Chair’s Message

Hi everyone!
It continues to be a very busy year for the Audit Division.
Our student coordinator, Lawrence Mossman, has been setting up student branches in various sections within the United States including Florida; Memphis, TN; Missouri; Iowa; and now in Boston, MA to coincide with the BOSCON conference in April 2016. Lawrence has started the development of a Student Branch Organizing Team to assist in our outreach effort to students as we continue to move forward with this project.

Speaking of BOSCON, the Audit Division will be participating in BOSCON 2016, providing speakers on audit-related subjects. Come and visit our booth to speak with our team and obtain information about the division and our Certified Quality Auditor certification preparation class. Planning has begun, so please check the Boston section website at www.asqboston.org for up-to-date information as it becomes available.

Our very popular free webinar series continues with our next webinar on October 6, 2015, from 1:00 p.m. – 2:00 p.m. Eastern Daylight Time. The subject and presenter have not yet been chosen. Watch your email for the webinar announcement and registration information.

If you have missed any of our webinars, you can access them from the Audit Division home page at asq.org/audit and scrolling down to “Featured Content.” To date we have “Advanced Audit Interviewing Techniques,” “A Risk Based Thinking Model for ISO 9001:2015,” “ISO 9001:2015 Update – Internal Audit Challenges,” and “Advanced Quality Auditing – An Auditor’s Review of Risk Based Thinking, Lean Improvement, and Data Analysis.”

If there are any topics you would like to see presented, please contact Angelo Scangas, our webinar chair, at Angelo@qualitysupportgroup.com so we can deliver important and timely webinars that are of interest to our members.

As travel budgets become tighter and the thirst for knowledge continues to increase, the Audit Division is partnering with the Software Division to offer alternate options to destination conferences in the form of “virtual conferences.” We are in the early stages of developing and testing various options for this offering, and initial tests look very promising. Stay tuned for continuing updates.

We are looking for nominations for the 2015 Paul Gauthier Award. The Paul Gauthier Award honors someone who has made, or is making, an original, significant, or lasting contribution to the field of auditing. If you know someone that you feel deserves this recognition, and you would like to submit a nomination, please contact George Callender, ASQ Audit Division Awards Committee chair, at callendg@bellsouth.net, to request “The Paul Gauthier Nomination Form.” Nominations must be submitted on the form for consideration. Please email nominations to George Callender by September 30, 2015. The award will be presented at our 24th Annual Audit Conference this October in Reno, NV.

If you need to become a Certified Quality Auditor (CQA), the next public offering

Continued on page 2
Audit Division Vision
To be the pre-eminent body for providing expertise on auditing and defining expectations for the audit profession.

Audit Division Mission
To develop the expectations of the audit profession and auditors. To promote to stakeholders auditing as a management tool to achieve continuous improvement and to increase customer satisfaction.

The Audit Report is published four times a year as a chief information resource for members and friends of ASQ’s Audit Division. Information about the ASQ Audit Division may also be found at asq.org/audit.

Reminder: All ASQ Audit Division endorsed communication and/or use of the Audit Division’s logo must be approved by the Audit Division chair.

Newsletter Publishing Guidelines

Authors Wanted!
The Audit Report staff is looking for authors. Share your expertise with other audit professionals while adding to your own credentials. Writing for the newsletter also earns CEUs to submit with your certification journal. If interested, please email submittals to lance@fullmoonconsulting.net. Guidelines are below.

Main Factors
1. Technical Merit
   - Includes correct facts
   - Relevant to our mission
2. No selling of services
3. Nothing offensive
4. Original content only. Nothing previously published or presented, without prior approval by review committee.

Additional Factors
5. Not too similar to something recently done
6. Desired subject matter: How timely is material?
7. Well written (not requiring extensive editing)
8. Needed length

Categories
Newsletter submittals should fit into one of the following categories:
- Tips From the Trenches: tools, tips, and techniques for auditors
- Faces in Auditing: new, up-and-coming professionals of note in the field of auditing
- Articles, case studies, or book reviews
- News Bytes: event coverage, announcements, and other audit profession-related news

Length
Desired length for tips, book reviews, articles, and case studies is 400 to 800 words. Tips and book reviews would be in the 400- to 600-word range, articles anywhere from 400 to 800 words and case studies, 500-plus words. If a submittal goes beyond 800 words, then we may look at breaking it into more than one part.

Review and Selection Process
All submitted works will be reviewed by at least two members of the Review Committee, which consists of the newsletter editor and four other members. The subject for a book review should be approved in advance by either two members of the Review Committee or by the newsletter editor. The newsletter editor will determine when accepted articles will be published. Submittal of an article does not guarantee publication.

Other
All articles containing photos should be submitted with the photo(s) as a separate jpeg attachment.

Calendar/Main Theme(s)
Submittals relating to the main theme and from division members receive priority.

March 1 Issue: Submit content by January 15 – Preview of ASQ WCQI and open topics
June 1 Issue: Submit content by April 15 – Recap of ASQ’s World Conference and open topics
September 1 Issue: Submit content by July 15 – training, certification, back-to-school, and Audit Conference
December 15 Issue: Submit content by October 31 – WCQI recap, year-end reflection, and looking ahead to next year

Volunteers Wanted!
Help shape The Audit Report by joining our Newsletter Committee. We are looking for two more volunteers to participate in our Newsletter Committee. Please email your resume to lance@fullmoonconsulting.net if you are interested and want more information. For other volunteer opportunities within the Audit Division, contact Lawrence Mossman at mossman@netins.net.

In the Next Issue:
Chair’s Message
Letter From the Editor
Feature Article: Conducting Internal Audits Using the DMAIC Process, by Upen Patel
Tips From the Trenches: TBD
Division News Bytes
Auditing in a Software Environment, by Nancy Boudreau

Advertising Rates:
Full page: $500 U.S. per issue
Half page: $250 U.S. per issue
Quarter page: $125 U.S. per issue
For submissions or questions, contact Lance Coleman, lance@fullmoonconsulting.net.
Letter From the Editor

Hello and Welcome to Fall!
For those of you like me, who faced 105+ temperatures this summer, we made it! We are also very excited to have made it to the relaunch of our annual Audit Conference, now in its 24th year, after a year’s hiatus for the purchase of new conference equipment. This issue of your newsletter is our conference edition and will feature the conference program, as well as other information about the conference, which take place in Reno, NV, October 29 – 30. As always, there are three conference tutorials to attend and certification exams that can be taken afterwards.

Two of our conference presenters—Kevin Posey and Kurt Stuke—provide articles that speak to the importance of interviewing technique and constancy of purpose, respectively. This issue’s Tips From the Trenches is presented by first-time author Danielle Frederick on the topic of establishing an effective corporate audit program. One of our conference sponsors, Walter Tighe of Sustaining Edge Solutions, provides insights into leadership’s role in ensuring compliance to ISO 9001:2015. We also have a message from our friends in the ASQ Design and Construction Division. Also provided in this issue is information on some of our key conference sponsors for your review. Our goal in presenting this issue is to give those of you attending the conference a brief preview; and for those who unfortunately can’t join us, a sense of what you may miss.

As always, thanks for your readership and support. Don’t hesitate to let us know how we are doing with our newsletter and to make suggestions for improvement. I hope to see you in Reno!

Warm regards and safe travels,
Lance B. Coleman
ASQ Audit Division Newsletter Editor
lance@fullmoonconsulting.net

Methods to Improve Your Business Performance

“Sustaining Edge Solutions provides excellent customer service. Our management system has resulted in financial gains for the entire organization.”
Richard Gomez, V.P. Quality
MedAire International

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- ISO 13485 Medical Devices
- Six Sigma Improvement
- Operational Assessments
- Kaizen Events
- Lean Manufacturing
- AS9100 Aviation, Space and Defense
- ISO 14001 Environmental
- Quality Systems Training
- Web-Based ELearning
- Performance Measurement
- Conduct Your Internal Audits

“Sustaining Edge Solutions gave us the direction and assistance we needed to implement our new AS9100 Aviation, Space and Defense Business Management System. They were professional, affordable and always on call when we needed them. I would personally recommend them to anyone looking to step up to the next level in their business.”
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Hawkeye Precision, Inc.

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Modular Mining Systems
Anderson Painting & Powder Coating

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Contact us at 888-572-9642 • admin@sustainingedge.com
Using the Appreciative Inquiry Method When Auditing for Performance and Improvement

by Kevin Posey, CQA, CBA, CQE, CMQ/OE, CSQE, CSSGB

The bodies of knowledge for auditors indicate that interviewing is a core competency for all certified auditors, yet it is still considered one of the more challenging aspects of a typical audit. In addition, there are limited training offerings that include concepts or practical application of interview techniques or discuss real-world scenarios in any length. Recent articles in Quality Progress on the appreciative inquiry (AI) method have offered interesting ideas on applying new interviewing techniques to quality auditing. This article seeks to expand and elaborate on how the AI method can be used effectively by certified auditors.

The following statement from Shu Liu (Liu, 2013, p. 32) is very provocative: “Appreciative inquiry is the study of what gives life to human systems when they function at their best. This approach to personal change and organizational change is based on the assumption that questions and dialogue about strengths, successes, values, hopes and dreams are themselves transformational.” The primary benefit for AI, according to (Ludema, Cooperrider, and Barrett) is “in the change of language; shifting from vocabularies of deficit (or nonconformance) to conversations of possibility that are unlocked by the unconditional positive questions of the method.”

Other benefits of AI are that it: 1) releases positive conversation within the organization—unconditional positive questions ignite a virtual explosion of constructive conversations that refocus an organization’s attention away from problems and toward hopeful, energizing possibilities, 2) builds an ever-expanding web of inclusion and positive relationships—an ever-increasing number of voices are included in conversations that highlight strengths, assets, hopes, and dreams. Respect, understanding, and strong relational bonds are formed, and 3) creates self-reinforcing learning communities—as positive vocabularies multiply, people strengthen their capacity to put possibilities into practice. Organizational members learn increasingly sophisticated vocabularies for doing things in new ways.

Work by Jon Morris (Morris, 2008) discussed more specifically how the AI methodology can apply to and enhance a company’s audit program and help the organization move beyond compliance to greater efficiency, effectiveness, and continuous improvement. Specifically, Morris showed that AI can help the audit process deliver more value and do it earlier in the audit process. He also showed that AI methods helped address and change previously negative opinions of the audit process, leading to more open dialogue and improvement opportunities. Most importantly, all the prior benefits were gained with no sacrifice of compliance to regulations or standards.

So, how do we apply the AI method to our audit program, and where does it make sense to apply it? For multiple reasons, AI does not fit well with the objective of third-party certification, compliance, or regulatory audits, and may not be the preferred method for second-party audits for supplier assessment or corrective action. However, AI methods fit well wherever efficiency, effectiveness, or continual improvement is valued, desired, or even required. This is especially true for internal audits and second-party supplier audits where strategic partnerships and growth are valued over simple economic considerations.

Let’s look at some audit interview questions that have been adapted from the appreciative interview protocol (Ludema, Cooperrider, and Barrett). One quick and intuitive way to begin is to use organic metaphors for the process or organization, such as seeing the process or organization as a river or a fruit tree. These metaphors and AI-based interview questions can help stimulate the positive questions and responses.

Some other examples or guidelines for forming AI questions for your organization:

1. Think of a time in your involvement in (process, area, department, or division) when you have felt most excited, or most engaged.
   a) What were the forces and factors that made it a great experience?
   b) What was it about you, others, and your organization that made it a peak experience for you?
   c) How can we apply this to another (process, area, department, or division)?
2. What do you value or enjoy most about (process, area, department, or division)?
3. What are your organization’s best practices in (process, area, department, or division)?
   a) Are they consistently applied across all (process, area, department, or division)?
4. What are the unique aspects of your culture that most positively affect the effectiveness or continual

Continued on page 5
improvement of (process, area, department, or division) and its work?

5. What is the core factor that “gives life” to your (process, area, department, division)?

6. Tell me about a time when finding and correcting a problem with the (process, area, department, or division) saved the day.

The purpose of our AI questions is to allow collection and analysis of all of the best of “what is” information, and create a bridge to the future “might be” state. We might also call our AI interview questions a series of “provocative propositions” or critical key questions (as in Morris, 2008). For example: “What if revealing system efficiency, effectiveness, and best practices was just as likely as finding nonconformances?” or even “What if the act of asking audit questions began a process of change for the better?” or finally, “What if audit results became a key input to the CEO’s strategic plan?”

In summary, appreciative inquiry is a powerful tool for forming and phrasing audit interview questions to elicit objective evidence of efficiency, effectiveness, and continual improvement. Further, the AI method is perfectly suited to assist the organization in defining the dream or “might be” state of improved operations. AI methods also address a fundamental weakness of conformance- or compliance-based auditing by providing tools for evaluating whether a quality management system has been implemented and maintained effectively, especially in an environment of limited resources. AI audits are also ideally suited to assist the organization in identifying, spreading laterally, and carrying forward best practices as well as encouraging continual improvement. And best of all, AI can accomplish all of the above good things without sacrificing conformance to regulations or standards.

About the author: Kevin Posey is a quality and regulatory executive consultant with international experience in quality management, product development, manufacturing, and regulatory approval for medical devices, defense and aerospace, mining and exploration, as well as industrial equipment and controls. Posey also consults, trains, writes, and speaks on quality management, auditing, innovation, and medical devices. His has an undergraduate degree in aerospace engineering and an MBA in international business. Posey is the education and training chair for the Audit Division, a founding member of the Innovation Interest Group, and an ASQ Senior member, with certifications as a Quality Auditor (CQA), Biomedical Auditor (CBA), Manager of Quality/Organizational Excellence (CMQ/OE), Quality Engineer (CQE), Software Quality Engineer (CSQE), and Six Sigma Green Belt (CSSGB).
TIPS FROM THE TRENCHES:
Corporate Quality Audits:
Beyond the Closing Meeting

by Danielle Frederick

Corporate Quality Audits
You’ve been tasked with implementing a corporate quality audit program for your multi-site company. You decide to perform annual audits at each site and write a procedure to govern the program—you consider qualified auditors, agendas, reports, and responses. Done? Granted, many corporate quality audit programs may be as basic as performing audits each year, but is the company truly benefiting from this exercise? The short answer should be “yes.” Any audit that results in a correction to a nonconformance improves the local quality management system (QMS) for the audited site. The program ensures that each site maintains compliance to your company’s expectations and QMS requirements. Good job! But, you know there must be opportunities to take the program, and the audit results from each site, beyond the audit closing meeting.

Quarterly Updates
Communication is a basic, yet powerful, tool to steer a corporate quality audit program beyond each individual site’s audit and keep the program “alive” after the closing meeting. I prefer a formal, quarterly update. This communication tool easily and efficiently conveys the same information across the organization. The audience for the update should include auditors, site quality managers (SQMs), and corporate quality management (CQM), such as directors and VPs. With the correct audience, a quarterly update effectively keeps the focus on short-term objectives of the program: Are audits on track with the schedule? Are reports and responses issued in a timely manner? Are there any red flags that require attention across the organization? Updates provide information used in strategic planning for future audits in addition to an overview of the program performance. Based on trends in findings across sites, you may want to shift audit scopes.

Plan Ahead
You can collect a lot of information from the audit program. Determine what you want to report to the organization. Keep the update focused on a few key topics. Ask a few questions: What is the benefit to the organization by communicating this information? How can I present the information concisely in an update? A few essential elements for audit program updates include audit schedule and status, findings, and positive practices. Let’s take a closer look at some examples for each element.

Audit Schedule and Status
Is the program compliant with the procedure requirement? Are audits being performed as scheduled with reports and responses submitted on time? A simple table (see Table 1) conveys the snapshot on the “health” of the audit program. List each site that is scheduled for an audit during the year, the auditors assigned, and the status of each audit (e.g., scheduled, performed, pending report, pending response). When people know dates and status will be shared across the organization, the level of commitment to meet due dates is escalated.

Findings – Internal Corporate Quality Audits
Categorize findings into key categories (e.g., ISO 13485 clauses). Use basic Pareto charts to display findings data. You can chart the total number of findings issued in each category year-to-date. Format the chart so that each vertical bar is compiled of a count from each site that had a finding in that category. Looking at the chart, you can see how many sites had findings in a given category and how many findings in each category. With a second chart compare year-over-year findings by category. Benefits include early detection of potential systemic issues and audit

<table>
<thead>
<tr>
<th>Site</th>
<th>Audit</th>
<th>Auditors</th>
<th>Status</th>
<th>Dates</th>
<th>Report Issued</th>
<th>Response Submitted</th>
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<td>CQA-14-02</td>
<td>AN/PL</td>
<td>Complete</td>
<td>February 19 – 20, 2014</td>
<td>February 26, 2014</td>
<td>April 8, 2014</td>
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<td>Pending Response</td>
<td>June 17 – 18, 2014</td>
<td>July 8, 2014</td>
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<td>PL/TU</td>
<td>Scheduled</td>
<td>Planned Q3</td>
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</tr>
</tbody>
</table>

**Table 1:** Example of audit status update

Continued on page 7
planning (focus areas for future audits). Sites view how they compare with other sites’ findings: Where are findings being detected? Should a site focus an internal audit in a specific area before their corporate quality audit occurs?

**External Audits – What Do Customers Find?**

You know what internal corporate quality auditors report as findings, but what are your customers finding when they audit the sites? Compare CQA results to customer audit results. Examining the results of external audits can provide insight to the industry trends in audit focus. These results should be factors influencing the scope of future audits.

**Positive Practices**

Findings are important because a nonconformance requires correction. However, identifying positive practices during corporate quality audits can also greatly benefit the organization. If an auditor identifies an area of the QMS that a site maintains exceptionally well or a site developed a unique approach to address an issue, encourage auditors to share that information in audit reports. Include an overview of select positive practices in the quarterly update. Chances are high that another site may benefit from the sharing of positive practices.

**Benefits of Quarterly Updates**

Granted, pulling together a quarterly update of the corporate quality audit program can be a time-intensive activity, but the benefits of improving communication of audit activities are worth the time. The update keeps everyone on track with the schedule, report issuance, and response submission. It creates awareness across sites of findings by category and focuses attention to categories with high numbers of findings. Ultimately,
updates improve the corporate quality audit program and the overall QMS. Other topics to include in updates could be auditor training/qualification and general industry news. A well-planned, concise, quarterly update enhances communication by sharing information across the entire organization. A successful corporate quality audit program does not end at each audit’s closing meeting.

About the author: Danielle Frederick is based in the greater Philadelphia, PA, area. She is currently the quality audit manager at West Pharmaceutical Services, Inc., PDS division, and has more than 20 years of experience in regulated environments including medical laboratory, pharmaceutical, and medical device. She is an ASQ Senior member, ASQ Certified Quality Auditor (CQA), and Certified Six Sigma Black Belt. For questions or comments contact her at dfrederick0601@aol.com.

Letter From the DCD

The ASQ Design and Construction Division (DCD) is looking forward to the upcoming Audit Conference this October in Reno, NV. We have been very busy over the course of this program year and look forward to sharing our progress with our colleagues and friends. For this year’s conference, the DCD is providing a full slate of speakers we believe will interest all conference attendees.

Best Booth Ever

With assistance from ASQ headquarters, we completely revamped our booth for this year’s World Conference on Quality Improvement (WCQI) in Nashville, TN. We felt we were “Best in Show”—other conference attendees must have felt the same, as we enjoyed unprecedented traffic over the entire course of the WCQI. Special thanks to Jeff Williams and Benjamin Trujillo for making it happen. Come see it in Reno.

Certified Construction Quality Manager

Shortly after last year’s October conference we recommenced development of our Certified Construction Quality Manager (CCQM) certification proposal. The effort is in its early days and proving to be quite an adventure.

As ASQ includes members from 140 countries, we decided to use LinkedIn social media to “crowd source” new 21st century content from a broad base of participants. Based on his experience developing and managing three LinkedIn groups, one of which has more than 9,000 members (new quality manager), executive board member Brian Palmquist volunteered to lead the effort. He established a CCQM LinkedIn subgroup to the ASQ Design and Construction Division group. The CCQM subgroup has grown to include representatives from more than 20 countries so far. Additionally, the CCQM Body of Knowledge (BoK) continues its evolution, which he will share at the October conference. Some highlights so far:

- Being temporarily suspended by LinkedIn for being too aggressive in seeking content with a post called “Boy Are You Wrong!”
- Discovering that even in social media, quality professionals still prefer tables and spreadsheets
- Recognizing and tabling the eight classes of criteria ASQ uses to evaluate potential certifications
- Carrying on the excellent BoK work started by many predecessors

In addition to the usual trials and tribulations, Brian has learned much about what generally works and does not work in social media. He will present these lessons learned as part of his presentation in Reno, as it has value independent of the CCQM effort.

Conference Training

We have a scheduled training in Reno with attendees from American Institute Steel Construction (AISC), which may boost overall conference attendance by up to 10 percent. We are looking forward to an ongoing collaboration with AISC.

WCQI 2016

We have already started planning for next year’s WCQI in Milwaukee, WI.

Regards,
Anita McReynolds-Lidbury,
Design and Construction Division Chair
We are excited and pleased to offer the program on page 10 for our 2015 Audit Conference. Go to asqauditconference.com/Program.html for descriptions of each session.

Track 1: Revealing the Path to Process Improvement and Performance Excellence (Sessions A and E)

Track 2: Influencing the Journey to Improve Revenue and Customer Satisfaction (Sessions B and F)

Track 3: Risk Based Thinking From the Quality Perspective (Sessions C and G)

Track 4: Design and Construction (Sessions D and H)

Thursday, October 29, 2015
7:00 a.m. – 8:00 a.m.: Continental Breakfast
7:00 a.m. – 4:00 p.m.: Registration and Bookstore

8:00 a.m. – 9:30 a.m.: Opening Remarks and Keynote
Noon – 1:30 p.m.: Lunch Announcements and Keynote
5:30 p.m. – 7:00 p.m.: Audit Division Annual Business Meeting (All conference attendees are invited to participate)
7:00 p.m. – 10:00 p.m.: Thursday Evening Reception (All conference attendees are invited to participate)

Friday, October 30, 2015
7:00 a.m. – 8:00 a.m.: Continental Breakfast
7:00 a.m. – 4:00 p.m.: Registration and Bookstore
8:00 a.m. – 9:30 a.m.: Opening Remarks and Keynote
Noon – 1:30 p.m.: Lunch Announcements and Keynote
4:45 p.m. – 6:00 p.m.: Closing Reception for All Conference Attendees

Book Signings:
9 Keys to a Successful Audit
Denise Robitaille

Advanced Quality Auditing: An Auditor’s Review of Risk Management, Lean Improvement and Data Analysis
Lance B. Coleman Sr.

Preconference Tutorials
Below is a list of the preconference tutorials. To read a description of each, go to http://asqauditconference.com/Refreshers_Tutorials.html.

<table>
<thead>
<tr>
<th>SESSION CODE</th>
<th>SESSION TITLE</th>
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<tbody>
<tr>
<td>9358ILT</td>
<td>Certified Quality Auditor Exam Cert Preparation</td>
</tr>
<tr>
<td>WKSP1</td>
<td>Auditing Your Potential: Verify-Improve-Lead</td>
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<tr>
<td>WKSP2</td>
<td>Hoshin Kanri: Strategic Planning and Execution – Linking Quality and Audit Systems With Strategic Plans</td>
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<td>WKSP3</td>
<td>ISO 9001:2015 Transition Workshop</td>
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<td>WKSP4</td>
<td>Writing Exceptional Audit Reports</td>
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<td>WKSP5</td>
<td>Failure Mode and Effects Analysis</td>
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<td>WKSP6</td>
<td>ISO 9001:2015 – Transition Workshop</td>
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<tr>
<td>WKSP7</td>
<td>Leveraging the SIPOC Model to Place the Customer First</td>
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<tr>
<td>WKSP8</td>
<td>Process Improvements That Lessen Headache Hours</td>
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<tr>
<td>WKSP9</td>
<td>Auditor Charm School: Extended Edition – A Workshop for Practicing</td>
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</tbody>
</table>

Preconference tutorials are subject to cancellation should they not meet minimum registration requirements.

Bureau Veritas Certification, the independent third-party registrar of Bureau Veritas Group, offers certification and verification to help clients meet the growing challenges of quality, safety, environmental protection, and social responsibility. Created in 1828, Bureau Veritas Group has more than 61,000 employees in over 1,400 offices and laboratories located in 140 countries.

Bureau Veritas is recognized and accredited by major national and international organizations around the world.
## 2015 Audit Division Conference Sessions

### THURSDAY, OCTOBER 29

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<th>Time</th>
<th>Track A</th>
<th>Track B</th>
<th>Track C</th>
<th>Track D</th>
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<tr>
<td></td>
<td>JD Marhevko</td>
<td>Scott Smith</td>
<td>Sharon Tay</td>
<td>Chris Pollack</td>
<td>Kenneth Wexler</td>
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<td>Larry Whittington</td>
<td>Open Patel</td>
<td>JP Russell</td>
<td>Brian Palmquist</td>
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<td></td>
<td>Tomoko Okumura, Nobu Hiyoshi</td>
<td>Rajamani Puthucode</td>
<td>Denis J. Devos</td>
<td>Brian Palmquist</td>
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<td>2:45 p.m.</td>
<td>A4: Advanced Interviewing Techniques for Audits</td>
<td>B4: Living Data: Leveraging Qualitative Data for Auditors</td>
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<td></td>
<td>Kevin Posey</td>
<td>Kurt Stuke</td>
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<td>3:45 p.m.</td>
<td>A5: The Certified Software Quality Auditor Panel Discussion</td>
<td>B5: The Elephant in the Room</td>
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<td></td>
<td>Nancy Boudreau, Byron Mattingly, Nancy Pasquan</td>
<td>Jerry J. Mairani</td>
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### FRIDAY, OCTOBER 30

<table>
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<th>Track F</th>
<th>Track G</th>
<th>Track H</th>
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<tbody>
<tr>
<td>9:45 a.m.</td>
<td>E1: Optimizing Auditing: Insights From GMP Quality Audits</td>
<td>F1: Just In Time for Quality</td>
<td>G1: Medical Device Client and Supplier Management</td>
<td>H1: Management Buys in When Quality and Risk Step Up</td>
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<tr>
<td></td>
<td>Kenneth Wexler</td>
<td>Jocelyn Phillips</td>
<td>Barrett Craner</td>
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<td>2:45 p.m.</td>
<td>E4: The Marriage of the PFMEA and Control Plan ... A Dynamic Control Plan</td>
<td>F4: In Search of Quixote: Auditing and Storming Windmills</td>
<td>G4: How to Survive an FDA Inspection</td>
<td>H4: $4.5 Billion Transbay Terminal (SF)</td>
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<td>JD Marhevko</td>
<td>Kurt Stuke</td>
<td>John Freije</td>
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<td>3:45 p.m.</td>
<td>E5: Executive Roundtable</td>
<td>F5: Insider Advice on Drafting Quality Agreements in the Medtech Space</td>
<td>G5: Risk Control of the Software Development Life Cycle</td>
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Upcoming Webinars:

**Auditing Beyond Compliance**  
By Janet Bautista Smith

- **Wednesday, October 7  
11:00 a.m. – Noon Eastern Time Zone**

This webinar introduces a portable audit model to facilitate a simple, flexible, and effective audit of single or multiple quality system standards and achieve both compliance and initiation of improvement initiatives. This model is similar to a universal adaptor plug, allowing easy connection and interchangeability of the multiple standards even under rapid system changes typical of modern-day operations. This universal plug will allow focus on compliance verification and improvement at a high level of consistency with minimum process disruption and cost.

Emphasis is not only on compliance but also on improvement partnership with operations through the use of strategy models. These strategy models will help accentuate the internal audit role as a dynamic element and catalyst for improvement. Real life-based examples will be discussed to demonstrate the application of this audit model to clarify theories that are commonly viewed as abstract by the novice and, in some cases, misunderstood by experienced professionals.

A simple model built around the concept of Auditing Beyond Compliance is a tool for initiating the discovery of your system’s “hidden factories.” Hidden factories include the many forms of risks (such as process variations, wastes, etc.) not typically uncovered during the traditional compliance audits. This model can also be applicable in preparing your system for the upcoming ISO change to ensure continued compliance and at the same time apply basic lean tools in identifying improvement opportunities. It is not required to have a lean experience to understand and implement this Auditing Beyond Compliance model.

This is the breakthrough from a dormant internal audit program into a proactive tool for added-value improvement. Lean methodology is integrated through simple models that don’t require one to be a lean or Black Belt guru. The focus is using logical sense to understand and apply the concept.

Concept is based on the speaker’s book, *Auditing Beyond Compliance: Using the Portable Universal Quality Lean Concept*.

Lapsing Purpose  
*by Kurt Stuke*

**Abstract:**

In this brief article, the purpose of auditing is explored. The nature of purpose itself and the dynamic between leading and serving is also examined. Ultimately, an auditing purpose that dwells in plurality and focuses on growth (and not risk mitigation) is advanced.

We often long for the “easy” questions during the course of an audit. Easy questions, like shade on a hot summer’s day, afford us the hope of at least temporary shelter. But, in practice, we soon learn that easy questions rarely result in easy answers. At times it feels as if the easier the question, the more difficult the answer. Undaunted by our “unhandsome condition,” we persist.1 We chase these elusive answers for at least two reasons. First, it is our job; our role, like a current, directs us. Second, it is sometimes the case that seeking answers to easy questions forces us to engage the current, described by Thoreau as “an emblem of all progress.”2 Insight and change may dawn when the current lapses.

Continued on page 13
Robert K. Greenleaf, founder of the servant leadership movement, advanced a very easy question when he asked: “What is it you are trying to do?” His simple question presses upon our attention the importance of purpose within our craft. More directly, what is the purpose of auditing? Out of the vast set of questions we pursue on a daily basis, Greenleaf’s simple question, through our response, shapes our mindset and sets the very field in which we dwell and practice.

How do we begin? As auditors, we are trained to focus on the “facts of the matter.” We hope that facts, when coupled with logic, will result in data-driven decisions. In turn, data-driven decisions lift us from the messiness born in living toward the higher and more desirable ground of objectivity. Therefore, facts seem a very reasonable starting point. But if the “facts of the matter” are dependent upon purpose, as posited by Deming within *The New Economics*, and purpose is manifold, then, how do we choose one starting point among the many possible starting points?

Audit program managers, for example, might shape their answer based on the sheer frequency with which they are forced to justify corporate existence. Upper management often (although not always) needs to be sold and resold on the return on investment from specific audits and from auditing programs in general. Purpose, when glimpsed from this perspective, might glimmer with the systemic benefits rendered through auditing.

Perhaps, due to the reality of fighting the good organizational fight and the relentless budget skirmishes that follow, the midlevel managers and fiscal realists among us might be spurred by the tactical necessity of defending financial boundaries. From this angle of vision, auditing is the sole mechanism by which the company will keep the wandering hordes of risk and noncompliance outside of the gates. For these wary veterans, purpose might reflect the financial need to fund and preserve auditing and quality departments in general.

The quixotic types in our midst might be driven through an impassioned concern for the organization. Windmill tilters may define purpose in a way that is far more idealistic than financial or practical. At the heart of this vision is the promise to deliver an improved quality of life while possibly slaying inefficiencies and banishing risks along the way.

How do we arrive at a single purpose given so many possibilities? We could advance the lone answer of “we audit to mitigate risk” as a way of honoring all noted and even unnoted responses. It is not an unreasonable answer; risk mitigation resonates with the vast majority of perspectives. How many times have we explained internally and externally that the identification, analysis, and treatment of risk is of vital importance to an organization? The answer is typically well received as it lends a hard-dollar expression of value. The answer is valid but there are a number of types of auditing and instances of audits that do not “fit” into this particular reductionist “glass slipper.”

Consider the performance audit. As suggested by the *ASQ Auditing Handbook*, the purpose of performance auditing is to assist an organization’s management in driving improvement. Cycle-time reduction is one obvious performance goal that lends itself to measuring and auditing. Risk mitigation seems far afield from the purpose driving performance auditing. It could be objected that process
improvement is an expression of risk mitigation and therefore the singular answer does apply, i.e., the “glass slipper” fits. The issue here is that the semantic or definitional boundaries of risk mitigation would have to be so extended that the difference between risk mitigation and process improvement—even quality itself—would be eroded. That is, the objection entails equating risk mitigation with quality. If the two are the same then Deming’s objection concerning purpose (from above) applies. If so, purpose remains plural and so must the definitional intention (at least if we wish to honor Deming’s notion of profound knowledge within our expression of purpose).

What if, in our search for purpose, we were to cast our gaze beyond the “facts of the matter” and following Parker Palmer’s suggestion, sought the underlying reality that guides all “true professionals?” When watching the current, we do discern a singular underlying pull: We lead through auditing by serving the needs of our customers. Risk mitigation represents a large portion of that need but, as noted above, auditing may drive compliance, performance, or be leveraged for other organizational advances as well.

It is possible to raise a very minor objection to this formulation of purpose as leadership precedes service within the formulation itself. Order suggests that leadership possesses priority over service in auditing. The stressing of leadership does not mandate, however, that leading through auditing entails neglecting service. What is being asserted is that successful leadership through auditing requires the prioritization of leadership, which, in turn, requires knowledge of need and the subsequent technical “know-how” to address the noted need meaningfully.

It appears as if, in this case, we have articulated at least one answer—and a cogent one—to Greenleaf’s question. The answer resonates strongly with our field’s current, commonly held beliefs, and often implemented practices. But despite the allure of the answer, it, like all else, must be tested. We must, after all, rise above our “selves” if the answer is to be trusted.

One possible method of evaluation was forwarded by Greenleaf himself in the form of yet another simple question. For the purpose of auditing, his “best test” may be articulated as: “Do those people and organizations audited grow as a result of our auditing?” Growth was defined in terms of becoming “healthier, wiser, freer, and more autonomous.”

Our response (if we are being honest and, of course, allowing for exceptions) will be more negative than positive. We hone our focus in order to optimize return on time invested and to leverage mitigation. Our narrowed focus does improve our ability to assess, prioritize, and articulate client need. But growth, as described above, is typically outside of our focus. Not including the growth of the auditee, be it at the individual or organizational level, is like trying to take care of a person without caring for the person. It is the equivalent of treating a nonconformity without addressing the cause systemically. Without growth, the root causes driving nonconformities will not only persist but will most likely thrive. These highly adaptive and emergent forces, unlike our bodies of knowledge, are not bound by logic or reason; they will swarm the host culture and be evidenced through several possible symptoms, e.g., a lack of accountability, a reigning sense of apathy, a reactive approach to issue resolution, an environment ripe with political in-fighting, etc. Once abnegation is deeply rooted, these cultures are best depicted as “fallen.” They are marked by despair and brokenness. As difficult as it is to introduce quality to fallen organizations, worse still, is an existence within such cultures.

As auditors, we have experienced these symptoms and culture. Following the current, we prescribe policies, suggest the possibility of more rigid processes (as supported by data of course), or extol the virtues of externalized standards in order to curb what is lacking. In short, we tend to rely on mitigation, a type of negation, to fight negation. Negation can, in some instances, facilitate growth. Weeding, for example, is absolutely necessary when growing a garden. But the garden will not flourish without attending to the other equally vital needs, e.g., watering, feeding, shading, structural support, etc. Auditors and gardeners alike have experienced working in a “garden” that was well weeded yet did not “live up” to aspirations. Negation, more often than not, does not produce growth but merely yields negation.

The results suggest that when we define purpose in terms of leading first and serving second (even with the best of intentions and under the most reasonable of circumstances), it may be at the expense of those we would serve. If we dare to front the current, to turn away from the accepted “surface of things,” we may glimpse the difference that stressing service lends. Our purpose calls us not just to be good at what we do, but, first and foremost, to be good for something and for someone. A living purpose, born among the fallen-ness of the ordinary and of the reality of our clients, rejects abstraction and the myth of objectivity. Facts are reconstructed as “vehicle[s] of some humanity” and not as glimpses of perfection. The exhortation here is to redefine purpose so that the fragile shore-crafts under our care can do more than stay afloat in safe harbors; like us, may they dare to turn their bow into the current for the sake of growth and the possibilities ahead. For many of us, the hope of driving positive change in the lives and organizations we touched was our purpose when we entered the stream. May that current not lapse.
References


About the author: Kurt Stuke has served Adecco, a human resource solution provider, for more than 20 years. In his current role, Stuke leads the operations auditing group and is responsible for finding creative ways to drive positive change. Stuke has a doctorate in leadership and advanced degrees in philosophy and theology. His certifications include CMQ/OE, CQA, CQIA, and LSSBB.

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ISO 9001:2015 Begins With Leadership

by Walter Tighe

As quality professionals, many of us have shared in the frustration regarding the lack of top management commitment, and specifically the lack of hands-on involvement with the company quality management system.

What about management review meetings? Sure, the process of management review meetings does require top management involvement; however, too many times the company quality manager is the delegated source of data collection, measurement representation, and communication to all management review meeting attendees on the quality system effectiveness, or worse, the lack of process effectiveness.

Will the ISO 9001:2015 standard make a real difference in promoting leadership involvement? Yes, I certainly think so, but it will require increased discussion and integration of the quality group and the leadership team. Having accountability requires this. Meaningful involvement and learning from the quality group for top management will be required in the early stages of this transition—a top priority and an essential step.

Let’s face reality. The ISO 9001 standard has not had any meaningful new requirements in 15 years! A mature, certified quality management system has most likely remained in the “been there, done that” stage for many years. Unless you’re working for a technology juggernaut or a progressive auto manufacturer, such as Tesla Motors, radical change has not affected your documented operational management system in years. Consequently, your leadership team’s involvement has been administered in a two- to four-hour management review meeting every quarter or, even more likely, once or twice a year.

Real involvement stems from top management when they realize the quality department is not a departmentalized function, but an integrated unit of established controls and monitoring methods. These methods are monitored against approved criteria, which are aligned with the company business objectives.

A quality truism: When your leaders are accountable, they will want to know what’s required. They will need to know all of the new requirements that will require their attention, time, and necessary resources.

Let’s take a look at the significant leadership differences in the new ISO 9001:2015 standard, and the changing role of the quality group with this new transition.

1. **Understand the needs, expectations, and the requirements of interested parties that are relevant to the QMS. Monitor and review information about these parties and their relevant requirements.**

   This is a new requirement of the standard that is going to take some effort. Typical examples of interested parties from a leadership team would consist of customers, suppliers, and regulatory agencies. What should end up on your list of interested parties is dependent on the size of the organization, your market, the people who perform the work, and the complexity of your organizational processes.

   Here’s something to ponder: What are the needs, expectations, and requirements of the company quality group? Most likely, the quality group will be the body delivering information to the leadership team on the new requirement of “monitor and review information about these interested parties and their relevant requirements.” ISO 9001:2015 Annex A.3 states, “It is for the organization to decide if a particular requirement of a relevant interested party is relevant to its quality management system.” The quality group must have an active role with determining how this clause is applied so that it is workable, beneficial for the organization, and is not treated as a simplified task.

   What methods will you use to identify and monitor this new requirement? Will you use the management review meeting so action plans can be developed with responsible, assigned personnel and the necessary resources allocated? What kind of objective evidence/records will you maintain, and how will they be monitored?

   The degree to which the leadership team and the quality group execute these requirements will directly affect the extended requirements of risk, quality objectives, and planning to achieve them. To be successful, the quality group must ensure understanding of the requirements through effective training on the new standard and hands-on involvement with the leadership team.

2. **Ensure that the quality policy and quality objectives are established for the QMS and are compatible with the context of and strategic direction of the organization.**

   Compatibility in this context requires integrating quality into business processes, as process objectives must now be more clearly aligned with your company’s strategic direction, otherwise known as long-term business goals.

   Define quality objectives that are compatible with the context and strategic direction of the organization. Can the quality group or a quality manager solely define organizational context and strategic direction to ensure the quality objectives’ compatibility? Never. A much broader look at...
the role of the management system is now required by leadership and its related processes.

The “how to” of achieving quality objectives is explicitly specific with the new requirements of (a) what will be done; (b) what resources will be required; (c) who will be responsible; (d) when will it be completed; and (e) how the results will be evaluated. If an organization continues to use management review meetings and the output of documented meeting minutes for this evidence requirement, this will clearly require increased analysis and detail within a project management framework. The level of involvement between leadership and the quality group will be increasing with quality objectives results evaluation and the need to ensure compatibility with the context of and strategic direction of the organization.

3. Ensure the integration of the QMS requirements into the organization’s business processes.

An ongoing debate is that a wide gap of distinction exists between company quality processes and business processes. Experience tells us that wide gaps do exist in some organizations. How many times have we heard “that’s an ISO requirement,” or “the standard makes us do that”? This results in duplication of process measurement and increased labor. This can include separation of information on quality and business performance, measurement methods used, trends and indicators, and responsiveness to actions required.

An aggressive company business plan should include the integration of numerous business quality-related preparations and the controls required to expand operations and business opportunities, yet still maintain overall operational excellence. The impact quality has on a company’s success is often well understood. However, companies have traditionally struggled to integrate requirements and establish metrics that can easily represent the effectiveness of quality in the organization.

Early leadership involvement will be critical for achieving an effective ISO 9001:2015 transition. The company quality group must take the lead. Establishing a solid foundation for required planning, assignment of responsibilities, authorities and related communication methodologies will require a continuous active role within the leadership team and the quality group. Moving quality out of the quality department is now expanding more than ever before.

About the author: Walter Tighe is president/owner of Sustaining Edge Solutions, Inc. a management systems consulting and training firm in Phoenix and Tucson, AZ. Founded in 2002, the company is a full-service provider of design, development, and training of global management systems such as ISO 9001, AS9100 Aerospace, 14001 Environmental, 13485 Medical Devices, ISO/TS 16949 Automotive, 27001 Information Security, Lean and Six Sigma improvement.

Tighe has more than 28 years’ expertise in operational and quality management systems improvement. He has an MBA, is a member of the Institute of Management Consultants, an ASQ Senior member, an ASQ Certified Manager of Quality/Organizational Excellence (CMQ/OE), and an RABQSA Certified Quality Management Systems Auditor. Since 2004, Tighe has been a current member of the ASQ Phoenix Section Executive Committee, performing the role of newsletter editor.
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