

CHAIR'S CORNER

Steven S Prevette
Fluor Hanford

We had a great visit and tour to the Kestrel winery this month. Fourteen members and guests attended. Kestrel is considered a medium sized operation, as compared to the huge operation at Columbia Crest, which we toured a while back. After the tour, we tasted four wines, with each paired with a cheese chosen to match the wine. A good time was had by all who attended, and several of us purchased wine to take home.



Finances. We finished the financial audit for last year (which ran June 2006 to June 2007). We started with a balance of \$7531.85, and ended with a balance of \$10,198.01. We currently hold \$5462.28 in a CD, the remainder in the checking account.

Primary sources of income were:

\$1,638 from ASQ national (your dues to the Section)
\$2,458 profit from the Two Day Statistics Workshop in March

Primary expenditures were \$734 towards dinner meetings (costs exceeded the member fees)

A copy of the complete financial report is available to any member upon request (drop Howard Rew or I an email). We basically broke even, with the profit from the workshop raising our balance. You may notice that the newsletter is not listed as an expense. With the shift to electronic publishing, the cost of the newsletter is minimal.

What to do with all this money? The Section has stopped deficit spending, largely due to better attendance at dinner meetings, and shifting the newsletter to an electronic format. We have another Two Day Statistics Workshop the end of October, with 10 people registered so far, so we should make another profit from that session. We've reached the goal I established five years ago – stop hemorrhaging money achieving financial stability. But – we are a not for profit organization. We should be using the money from the workshop for worthwhile projects for the Section. We did stop doing the scholarship a few years ago due to lack of interest on the part of students in the scholarship. What do you think we should do? Subsidize the dinner meetings more? Invite guest speakers from afar?

“Extreme Member Value”. Alvin Langstaff represented Section 614 at the “Extreme Member Value” meeting in Milwaukee WI last month. Representatives from ASQ Sections and Divisions met to help plan the future of ASQ. Alvin will discuss his experience in the newsletter and at the next dinner meeting.

Section Officers. It seems like the year has barely begun, but it is time to start working on nominations for next years' officers. I'd love to see some new folks get involved with the section as officers. I'm on my fifth year out of the last six as your Section Chair. It's been fun – and I'd love to share the fun. If you are interested in volunteering (self-nomination) or nominating another member, please contact any officer, or Dennis Arter (nominations chair).

See you at the next meeting.

- **Steve**

MAKE A SMALL FORTUNE!

by Ron Rosenberg

Normally, I spend my time on airplanes catching up on my reading, or working on projects that require minimal distraction.

I don't make a habit of talking to people during the flight - not because I'm anti-social, but because this is prime productivity time for me that I can't afford to squander. That, and trying to talk over the noise of twin jet engines is bad for my voice.

But for some reason, while we were still on the ground, waiting to push back from the gate, I ended up in a conversation with the woman sitting next to me. It turns out that she is the training director for a well known national restaurant chain. Since I just had three disappointing experiences in three different restaurants in the last week, I thought it might be interesting to get her take on it all.

We talked about the lack of small, independent, "mom and pop" restaurants in the area, and naturally, the conversation ended up at the conclusion that most small restaurant owners don't have the first clue about how to market their restaurants.

Then she shared what must be a standard "industry joke" in her field: "How do you make a small fortune in the restaurant business? Easy: Start out with a big fortune... and then wait six months."

And this is true in any business. If you don't understand your business, your competition, and your unique fit in the market, you're going to be out of business before you even know what hit you.

Ron Rosenberg, President of QualityTalk, Inc., helps people get more customers than they know what to do with, and keep them for life. QualityTalk, Inc., Raleigh, NC 27614, 919-488-9107.

VICE CHAIR'S CORNER

Jo Haberstock
Fluor Hanford
Vice Chair, ASQ Section 614

Happy Fall, Everyone! Soon it will be Halloween – have you decided who (or what) you are going to dress up like this year? Oh c'mon, have some fun with the holiday!!

For my column this month, I've decided to expand a little on something from Ron Rosenberg's article, as it got me

thinking about some of my recent experiences in restaurants and retail stores in this area.

Whenever I hear or read about a new eating establishment or retail store opening up in the local area, I start to wonder about both the quality of the products/food and of the service they will offer. I wonder if they will offer better or worse service than some of the stores I have shopped or places I have eaten in recently. I really do think about these things! Okay, I admit it - I guess I can be a bit of a fanatic when it comes to customer service.



Is it just me? Does it seem like it is getting harder and harder these days to get good customer service? And I'm just talking about getting good service, not exceptional, Tom Peters "WOW" service. I think it's kind of sad that I have to tell myself to try to lower my expectations a bit when I go to a new restaurant or store, so that I won't be too disappointed if the people working there don't exactly knock my socks off with their attitudes toward customers.

I really don't think my expectations are too much. I would like to be greeted when I go into an establishment and preferably by someone who smiles when she or he says "Welcome to XYZ!" Then an offer to help me would seem appropriate (even if I truly am just looking) – something like "Are you looking for something in particular?" or "How can I help you today?"

How hard is that? Aren't workers being paid (and hopefully, also getting at least a little training) to be nice to the customers who come in to their places of business?

Sometimes I wonder. In just the past couple of months, I have gone into several stores where I have found myself wandering around on my own for a long time trying to locate a specific item, without even one team member greeting me or asking if they can be of help. And if I take the initiative myself to go in search of assistance, some workers react as though I am bothering them. (Oh, so sorry for interrupting your discussion with a co-worker about your plans for after work tonight, and for thinking that maybe you could, um, treat me like someone who might actually want to buy something!) I have also had the displeasure of dealing with workers who clearly don't even want to be there – one that comes to mind did actually greet me nicely and offer to help me find something, but the whole time he was helping me he was complaining (to me, the customer!) about his manager and all the things that aren't being done the way he thinks they should be at that store. Yikes! Now that's the kind of worker I sure wouldn't want helping my customers ... helping them right out the door and across the street to my competitor!!

"There is only one boss. The customer. And he can fire everybody in the company from the chairman on down, simply by spending his money somewhere else." - Sam Walton

What is the answer to less-than-stellar service? I'm not sure. I don't believe there is a one-size-fits-all answer.

Having worked in the fields of training and procedures, I know that the answer does not lie solely in additional training or in detailed, step-by-step instructions. I believe it is important that management explain to workers (starting in the job interview, through hiring and new employee orientation, and then through regular discussions about expectations and sharing of customer feedback) the importance of the role they play and the positive value they can add every day to each customer's experience.

Don't get me wrong - I'm not saying all of my experiences have been unpleasant or that the majority of workers I've encountered have bad attitudes toward customers and customer service. I have experienced *great* customer service at several stores and restaurants. And when it's great, it really is great! I appreciate that kind of attitude and attention. Maybe I will share some of those stories another time. (It's all about quality.)

-Jo Haberstock

EDITOR'S RANT

Rich Higgins
CH2M HILL, Hanford Inc.

Be careful what you ask for!

In my last column, I discussed how much I enjoyed doing event investigations and root cause analyses. And shortly after sending out the August newsletter, I left my cell phone at home and spent a romantic 3-day weekend with my wife in beautiful Victoria, Canada. And on the way home, we took in a great art show in Bellevue. A great weekend!!!

On Monday morning, July 30, I had no fewer than 10 voicemails advising me of a radioactive liquid waste spill at one Hanford's single shell tanks, and that I had been assigned to do the event investigation.

The spill was "only" about 100 gallons of waste, and no one got contaminated, and nothing escaped from a radiologically controlled area. But the consequences were huge. Several employees reported experiencing

adverse health effects following the spill, so about two weeks into CH2M HILL's investigation, the Department of Energy (DOE) launched a Type A Accident Investigation, the highest level of DOE investigation.

CH2M HILL published its investigation report on September 17, and DOE published Volume I of its investigation report on September 20 and Volume II was published shortly thereafter. You can access DOE's reports at <http://www.hss.energy.gov/>. They are in the red box at the left of the screen. The conclusions documented in CH2M HILL's report are similar to those in DOE's report.

The two root causes we identified were less than adequate (LTA) engineering design and LTA management of change.

Here is the Reader's Digest condensed version of what happened.

A positive displacement pump was being used to pump a heavy sludge-like waste out of underground storage tank S-102. The tank has a capacity of about 750,000 gallons, and we were working on the last 5% of the waste when the event occurred.

As occasionally happens, the pump internals had become clogged with waste on the evening of July 26 and the pump would not run. So, at about 2:00 a.m. on July 27, the pump was run in the reverse direction (as designed) to clear the obstruction. However, unbeknownst to the operators, the pump suction had become clogged as well. As a result, when the pump rotated in reverse, the pressure in the suction cavity forced waste up into a waste dilution water supply line that feeds clean raw water to the pump suction. Unfortunately, there were no backflow preventers or check valves to stop the flow, and the pressure in the line ruptured a rubber water supply hose in the area near the pump motor. Luckily, no one was in the area at the time.

Believing that the pump had cleared, operators preparing to shut the system down for the night discovered high radiation levels (about 200 millirem/hour) in the area, and they quickly evacuated the area. Several hours later, after the sun had come up, workers entered the area again to determine the source of the high radiation level and saw the spill. Authorities were notified, and the rest, as they say, is history.

Here are a couple of Quality-related lessons learned from the spill.

- 1) The safety analysis for tank systems required backflow prevention for systems connected to waste transfer systems. However, few considered the dilution line to be physically connected to the transfer system. But one reviewer of the original design documented a concern in 2002 that the dilution line might become pressurized during reverse pump operation.

Unfortunately, the response to that concern was not well documented, and it apparently got lost in the system. This was a latent weakness waiting for the right conditions to rear its ugly head.

- 2) The design of pump's suction configuration was changed over the years, such that the pump installed into S-102 in July 2007 was fundamentally different from the original 2002 design. The area available for flow was reduced by more than 50%, reverse pump speed was tripled, and the dilution line supply port was moved from the suction screen to inside the pump suction cavity. The changes were individually reviewed in accordance with site procedures, but the sum of the changes was not reviewed as a set.

The undetected latent condition in the 2002 design review now had the right conditions to cause a problem. With the suction screen almost completely obstructed, the pressure in the suction cavity increased to 9 times above what was possible at the original pump speed, and flow found the path of least resistance and ruptured the supply hose.

Lessons Learned.

- 1) Make sure that documented comments of design reviewers are appropriately dispositioned and formally closed prior to approving engineering designs.
- 2) Conduct formal change analyses that evaluate all previous changes as a group in an attempt to determine if any new or increased hazards have been introduced by those changes. Consider implementing Management of Change practices as discussed in OSHA 1910.119, Process Safety Management.

With an event of this complexity, there are many more lessons to be learned. But these two are the big ones.

- Rich Higgins

ASQ SECTION 614 DINNER MEETING WEDNESDAY, NOVEMBER 7, 2007

Healthcare Today: Where Does "Quality" Fit? -- Kellie Hamblin, RN

Healthcare is tumultuous and, as a business, has an uncertain future. Quality professionals who have been involved in healthcare quality for the past decade have witnessed the rising tide of expectations for quantitative data build into a tsunami of demand. The growing pressure for valid and reliable information regarding the quality of medical care and services is coming from all stakeholders, including the federal government, state governments, commercial payers, consumers and

employers. Those who are interested in the clinical and service data expect the measures to drive the level of payment provided for care and services. Better performers will get more money; while worse performers will get less money.

This presentation will focus on what has been demanded at the federal level and how it is now spreading beyond government programs.

We will focus particularly on President Bush and Secretary Leavitt's "Value Driven Healthcare" plan and the "Four Cornerstones" which is the federal government's first step in the design and implementation of a national plan to make health care more efficient, affordable and reliable.

At the state level, Governor Gregoire has successfully supported new legislation that puts the federal government's principles and demands into law in Washington State.

Join us November 7 for an insightful discussion of the following – and more:

- What does this mean for recipients of Medicare and other federally funded medical programs?
- What does it mean for everyone else?
- What role do quality professionals have?
- What do doctors, nurses and administrators know about Six Sigma, Lean, or any other quality improvement methodologies?
- Does it matter?

About the Speaker:

Kellie Hamblin is an RN and a healthcare quality professional. Her healthcare career began in hospital based nursing seventeen years ago; the past twelve years she has focused on quality improvement in healthcare in a variety of settings including hospital based clinical and operational improvement, primary care, dental clinics and selected specialties. She has also worked closely with managed care providers to improve quality and manage costs by designing and implementing case management, utilization management and process improvement structures. Kellie earned her Associate Degree in Nursing from Columbia Basin College in Pasco, her BSN through Graceland University (Lamoni, Iowa) and her Masters in Business Administration from Regis University (Denver). Kellie also maintains a "Certified Professional in Healthcare Quality" (CPHQ) designation from the National Association of Healthcare Quality (NAHQ).

Meeting Details: The meeting will be held at the Shilo Inn, Richland, with check-in/networking at 5:30 p.m., chapter business and buffet dinner at 6, and the presentation at 7. Cost is \$17 for ASQ members, \$20 for non-members, or \$5 for just the presentation. Reservations are required and requested by November 1. Send an email to prevette@owt.com <blocked::mailto:prevette@owt.com> with your name, phone number, member status and type of reservation, or call 373-9371. For more information about this meeting, the speaker, and other ASQ activities: <http://www.asq614.org/> <<http://www.asq614.org/>> .

WEBSITES FOR OTHER ASQ SECTIONS

Seattle Section (#606): www.asq-seattle.org
Spokane Section (#619): www.spokaneasq.org
Southwest Washington – Vancouver Section (#627):
www.asqswwa.org
Portland Section (#607): www.asqpdx.com

PUBLICATION INFORMATION

The ASQ Columbia Basin Section 614 newsletter is published on a regular basis to inform members (and potential members!) about Section 614 activities and other news/information we feel may be of value to quality professionals. To be considered for the next newsletter, input must be received by the 22nd of the month. Publication/Editorial Staff: Rich Higgins (Rich_Higgins@charter.net).

QUALITY IN FEDERAL REGULATIONS

Regulation of small businesses by federal agencies is an important, sometimes controversial, issue. Practitioners focused on quality-as-process and quality-as-result may have an opportunity to contribute in that process.

The Office of Advocacy of the U.S. Small Business Administration is seeking nominations of federal rules in need of review and reform. The "Top 10 rules nominated by small business owners, trade associations, and others will be transmitted to appropriate federal agencies for review and reform. The r3 Program has been established.

The r3 program is intended to help small businesses address the cumulative Federal regulatory burden, which is now estimated to exceed \$1.1 trillion.

Through the r3 program, we believe federal agencies will do a better job of identifying and revising rules that need to be reformed.

The link = <http://www.sba.gov:80/advo/r3/>

Reports from the US-SBA Office of Advocacy indicate - - -
"Complying with all federal regulations now costs our economy \$1.1 trillion per year; that's more per household than the cost of healthcare," said Thomas M. Sullivan, Chief Counsel for Advocacy. "Advocacy's Regulatory Review and Reform initiative can help lighten that load by streamlining and updating outdated and ineffective regulations. We are calling for rules needing reform, and we are asking for constructive suggestions about how to improve them."

- Jerry Brong

CAREER CONNECTIONS

The Respiratory and Monitoring Solutions Group of Covidien, formerly Tyco Healthcare is currently recruiting for the following positions:

SOFTWARE QUALITY ENGINEERING MANAGER – Boulder, CO

Position Summary: Oversee and manage Software Quality Assurance Engineers ensuring that software used in the development, manufacturing, and as part of medical devices is developed according to good design practices as set forth by regulatory authorities (e.g. FDA/TUV).

Minimum Requirements:

- BS degree in Electrical Engineering, Computer Science, or Computer Engineering
- 6+ years exp in software test or software quality engineering with embedded software as part of a medical device
- Experience in a management role
- Working knowledge of and auditing experience to the FDA Quality System Regulation, ISO 13485, & Medical Device Directive
- Skilled in product risk assessment (ISO 14971), requirements management and tracing, defect tracking, configuration management techniques, and how they are applied in the software development lifecycle
- Understanding of current Software Quality techniques, software industry standards (e.g. ISO, IEEE, CMMI), and FDA Quality System Regulations and their impact on internal procedures, software quality, safety and efficacy of products
- Working knowledge of C, C++
- CSQE Certification

SR. SOFTWARE QUALITY ENGINEER – 1 position Boulder, CO & 1 position Carlsbad, CA

Position Summary: Ensuring that software used in the development, manufacturing and as part of medical devices is developed according to good design practices and follows the corresponding requirements set forth by local procedures, regulatory authorities and notified bodies. Provide leadership, oversight and training to division manufacturing plants for computerized system validation.

Minimum Requirements:

- BS in Electrical Engineering, Computer Science, or Computer Engineering

- 5+ years in software quality engineering role dealing with embedded software that is part of a medical device.
- Working knowledge of the FDA Quality System Regulation, ISO 13485, and the Medical Device Directive
- Skilled in product risk assessment (ISO 14971), requirements management and tracing, defect tracking, configuration management techniques, and how they are applied in the software development lifecycle
- Understand current Software Quality techniques, software industry standards (e.g. ISO, IEEE, CMMI), and FDA Quality System Regulations and their impact on internal procedures, software quality, safety and efficacy of products
- Working knowledge of C, C++, and LabVIEW

REGULATORY AFFAIRS SPECIALIST – Boulder, CO

- Position Summary:
- Ensures compliance to FDA and other applicable regulations. Prepares, analyzes, and submits dossiers to various governing agencies in supporting business growths. Supports applicable regulations including ISO, local, state, and/or federal requirements.
- Minimum Requirements:
- 5-8 years of RA experience
- B.S. or B.A. degree required.
- Must have knowledge of U.S. and/or European/International regulations and standards
- Experience in preparing regulatory submissions
- Experience interacting with FDA and/or other regulatory agencies

COMPLIANCE OFFICER – Boulder, CO

Position Summary: Develops, establishes and maintains quality assurance and regulatory programs, policies, processes, procedures and controls to ensure that the performance and quality of products conform to established standards and agency guidelines.

Minimum Requirements:

- BS/BA degree or equivalent experience with 3-7 years medical device.
- 2 years auditing experience; hands on experience managing and/or supporting FDA and Notified Body inspection/audits.
- Comprehensive knowledge of FDA Quality System Regulation, ISO, Medical Device Directive, Canadian Medical Device Regulation, and other international requirements.
- Knowledge of all Quality System elements, including Complaint Handling, CAPA, Design Control, Validation Review
- ASQ Certified Quality Auditor and Lead Auditor training are highly desired.

For more information about these and other opportunities go to: www.covidien.com/careers. Pull up jobs for Boulder, CO. Respiratory jobs are listed under Nellcor/Puritan/Bennett.

Recruiter Contact Information:
Deborah.Cason@covidien.com

To be considered for posting in the newsletter, announcements must be submitted by an ASQ member and be of potential service to other members. Announcements may include job postings, training opportunities, or requests for assistance. Due to space limitations, please keep them brief.

2007-2008 SECTION 614 LEADERSHIP TEAM

Section Chair and Publicity	Steve Prevette	Audit	Dave Sandoz
Vice Chair and Programs	Jo Haberstok	Division Liaison, Web Team Lead, Section Historian, and Examining	Dennis Arter
Secretary	Howard Rew		
Newsletter Editor and Treasurer	Rich Higgins	Certification/Recertification	Howard Rew

You can find out more about Section 614, including contact information for Leadership Team members, on our website at www.asq614.org.

If you are interested in helping with any of the Section teams, please contact the team lead or an officer. We are always looking for willing volunteers!