerte, McGraw-Hill Professional, 2013, 272 pp., $40 (book).



There is a significant amount of literature related to different improvement programs focused on tangible aspects while neglecting the importance of organizational culture. Too few managers recognize the importance of addressing culture. This book focuses on the links among culture, *kaizen* core beliefs and various methods and tools that can be observed in organizations practicing *kaizen*.

Kaizen is not change for the sake of change, or even just change for the sake of improving business—it is change to de-

velop people. The goal is to develop people and help them think differently about the processes they work in. It is not about making things better, but instead making better people.

A core belief of *kaizen* is the importance of checking process and results. With a *kaizen* culture, changes are conducted as experiments, as hypotheses to be tested, rather than opinions to be defended. The transformation to a *kaizen* culture requires that we use scientific methods not as a tool, but as a way of thinking.

This book focuses on long-term adaptability. It is well-structured and easy to read, without jargon. Many real-world examples contribute to the convincing presentation. Its aim to highlight managers' role and that organizational communication is unique. Even rhetoric is briefly addressed. The book should be read by anyone interested in organizational change and by any manager eager to support the organization's survival.

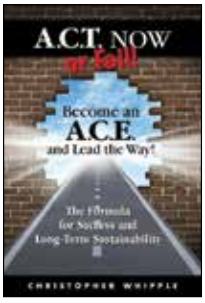
Bengt Klefsjö
Luleå University of Technology
Sweden

A.C.T. Now or Fail! Become an A.C.E. and Lead the Way!

Christopher Whipple, Advanced Corporate Teams, 2013, 366 pp., $45 (book).

Whipple's book builds on the work by quality gurus and other quality professionals. The author's established definition for quality makes it very clear that improving quality needs to account for an individual's perception of all characteristics associated with a product or service and the price paid. A business that strives to increase value and decrease cost will be able to sustain sales growth with competitive advantages in the marketplace over their competitors.

Whipple uses Advanced Corporate Training (A.C.T.)/Teams and Advanced Corporate Executives (A.C.E.) to illustrate his process. A variation on the pyramid is a new and better pictorial for the collaboration required for effective implementation. The pyramid on its side displays collaboration across all functions dealing with supply and information flow for internal and external customers.



His findings show great leaders motivate their followers, which enables the business to achieve long-term sustainability. The economic climate is always changing. It is important to develop strong leaders. Today's leaders must communicate confidence to the market and strength to competitors. Strong leaders make the difference between success and failure. They know the capabilities required to be successful.

The quality profession has evolved over time to its present state. Whipple's book presents the next evolutionary steps. People are important and training, communication and collaboration will be required to achieve goals of a successful sustainable business. All business professionals should read this book.

John J. Lanczycki, Jr.
Creative Planners
West Springfield, MA

RECENT RELEASES

The Certified HACCP Auditor Handbook

ASQ Food, Drug and Cosmetics Division, John G. Surak and Steven Wilson, eds., ASQ Quality Press, 2014, 312 pp., $80 member, $115 list (book).

Global Supply Chains: Evaluating Regions on an Epic Framework

Mandyam M. Srinivasan, Theodore P. Stank, Philippe-Pierre Doriner and Kenneth J. Petersen, McGraw-Hill Professional, 2013, 448 pp., $70 list (book).

Taoism and Statistics

Reach greater heights of statistical thinking

TAOISM IS A philosophical, ethical and religious tradition that emphasizes living in harmony with the Tao, a Chinese concept for the way, path or route. When you understand the Tao of building statistical formulas, your ability to develop meaningful performance measures is enhanced.

Statistics has two branches: The first describes objects (descriptive statistics) and the second predicts outcomes (inferential statistics). The second can be described as the study of variation. Minimizing variation improves the accuracy and precision of predictions. There is a simple pattern to the study of variation that, if it were taught, would ease the pain and suffering of new quality practitioners.

Many statistical formulas relating to the study of statistical variation are based on a simple premise:

$$\frac{\text{actual data} - \text{expected data}}{\text{existing variation}}.$$

For example, a t distribution has the following equation: $x - \mu / s$, where x is our data point of interest, μ is our population mean and s is our standard deviation. In this equation, we are interested in the probability of our data point being the true population mean. So, we compare the actual value (x) to what we perceive the population mean (μ) to be. We can compare the difference to the variation (s) that exists. All formulas relating to hypothesis testing and building confidence intervals are built this way.

The study of variation becomes more complicated when we discuss the relationship between two or more things. The primary tool to study this relationship is analysis of variance (ANOVA). Though the formulas are more complicated, they are based on the basic premise of:

$$\frac{\text{actual data} - \text{expected data}}{\text{existing variation}}.$$

In ANOVA, the numerator is best described as explained variation and the denominator as unexplained variation. Hypothesis testing compares differences between groups as they relate to the differences in the entire data set, otherwise known as among groups. When there are differences between groups, that difference is usually much greater than the variation within the data set.

For most new quality practitioners, their first exposure to variation is through the terms common cause and special cause variation. Common cause variation is the expected variation inherent in any process. Special cause variation is usually dramatic and can be attributed to one or more root causes. We can tie these two types of variation to statistics with the following relationship:

$$\frac{\text{actual data} - \text{expected data}}{\text{existing variation} = \text{actual variation}}$$

$$\frac{\text{expected variation} = \text{total variation}}{\text{common cause variation}}.$$

Process capability is based on the same statistical relationship. The basic equation for process capability is:

$$\frac{\text{upper specification limit} - \text{lower specification limit}}{6\sigma}.$$

Process capability

When stable, a process should perform between the upper and lower specification limits, which represent the amount of variation that the customer expects or allows from the process. Sigma (σ) is the variation found in the population of things being produced by the process. Generally, quality professionals aim to minimize process variation (6σ) so that products and services are within specification limits and meet customer requirements. We can restate process capability as:

$$\frac{\text{allowed variation}}{\text{common cause variation}}.$$

As quality practitioners become more experienced, they are often asked to develop performance measures for their processes. Developing performance measures is a difficult task. It becomes easier after you understand how the smart people before you developed the formulas we use today. Understanding the Tao advances you on the road to thinking statistically. QP

SCOTT A. RUTHERFORD is the director of the U.S. Navy Mid-Atlantic Regional Calibration Center in Norfolk, VA. Rutherford holds a master's degree in operations research from the University of Delaware in Newark. A senior member of ASQ, Rutherford is past chair of the ASQ Hampton Roads Section in Virginia and has been an ASQ-certified Six Sigma Black Belt. He also blogs as part of the ASQ Influential Voices program.

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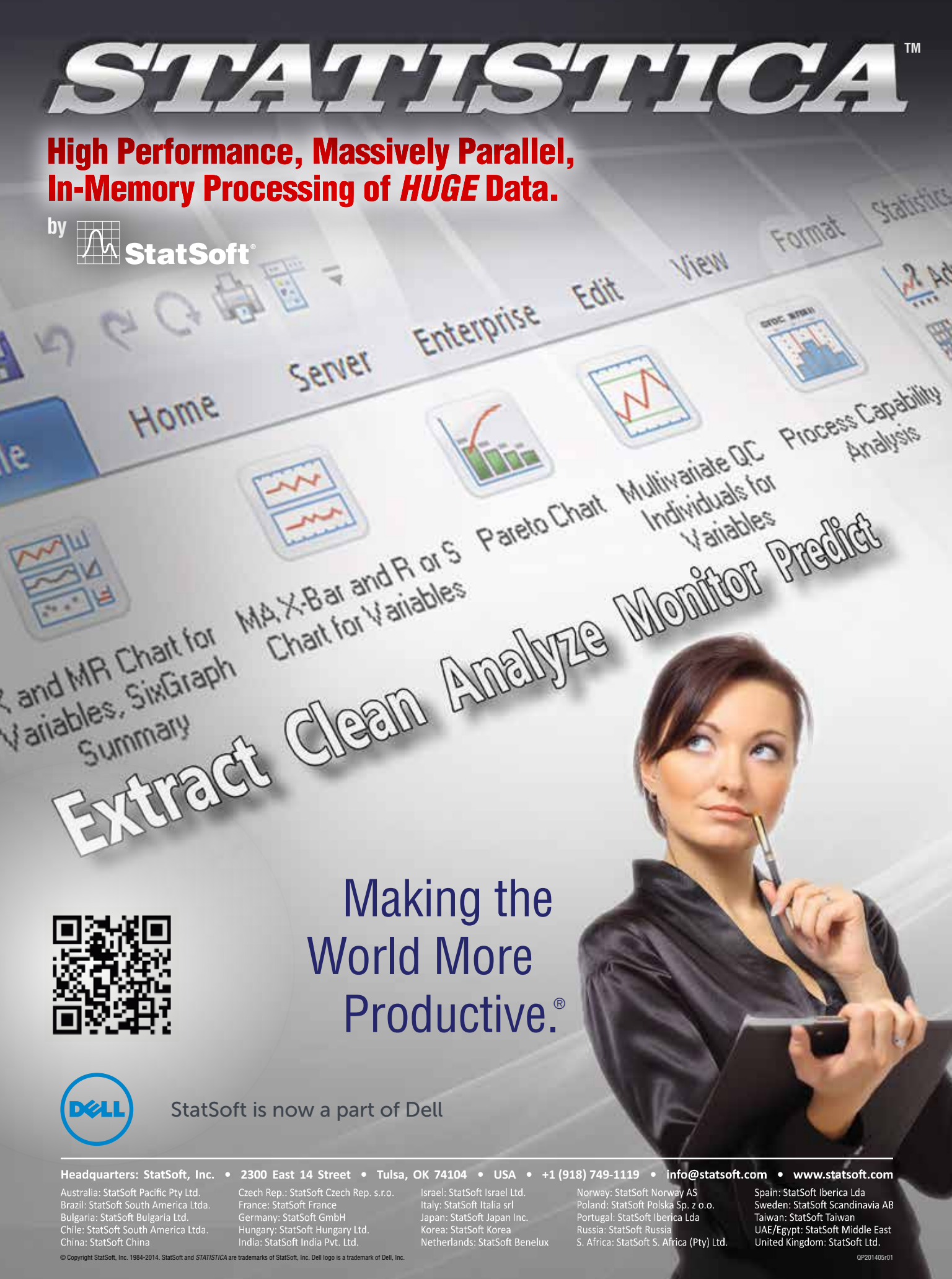

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