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Letter From the Editor

Lance B. Coleman

Hello Everyone,

I am excited as we look ahead farther into 2017 to our 26th Annual Audit Conference, October 12-13 in Addison, TX.

Included in this issue are articles on “MDSAP and the Case for Quality” by David Manalan; “Auditing the Tapestry of ISO 9001:2015 Requirements” by Cathy Fisher; “International Auditing, Part 2” by myself; as well as an extensive News Bytes section.

Thanks as always for your support in reading our newsletter. I hope that you continue to benefit from reading it and appreciate any feedback you care to give. I hope you were able to stop by our booth at this year’s World Conference on Quality and Improvement, meet the Audit Division leadership team, and let us know how we are doing in running our division. As always, please let us know if there are any topics that you would like us to cover in the newsletter. I look forward to meeting you in person at our annual conference this fall!

Kind regards,

Lance B. Coleman

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 résumé 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.



Division Vision

To be the pre-eminent body for providing expertise on auditing and defining expectations for the audit profession.

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.

Upcoming Webinar

Lean Rapid Plant Assessments for More Efficient Audits

Description

Have you ever felt that the plant tour was a waste of time at the start of your audit? Adding aspects of the lean rapid plant assessment to your audits can add significant value to those tours and your audit reports. The lean rapid plant assessment will allow you to maximize the return on a typical plant tour for audits where assessing lean, efficiency, or effectiveness is an important goal.

In this presentation, we will cover a brief history and background of the Rapid Plant Assessment methodology as created by **Dr. R. Eugene Woodson**. We will cover what the RPA is, and also what it is not. We will discuss the benefits of the RPA, and how and why the RPA can be used in appropriate audit situations. Next, we will go through the details of the two assessment tools that make up the RPA and discuss how they are used, with real-life examples. We will then conclude with opportunities to discuss more real-life or general examples from Dr. Woodson's work, along with some analysis and discussion about the long-term benefits of use of the RPA method over time to identify improvements and show progress.

AUDIENCE TAKEAWAYS

After the session, the attendees will take away detailed knowledge and practical application of the rapid plant assessment method and how it can be integrated with the plant tour portion of on-site first- or second-party audits.

ABOUT THE PRESENTER

Kevin Posey is a quality and regulatory executive with international experience in quality management, product development, manufacturing, and regulatory approval for medical devices, defense and aerospace, and mining and exploration, as well as industrial equipment and controls. He also consults, trains, writes, and speaks on quality management, auditing, innovation, and medical devices. He received an undergraduate degree in aerospace engineering to which he's added an MBA in international business. He is a founding member of the Innovation Interest Group and an ASQ Senior member.

PLEASE REGISTER

<https://attendee.gotowebinar.com/register/1824261695875889155>

After registering, you will receive a confirmation email containing information about joining the webinar on June 29, 2017, at 11:00 a.m. EDT.

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 should be in the 400- to 600-word range, articles should be anywhere from 400 to 800 words, and case studies should be 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.

ISSUE	SUBMITTAL DEADLINE	ISSUE'S MAIN THEMES
March 1	January 15	Preview of ASQ WCQI and open topics
June 1	April 15	Recap of ASQ's World Conference and open topics
September 1	July 15	Training, certification, back-to-school, and Audit Conference
December 15	October 31	Conference recap, year-end reflection, and looking ahead to next year

Tips From the Trenches

International Auditing, Part 2

In part one of this two-part series, we discussed how to successfully plan for an international audit. Now let's look at successful engagement while on the ground in a foreign land.

To begin, you want to arrive two days before your audit is scheduled to start. This way your body can begin to adjust to the time difference; plus, it gives you an additional day to recover after what will be a long and tiring journey. Confirm with the auditee that you have arrived safely in town (assuming they weren't the ones to pick you up from the airport). Also, be sure to have at least one contact phone number from the auditee whom you can call after-hours if any issues arise that you cannot handle. As you arrive in town and throughout your visit, you will want to take into account any local safety concerns above and beyond the standard security precautions you employ when traveling domestically. Robbery, fraud, kidnapping, identity theft, and more can occur at or near airports, expensive hotels, and in seemingly ideal settings. For example, in Shanghai on Nanjing Road (their Fifth Avenue), ATMs are in booths built into building walls with doors to prevent distance viewing and theft of your credit card number and PIN. At a \$300 a night hotel in downtown Cape Town, your room key is checked by security before you are allowed to go up on the elevator to your floor. You need to research not just the culture, but also any potential safety or security risks in the area that you are traveling to. During your last audit team meeting, before beginning the audit on the next day, you will go over audit purpose, scope, and assignments as well as any potential workarounds expected from conducting an audit at a non-English speaking facility. Additionally, you will want to go over any cultural basics that you feel would be important for getting off on the right foot: Do you greet the highest-ranking person in the room first? What are the rules for the proper exchange of business cards? Are there any nuances around male-female interaction?

When auditing in the United States we often use a combination of the element and process approaches. The ratio of the methods used (50/50, 60/40, and so forth) would be determined by the purpose of the audit, the nature of the auditee, and a variety of other factors. When auditing a facility where you don't speak the predominant language, you should plan to spend more time out on the floor than typical. Walk the process. Let the process-based

approach take prominence. It is easier to understand something when you are looking directly at activity taking place. Allow longer time for the facility tour—90-120 minutes (to allow for stopping, asking detailed questions, and taking notes)—instead of the typical 30-minute tour that we would expect here in the United States. You would still want to use the elemental approach as well as matching the auditee's internal procedures and records to external requirements. Here's how.

In the United States, it is easy to be spoiled when conducting audits. We usually have more than one person pulling documents and records to support the audit, and there is often one person per audit team member! When traveling internationally, you will have, at times, one person who speaks English that you have to share amongst your audit team members. When this is the case, it is important to implement a strategy that will allow for other team members to continue working while one auditor at a time engages with the interpreter. An interesting fact about the romance languages (Spanish, French, or Italian) is that if you know what you are looking for in a document, you can figure out certain key words. This is also the case when reading German as English is considered a Germanic language. Typically, there are enough to confirm what the main aspect is of a required document. Make notes for specific, more detailed questions to ask when the interpreter becomes available. Thus the time needed with an interpreter when reviewing documents or records is minimized. Look below for examples at the French, Spanish, German, and Italian words for "segregate" and "nonconforming" to understand how this could be the case.

- French: séparer, non conforme
- Spanish: segregar, no conforme
- German: trennen, nicht konform
- Italian: segregare, non conforme

When you are working with the interpreter, it is especially helpful to use tiered questioning:

- Please explain how your so-and-so process works.

Continued on next page

- Where does it say that in your procedure?
- What is your evidence that this process is implemented as described?

As you are managing time for your audit, you will need to factor in that going through the interpretation process will just make everything take longer. Also be aware that, even when translated into English, some words may have a different meaning across different countries. Review process maps and flowcharts, when available, to understand how work flows throughout the facility, and help identify areas of possible concern.

Let's take the example below of questions you might ask to assess the control of the nonconforming material process in a facility that you are auditing where the number of English speakers are limited. You will notice that in addition to asking for explanations, you ask them to "show me" how they implement their system. Also, to "show me" in documents and records evidence of what they have described. Again, remember, at least in the Romance languages, you can often more or less make out what is being said if you know what you are looking for. In non-Romantic languages, look for completed records, and then you have to take the auditee at their word.

- ▶ What do you do when nonconforming material is found?
- ▶ How do you document nonconforming material?
- ▶ How do you dispose of nonconforming material?
- ▶ How do you identify the material itself as nonconforming?
- ▶ How do you keep nonconforming material from being used?
- ▶ Is what you have told me documented in a nonconforming material procedure?
- ▶ Can you show me where in the procedure?
- ▶ Can you take me to examples of nonconforming material in your facility so that I can verify that it is segregated and/or marked as you describe?

Finally, and most importantly, the vast majority of suppliers, both foreign and domestic, want to show off their facility, want to provide quality products, and want to support a successful audit. With proper planning and strategic implementation of auditing best practices, while taking into account cultural and language differences, as well as logistical obstacles, we can help them to do so.

About the Author

*Lance B. Coleman has more than 20 years of leadership experience in the areas of quality engineering, lean implementation, and quality and risk management in the medical device, aerospace, and other regulated industries. He has a degree in electrical engineering technology and is an ASQ member, as well as an ASQ Certified Quality Engineer, Certified Six Sigma Green Belt, Certified Quality Auditor, and Certified Biomedical Auditor. He is also an Exemplar Global Principal QMS Auditor. Lance is chair of US TAG 302 – Guidelines for auditing management systems as well as a voting member of US TAG 176 – Quality management and quality assurance. Lance is the author of *Advanced Quality Auditing: An Auditor's Review of Risk Management, Lean Improvement and Data Analysis* (Quality Press 2015). Additionally, Lance is an instructor for the ASQ Certified Quality Auditor Exam Preparatory and FMEA courses. He is the ASQ Audit Division newsletter editor and chair-elect of the ASQ Lean Enterprise Division. As principal consultant of Full Moon Consulting, he has presented, trained, and consulted throughout the United States and abroad.*

News Bytes

2016 Paul Gauthier Award

John F. Mascaro, a long-time member of ASQ and the Audit Division, is the 2016 recipient of the ASQ Audit Division's Paul Gauthier Award.

The Paul Gauthier Award is the highest honor bestowed by the ASQ Audit Division. Each year the ASQ Audit Division seeks to recognize a person who has made or is making an original, significant, or lasting contribution to the field of auditing.

It is said that it is easy to sit up and take notice, what is difficult is standing up and taking action. The ASQ Audit Division is celebrating the fact that the 2016 Gauthier Award recipient stood up, took action, and would not take "no" for an answer. This year, we are celebrating his commitment, enthusiasm, longevity, and sheer, hard work.

This year's winner has put his whole heart and soul into the continued success of the ASQ Audit Division and auditing in general.

John has been a member of the ASQ Audit Division for more than 25 years and continues to display outstanding characteristics of leadership, professionalism, improvement, and development in the quality and auditing field.

He has held positions of Audit Division chair, vice chair of administration, vice chair technical, international regional councilor, and Region 14 councilor.

John has also served as conference chair for three very successful Audit Division conferences, and he has been a part of all of the conference committees working in arrangements and logistics.

He has significantly contributed to the development, methods, techniques, and approach to quality auditing and has demonstrated exceptional leadership and made fruitful contributions when promoting quality auditing, in both the national and international arenas.

John co-authored and participated in a leadership role in developing and implementing the ASQ Audit Division

Certified Quality Auditor preparation (refresher) course, and continues to be a presenter of that course.

In his role as chair of the ASQ Audit Division, he improved the division's overall performance within ASQ, including its responsibility to provide division members with improved opportunities for training and networking.

John continues his work with the Audit Division and currently holds the two positions of marketing chair and vice chair technical.

Congratulations, John, and thank you for your dedication to this division and to our profession!

2017 ASQ Fellows

Congratulations to the following Audit Division members who have achieved Fellow membership status in ASQ for their contributions and achievements to quality.

Owen Ramsey, Lloyd's Registrar Quality Assurance, Laurelton, NY – For outstanding contributions in advancing process understanding and deployment of Lean Six Sigma rapid improvement methodology initiatives, for planned and spontaneous talks at ASQ-sponsored and other technical forums, and for promoting and influencing the expansion of diversity within ASQ and non-ASQ leadership communities.

Jennifer Joy Stepniowski, Pro QC International, Tampa, FL – For drive and passion in raising the voice of quality, in addition to the ongoing dedication to and instructing of quality education that is accessible to all, continuous support of local section activities, and management excellence via a demonstration of professional competence in quality across industries and global cultures.

Sandra Storli, Zimmer Biomet, Gurnee, IL – In recognition of 30 years of quality-related experience supporting highly regulated organizations with quality systems, clinical trials,

and regulatory affairs compliance, and for activities within the quality community including the ASQ Northeastern Illinois Section, ASQ Food, Drug, and Cosmetic Division, ASQ Audit Division, and ASQ Learning Offerings.

William Taraszewski, Meda Pharmaceuticals, Decatur, IL – For outstanding leadership in quality management in the pharmaceutical industry, for devoted section leadership, and for career-long professional development in the field of pharmaceutical analysis.

Fellow membership status is awarded to individuals who are ASQ members in good standing and meet the following criteria:

- Have at least 15 years of quality-related experience
- Achieve requirements across six professional categories
- Are sponsored by peers and endorsed by their ASQ section or division
- Have been a Senior member for five years or longer

“ASQ Fellows are leaders in the quality community, working to improve their organizations and the communities in which they live,” said ASQ Chair Eric Hayler. “These are individuals who dedicate their time and expertise to make the world a better place.”

The new Fellows were honored at a ceremony at ASQ’s World Conference on Quality and Improvement, May 1-3, in Charlotte, NC.

2017 ASQ Crosby Medal

Congratulations to Audit Division member **Daniel J. Zrymiak**, who along with Roderick Munroe and Govindarajan Ramu, received the ASQ Crosby Medal at ASQ’s World Conference on Quality and Improvement this May in Charlotte, NC, for their work on the second edition of *The Certified Six Sigma Green Belt Handbook*.

The Certified Six Sigma Green Belt Handbook reference manual is designed to help those interested in passing the

ASQ certification exam for Six Sigma Green Belts and others who want a handy reference to the appropriate materials needed to conduct successful Green Belt projects. It is a reference handbook on running projects for those who are already knowledgeable about process improvement and variation reduction.

Daniel is a performance and functional excellence lead at Accenture in Vancouver, Canada, and a Fellow member and volunteer leader/committee member for various ASQ divisions, technical communities, and member units dedicated to advancing quality professionals. He is active with ASQ Quality Press as an author and reviewer. He joined ASQ in 1997 and became an ASQ CQA in 2000.

Congratulations, Daniel!

US TAG 302

The third meeting of US TAG 302 – Auditing management systems was held in Milwaukee, WI, March 2-3, to finalize the US position on the Committee Draft of ISO 19011, which is being revised. The second meeting of PC 302 – Auditing management systems (international committee of which the US TAG 302 is a member) took place in Milan, Italy, April 3-7. The expected outcome of this second international meeting is a draft international standard (DIS) of ISO 19011 which will be the basis for further revisions over the next 18-24 months. The next US TAG 302 meeting will be October 10-11, in Addison, TX, just prior to the annual ASQ Audit Conference.

Lance B. Coleman, Audit Division DMC member, is TAG 302 chair. Chiniqua Garcia of CR Bard is the TAG 302 secretary. If you are a resident of the United States, you can apply to be a member of TAG 302 and contribute to the revision of ISO 19011. Please contact Julie at standards@asq.org for an application to join TAG 302. If you live outside the United States and would like to be involved, please contact us and we will give you the contact information for the ISO member body in your country.

26th Annual ASQ Audit Conference

CONFERENCE OVERVIEW:

“Blueprint for a Successful Audit Program”

Acknowledge the Past, Embrace the Present, Prepare for the Future

Preconference: October 9 – 11, 2017

Conference: October 12 – 13, 2017

FOR PROGRAM INFORMATION VISIT:

www.asqauditconference.org

INTERCONTINENTAL DALLAS

15201 Dallas Parkway | Addison, TX 75001 | icdallas.com

Centrally located in the heart of North Dallas in Addison, just 13 miles from downtown, this vibrant, bustling district includes a wealth of shops, restaurants, and bars all within walking distance. This Dallas luxury hotel is an urban retreat with easy access to the northern suburbs, Love Field, and DFW International Airport. The hotel’s restaurant Q de Cheval has been recognized by the readers of the *Dallas Morning News* for the “Best Sunday Brunch in Dallas.”

DON'T MISS THIS AMAZING OPPORTUNITY!

MDSAP and the Case for Quality

This article provides a taste of what the Medical Device Single Audit Program (MDSAP) is about, how it's beginning to change auditing for medical device companies worldwide, and where to get more information. It also discusses some of the case for quality and suggests that this combination points in a future direction for the medical device industry.

The MDSAP's origins in the FDA included Kim Trautman and others who saw beyond the quality system inspection technique. The efforts that began with the Global Harmonization Task Force were the international coordinating body and continued as the International Medical Device Regulatory Forum, replacing the GHTF.



MDSAP's goal was to reduce the burden of regulatory oversight from various countries by using a one-audit-fits-all model. The program is also a benefit for firms that often host audits from five or six regulatory authorities in a year.

The current regulatory participants are Australia, Brazil, Japan, Canada, and the United States. The World Health Organization, European Union, and others will likely join.

In the United States, the FDA will accept the MDSAP audit as a substitute for routine inspections. In the MDSAP system, there are auditing organizations that are assessed for compliance using ISO 17021. Assessment is on a four-year cycle. You should expect Intertek, SGS, TUV, BSI, NQA, and other current notified bodies to become MDSAP registered.

During the development of MDSAP, some really important concepts began to emerge. In 1994 with the second edition of ISO 9001, everything was equal in auditing the quality system. If you were supposed to have a procedure, and didn't, that was an audit finding regardless of how important the procedure was to the quality of the finished product. If you are familiar with 1996 FDA-CDRH QSIT,

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About the Author

David A. Manalan, president and founder of INQC Consulting, has more than 50 years of experience with companies regulated by FDA, EPA, OSHA, and similar agencies. Beyond FDA quality system regulations, he has been active in environmental issues, especially in the areas of pollution prevention and toxic use reduction. David is an ASQ Fellow, a member of the Boston Section, an ASQ Certified Quality Auditor, Certified Biomedical Auditor, and Certified Software Quality Engineer. David worked on the ASQ task force to develop the Certified Biomedical Auditor Body of Knowledge and developed and taught courses for ASQ sections in medical device regulations, validation tools and techniques, CQA exam preparation, and CBA exam preparation.

you recall another underlying premise. By inspecting a few key systems, the compliance of the entire quality management system could be assessed.

When you look at some of the written materials on MDSAP, you'll be reminded of QSIT except for the numerical scoring of nonconformities. The mission of MDSAP is jointly to leverage regulatory resources and reduce the routine inspection burden for regulatory agencies.

By managing an efficient, effective, and sustainable audit program along with management of auditing organizations, this mission can be accomplished.

Basic Steps in the MDSAP Concept

First, a regulatory authority, such as the FDA, assesses an auditing organization and "recognizes" it. Next, the manufacturer is audited by an AO. The AO issues a report to the manufacturer and to the regulatory authority. The regulatory authority bases its decision on the report.

How do we construct or modify a QMS to meet the MDSAP? Generally, ISO 13485 will work using MDSAP to identify additional regulatory issues for inclusion.

What's the payoff for all this effort? Why would I invest in this? First, you may have only one audit per year or less frequently for regulatory purposes. Second, MDSAP provides the additional regulatory requirements that ISO 13485 refers to in citing "regulatory requirements." Third, the standardized nonconformity grading reduces the chance that a nonconformity's importance changes with the auditor. Lastly, FDA, Health Canada, and others will transition to MDSAP within three years.

MDSAP has an audit sequence flowchart that identifies five basic QMS elements. Risk management surrounds all five basic QMS system elements but doesn't include adverse events, adverse notices, registration, or market authorization.

Four primary processes are listed: management; measure, analyze, and improve; design and development; and production

(service) controls. A fifth process, purchasing, is listed because it is a supporting process for the other four.

MDSAP has four primary processes, and the QSIT has four major subsystems. The QSIT CAPA subsystem isn't apparent in MDSAP, but you're still expected to have a CAPA system if only to track and investigate complaints. It's not considered to be a standalone process. MDSAP has an audit model that instructs us in the overall audit as well as in the audit of specific processes. There are numerous lengthy documents explaining the system and its audits.

The big difference in MDSAP is a universal nonconformity grading system. It recognizes that some deficiencies are worse than others! After only 22 years, we've moved beyond "all missing items are the same."

First, severity is graded. This results in a number 1 to 4. Then, repeat nonconformities against the same QMS sub-clause that could add 1 to the previous grade. Finally, there are two escalation rules that could add 1 more to the total score.

How does this grading work? A simple matrix with "impact on the QMS and occurrence." Low impact, infrequent is 1; high impact, frequent is 4. Impact on the QMS is more important than frequency, so high impact and infrequent is 3. If this is a repeat, add 1. Absence of a documented process or procedure of any requirement, or release of a nonconforming medical device outside of the controls of the manufacturer's QMS, add 1. An Excel workbook is provided to take care of assigning a nonconformity score.

Nonconformity grading is judging the importance of quality based on sections of a standard.

MDSAP has pre-identified which elements of a QMS are most important.

Great, now you have had a taste of MDSAP. So why is the case for quality in this talk? Nonconformity grading is judging the

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The Audit Report

importance of quality based on sections of a standard. The case for quality is more detailed.

FDA-CDRH wants to move from compliance to excellence (Malcom Baldrige, anyone?). The case for quality is reaching beyond mere compliance; being better than the lowest common denominator. This is not as recent as you might think. Twenty years ago, the FDA was talking about a level of excellence—“state of the art”—the best we can do today. Thus, old methods and old results may not be acceptable in future devices.

State of the art is generally recognized as the “best we can do today.” It also appears in the Medical Device Directive. If your product can be “generally acknowledged as state of the art,” it has acceptable risk. MDSAP has pre-identified which elements of a QMS are most important. The case for quality is looking for innovative ways to assure high quality devices.

MDSAP is a systems-level approach—the case for quality is more of a product-level approach—but they both aim for excellence. Expectations are moving from compliance to practices that create higher quality outcomes by focusing on design and production. How will this happen? Collaboration with industry during pilot programs. Where will this information be captured and how will it be used? ASQ and AdvaMed are supplying resources. The FDA will document the results of pilots.

This is an area where we will see major change and adjustment in industry, and I’ll wager that the concept will spread to other industries and other audit standards.

More information can be found at <http://fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/> and <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm378185.htm>.



Auditing the Tapestry of ISO 9001:2015 Requirements



The requirements of ISO 9001:2015 are intended to be applicable to any organization, regardless of its type or size, or the products and services it provides. ISO 9001:2015 specifies requirements for a quality management system when an organization:

- a) needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and
- b) aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

Many of the new requirements found in ISO 9001:2015 challenge auditors to look beyond typically prescribed audit evidence and more deeply explore the interconnected nature of an organization's quality management system processes. In addition, the new ISO 9001:2015 requirements can be considered from multiple levels of an organization.

The model represented in figure 1 shows five structural levels that an organization can directly control:

The ISO 9001:2015 requirements can be viewed from this business ladder perspective as a way of defining and guiding the auditing of QMS activities. The business itself weaves the horizontal layers in a kind of tapestry. As an example, let's consider ISO 9001:2015 requirement section 4.1 "Understanding the Organization and its Context." This requires organizations to "determine external and internal issues relevant to its purpose and its strategic direction."

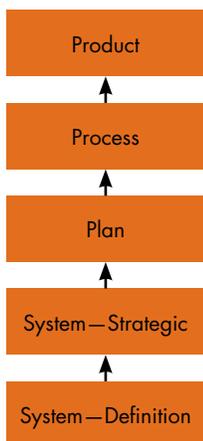
At the **system level**, this requirement can be considered from the standpoint of initially defining the QMS and its activities. For example, in defining the scope of an organization's QMS, consideration is given to such external and internal issues (illustrated in ISO 9001:2015 section 4.1). The external issues may include the target

About the Author

Cathy Fisher

is founder and president of Quistem LLC, which provides online and onsite management systems implementation, update, and assessment services for manufacturers and other industry sectors. Cathy has more than 30 years of respected auditing expertise, having led internal audit programs at many manufacturing organizations during her career. Cathy also has extensive experience conducting management systems registration audits, as well as establishing supplier evaluation and development programs. She has held numerous auditor certifications including ASQ CQA, RAB-Certified Quality Systems Auditor, and ISO/TS 16949 IATF-recognized auditor.

Figure 1 – Business Ladder



Continued on next page

markets served, customer expectations and satisfaction, accountability, product design, and services offered. From an internal perspective, the organization's technical competencies, inputs or resources to be transformed into outputs, and physical location could affect how to determine the organization's QMS scope. Auditors look to the scope of an organization's QMS to determine what technical expertise is required in auditing their QMS, as well as in anticipating the types of processes that would need to be included as part of the audit.

ISO 9001:2015 requirements can also be viewed from a **strategic perspective**, which influence changes to the QMS at the system level. Looking at the "Context of the Organization" requirement again, the organization's leadership would consider external and internal issues when formulating its business plan whether it is long-term (more than five years) or near-term (one to three years). Certainly changes in external and internal issues (refer to ISO 9001:2015 subsection 9.3.2, Management Review Inputs) could shape an organization's strategic direction going forward. For instance, if new technology alternatives are quickly absorbing market share, the organization would need to consider whether to adopt such new technology or identify an alternative business strategy. It may in turn change the scope of the organization's QMS. Likewise, organizations faced with an aging workforce internally need to consider succession planning and retention of organizational knowledge (refer to ISO 9001:2015 subsection 7.1.6) as part of their strategic direction. Auditors will find evidence of consideration for these changing external and internal issues in strategic/business planning discussions, management review results, and annual reports for publicly traded companies.

For the **planning level** of the business ladder, specific customer requirements may also drive external and internal issues that affect the organization's QMS. If a customer were to request a new product that requires extensive development activity for the organization, feasibility and risk consideration would highlight potential internal issues. This could include limitations in existing resources (refer to ISO 9001:2015 subsection 7.1.1) and external issues, such as availability of technology and employee competency to support the organization's development process. Thus, connections between context of the organization

(which is discussed in ISO 9001:2015 section 4.1), actions to address risks and opportunities (ISO 9001:2015 section 6.1), and operational planning and control (ISO 9001:2015 section 8.1) are recognized. Audit evidence at this level may include results from gathering customer and other project requirements and then a review of these requirements relative to the organization's capabilities.

Considering external and internal issues from the **process level** of the business ladder, organizations encounter daily issues in their ability to consistently control their processes needed for producing products and/or delivering services (refer to ISO 9001:2015 subsection 8.5.1). Daily internal issues could include attendance of the workforce—especially during cold and flu season, unexpected equipment breakdowns, or even a workplace fire or other disaster. External issues that affect an organization's operations could include availability of material/inputs, especially if there is a supply shortage or disruptions in utility services, such as electricity. Auditors can look for evidence of how organizations identify these issues (ISO 9001:2015 section 6.1), communicate them (ISO 9001:2015 section 7.4), and act upon them (ISO 9001:2015 subsection 8.5.1). This evidence might be found in production schedules, daily operations meetings, or shift changeover activities.

Finally, considering the **product level** of the business ladder, external and internal issues can exist here as well. For example, external issues could include near-term changes in customer demand affecting operating schedules and inventory levels. Recalls or other field events of competitors could also affect the sales of an organization's product. Internal issues at the product level could include processing errors that generate a large quantity of nonconforming outputs (ISO 9001:2015 section 8.7) or inventory inaccuracies that affect availability of product for shipment to customers. These events are excellent triggers for selecting appropriate audit samples to evaluate the effectiveness of an organization's QMS in consistently fulfilling customer requirements.

To adequately define and audit an organization's QMS, the application of each ISO 9001:2015 requirement at these different business ladder levels should be considered. In doing

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so, the interaction of ISO 9001:2015's requirements—and therefore an organization's QMS processes—becomes apparent.

In addition, each of these processes along the business ladder that address ISO 9001:2015 requirements should also be viewed from the plan, do, check, act perspective. This is the thread that holds the tapestry of the organization's business ladder together.

Rather than viewing ISO 9001:2015's requirements linearly or relative to one level of the business, auditors can assist organizations in recognizing the tapestry these requirements provide for defining, implementing, maintaining, and improving their QMS, which help the business to optimally function efficiently at all levels.

My proposed approach can be presented as follows:

- 1. Select any ISO 9001:2015 requirement.*
- 2. Identify what processes in your organization's QMS relate to that requirement at each of the business ladder levels.*
- 3. Also consider what audit evidence would be available in these processes to support the selected ISO 9001:2015 requirement.*
- 4. Remember audit evidence can be tangible observation or statement of fact.*

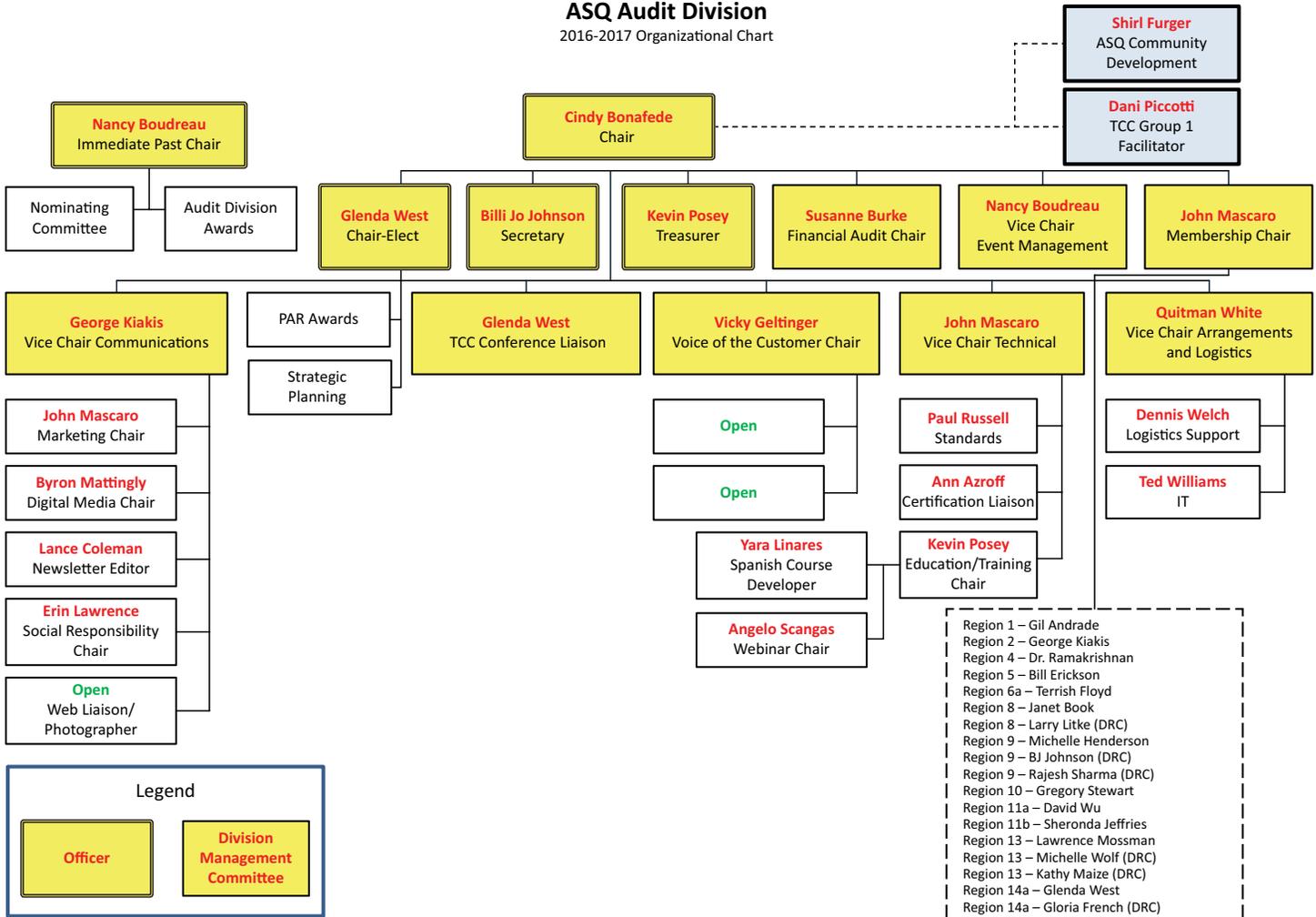
If inspired by this article, please feel free to email me at cathyfisher@quistem.com and share your ideas on how to audit different elements of the ISO 9001:2015 tapestry.

Volunteers Needed

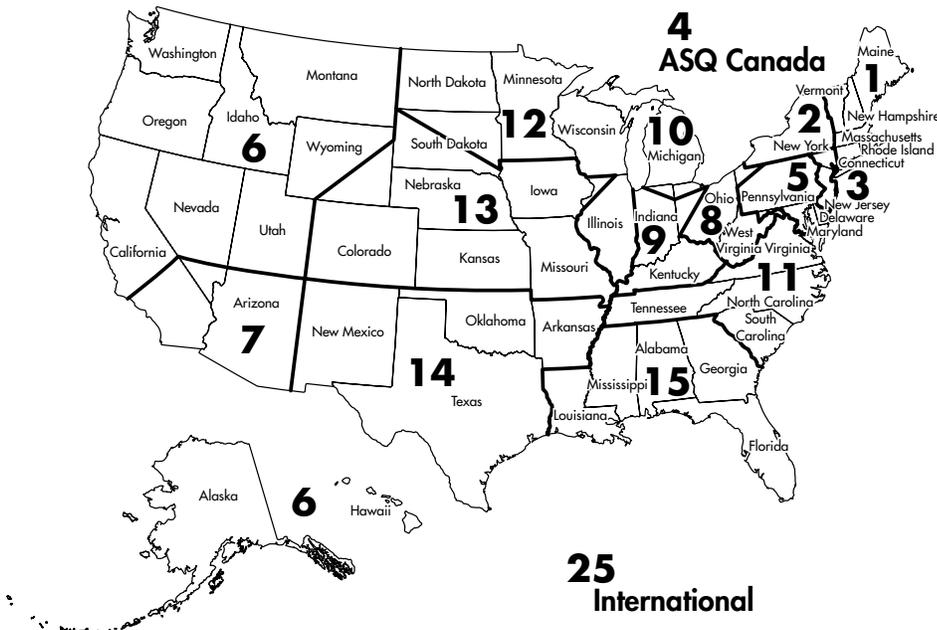
If have enjoyed reading our newsletter and are interested in being trained to become our next newsletter editor, please email me at lance.b.coleman@gmail.com.

If you are interested in other volunteer opportunities within the Audit Division, please let me know and I will forward your information to the correct person.

ASQ Audit Division
2016-2017 Organizational Chart



ASQ Region Map



May 2017

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Division News Bytes – World Conference on Quality and Improvement Recap and Other News

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