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Chair's Message

Welcome everyone. This is my first "Message From the Chair" as the 2014–2015 Audit Division chair.

I want to publicly thank George Callender, the previous chair of the Audit Division, for all the help, support, and mentoring he has given me these past two years, and congratulate him on two outstanding and successful terms as Audit Division chair. George will not be leaving us but will instead continue

as the immediate past chair so we can continue to benefit from his knowledge and experience.

I also want to thank our membership for once again making the 2013 Audit Division Conference in Tucson, AZ, a huge success. Based on feedback, the attendees learned a lot of new information and tools that they were able to take back to their own organizations and implement.

This conference was our first joint conference with the Quality Management Division. In this edition of the newsletter you will learn some interesting statistics about the composition of the conference attendees and experience some conference activities as captured through the eyes of our photographer, Nancy Crenshaw.

We are really excited about the new Performance Awards and Recognition (PAR) program that ASQ has begun implementing for divisions, sections, and interest groups. This has an impact on our strategic planning for 2014–2015 since PAR encourages divisions to plan and budget for activities that add member value. One of the more interesting features of PAR is that it rewards divisions for implementing new and innovative ideas that will excite our membership!

Our plans for 2014 and beyond include translating the Certified Quality Auditor preparation class into Spanish. This entails translating the course material, slide presentation, and *The ASQ Auditing Handbook*. Additionally, we will be training Spanish-speaking instructors. You can see the entire strategic plan on the ASQ Audit Division website.

2014 is a year of leadership change for the Audit Division. Cindy Bonafede has moved from the position of treasurer to chair-elect, and Glenda West is our new secretary. Mary Chris Easterly, whom many of you may know as a tutorial presenter at our audit conferences, is now the new Audit Division treasurer. Bruce Knutson is our new financial audit chair, Joyce Hopperton is our new vice chair of communications, and John Mascaro, a longtime member leader and past chair of the Audit Division, will be our new marketing chair. Welcome all to your new positions.

We have created two new positions this year for something I have considered is a gap in our communications channel. I think we can agree it is very important to communicate to members and potential members using the communication channels they use. To that end, our new social media chair, Mike Villa, has been tasked with keeping us current on Facebook, Twitter, and LinkedIn and keeping our website current with new material. Be sure to follow us! Additionally, our new webinar chair, Angelo Scangas, will be seeking presenters for our new quarterly webinar series that will be free for division members.

This is the first newsletter edited and published by our new newsletter chair, Lance Coleman. Though not previously a member leader for the Audit Division, you probably know Lance from one of his many published articles or classes. Lance is also in training to become a CQA refresher class instructor. If you would like to publish an article or participate in a webinar, please contact Lance. His contact information, as well as all of the member leaders' information, can be found on the Audit Division website.

Other members of the 2014–2015 leadership team include Nancy Crenshaw as Internet liaison, Doug Berg as vice chair technical, Susanne Burke as voice of the customer chair, Lawrence Mossman as membership chair, Ted Williams as the IT guy, and Quitman White as our vice chair of arrangements.

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 three 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.

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.

We also have a group of regional councilors that act as our “boots on the ground” when it comes to liaising with local sections. You can find the entire team on the organization chart that is published in this newsletter or by going to the Audit Division website.

Many people have already asked when and where we are having our Audit Division Conference for 2014. This year we are trying something different. The Audit Division—along with about 10 other divisions at last count—will be participating in a joint conference run by the divisions. The conference will be held in Orlando, FL, on Thursday and Friday October 30 – 31, with preconference tutorials on October 27 – 29.

One of the goals is to allow smaller divisions that may not be able to either fund their own conference or do not have the expertise or experience within their leadership team to manage a conference on their own to have an opportunity to participate in a conference where they can manage the content along with the larger divisions, without risk. This differs from the World Conference on Quality and Improvement in that the divisions are jointly running the conference and managing the content. As you can imagine, this contributes to a secondary goal of offering various topics for multiple areas of interest and industry sectors. This is particularly attractive to our members who belong to multiple divisions! But don't worry, as a sponsoring division the Audit Division will have an entire track of audit-related topics, and we will still be presenting the Certified Quality Auditor preparation class. Stay tuned for more information as it becomes available.

Looking forward to seeing everyone at WCQI this year in Dallas, TX. Please be sure to stop by our booth for the latest and greatest information about what's happening in the world of auditing. I have also heard that our voice of the customer chair, Susanne Burke, is planning something special for those who visit our booth.

Live long and prosper!

Nancy Boudreau
2014–2015 Audit Division Chair



Letter From the Editor

Hello, my name is Lance Coleman and I am extremely pleased to be the new editor of the ASQ Audit Division newsletter—*The Audit Report*. As this relaunch of our newsletter presents the first issue produced in more than 15 months, and we are looking forward to entering the spring season, I felt a broad theme of “preparing for the future” would be appropriate for this issue.

Needless to say part of preparing for the future is learning from the past. Hence the feature for this issue is “The History of Auditing—Part 1” written by ASQ Fellow Dennis Arter. Following this feature, our *Tips From the Trenches* column is “Audit Planning: A Condensed Guide” by John F. Mascaro, ASQ Fellow, former chair of the Audit Division, and contributor to the current ASQ Certified Quality Auditor Body of Knowledge. Looking ahead, ASQ Fellow Denis Devos writes on “a new approach to auditing processes based on process risk.” *The Audit Report* relaunch features a new format, new content, and new authors plus the return of some old favorites. The Newsletter Committee will work hard to make this *your* newsletter and continue to provide the best value possible for our readers. However, we will need your help. Let us know how we are doing. If there is information on the division you would like to see, certain topics you would like to see covered, or authors you would like to read, then tell us and we will try our best to make it happen. Better yet, become one of our authors and share your expertise with our profession. The submittal guidelines are at the back of this issue.

If you attend the World Conference on Quality and Improvement in Dallas, TX, please stop by the Audit Division booth to let us know how we are doing or just to introduce yourself and say hello.

Warm regards,

Lance B. Coleman
Newsletter Editor
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A Brief History of Auditing – Part 1

by Dennis Arter

Introduction

Audits are a fairly recent invention, having started in response to the Great Depression of the 1930s. Over time, they have evolved into two types: compliance and operational. Compliance audits verify that defined controls are implemented. Operational audits determine if controls are defined, applied, effective, and stable. Controls reduce unwanted risk. Both types of audit add value to the organization, as well as to society in general.

Eras of Management

Management practices are evolving as part of a larger trend toward risk management and sustainability. We are entering the fourth era of organization management.

First came the **control era**. The focus was on defining and controlling characteristics, conditions, and contaminants. This era of management focused on product. Mass production of interchangeable parts was the driver. Inspection was the primary tool. This era began around 1925. North America and Europe were moving away from agriculture, World War I, and into manufacturing. This era continued for about 50 years.

Then came the **assurance era**, where the focus was on defining and following processes. Control era principles were enhanced, not rejected. Assurance methods were in full application by 1975, as military and nuclear industries were developing and applying powerful and sometimes dangerous technologies. MIL-Q-9858 was the first to capture this new management approach. ISO 9001 followed this same path. So did the first publication of the Committee of Sponsoring Organizations of the Treadway Commission (COSO). “Say what you do. Do what you say” was the philosophy. Registration and certification of management systems began in this era. It lasted about 25 years.

As the century turned, we entered the **management era**. System thinking was added to control and assurance. ISO 9001:2000 was its grand entrance. We began to understand systems. Processes

were designed and applied to work in harmony with each other. Some of these systems promoted good, while other systems minimized evil. All of these management systems are a form of plan-do-check-act (PDCA). They support risk management.

We are now entering the **integration era**, where quality, safety, environment, security, finance, business continuity, etc., are providing a holistic approach for business and government. We do not reject our past tools and technologies. We continue to use the well-known control-, assurance-, and management-era methods, but are now in our new journey to identify and manage risk and promote sustainability.



Organizational Objectives

All organizations—be they for-profit, not-for-profit, government, or education—must have a reason for being. This is called the mission of the organization.

However, the mission of the organization will not happen by magic. It must be planned and coordinated by the organization’s leaders. These objectives—what we want to accomplish—fall under three general categories:

1. **Operational objectives** determine the goods or services to be offered. They also include the methods used to make and deliver those goods and services.
2. Without a revenue stream, actions cannot occur. So we also need **financial objectives**. Funds must come from someplace: customers, taxes, or grants. We need to monitor and track those funds so we do not run short. For-profit organizations need assurances that investors will be rewarded.
3. We are beginning to recognize an organization can affect not only people but environment around it as well. This influence

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FIGURE 1 Four eras of management

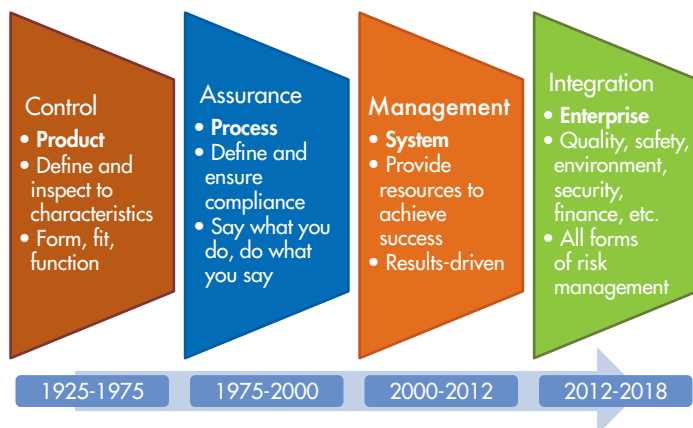


FIGURE 2 Where is risk?



might be beneficial or harmful or perhaps both. Thus, **social objectives** are becoming part of the strategic planning effort.

The organization's objectives are developed and transmitted by the officers or senior executives of the organization. The board of directors is charged with reviewing and advising those leaders.

Once the leaders have defined objectives, internal staff can turn them into actions. They develop and implement systems for defining, providing, monitoring, and improving the goods and services. Eventually, processes (actions) implement all these systems.

But this model is always modified by risk.

What Is Risk?

ISO 31000 was recently published. It has a very elegant definition of risk—the effect of uncertainty on objectives. Risk can be found at the objective, tactic, or process level.

Our objectives may be risky. This is **design risk** in that we might be setting ourselves up as much for failure as success. It can come from internal sources within the organization or external sources from outside. Design risk associated with organizational objectives is managed at the C-level within the enterprise (chief operating officer, agency director, chief financial officer, etc.). It is monitored by the board of directors.

We develop and apply tactics to achieve objectives. Our tactics might be robust or faulty. They could be thorough or incomplete. They could be too complicated to comprehend. This is also **design risk**.

Tactics are implemented through processes. Here we can have **design risks** (faulty processes) or **implementation risks** (imperfect execution).

Many people think of risk as something evil, as in accidents and mistakes. But risk can also be good, as in greater interest rates or winning a race. As humans, we choose to tolerate or accept risk every day of our lives. We drive cars. We light candles. We operate electric drills.

Tolerance for risk varies around the world and in several ways:

- The financial sector tends to accept higher risk than the medical device sector.
- Startup firms tend to be more risk tolerant than well-established firms.
- People in China accept more risk than those in Canada.
- Social norms can influence lifestyle choices, such as smoking or crossing against the light.

Another phrase for this tolerance of uncertainty is risk appetite.

So, we need to build in some management systems to identify and deal with all these many risks.

Controls Manage Risk

Systems and their implementing processes are the controls used by the organization to manage risk. They are designed to reduce uncertainty, so that quality, safety, financial, and other objectives are achieved. Without control there is chaos.

Internal controls are defined by the organization for the organization. At the highest level are corporate or agency policies. Mature organizations also have manuals to lay out the framework for achieving quality, safety, security, etc., at the operating unit. Policies and manuals are internal system plans for establishing and implementing controls needed to reduce risk.

Rather than invent these internal controls from scratch, we often use published international, national, and industry standards as our baseline. Then we customize these standard approaches to fit our own environment and culture. Sometimes we make them stronger; sometimes weaker. It all depends on the awareness and tolerance of risk by our organizational leaders.

The world is not a homogeneous place. There are people, organizations, and nations who wish to both harm and help others. It becomes necessary to impose government controls for the betterment of society as a whole. Laws, regulations, treaties, and agreements serve this purpose. We all agree that the planet would benefit from limiting ozone-reducing fluorocarbons in the air. Chemical weapons produced during the Cold War should be eliminated. Medical devices should meet certain standards of safety and efficacy. When these societal controls cross international boundaries due to trade, there is an incentive for nations and trading partners to use world standards, like ISO 22000 on food safety.

Time-tested Principles of Control

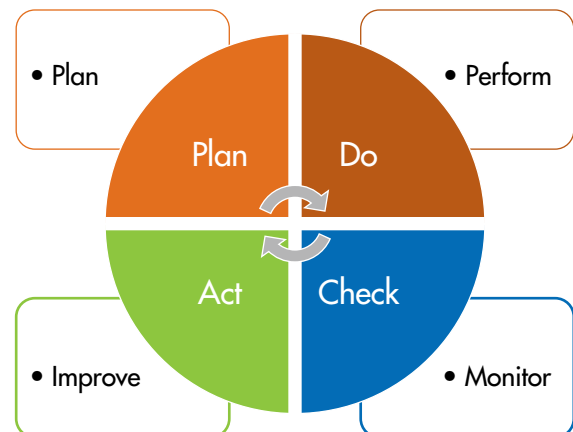
As stated above, management systems and their implementing processes are controls.

I have discovered that all current management systems are based upon the principles of PDCA. This cycle was first described by Walter Shewart. It was later made famous by Joseph Juran and W. Edwards Deming. It has been around for a long time.

The first step in managing quality, safety, environment, security, finances, sustainability, etc., is to decide what needs to be done and how to do it, i.e., “plan.” What are the requirements and how should we achieve them? What are the emission limits for a particular pollutant? What are the risks, their probabilities, and consequences? These decisions are often captured in manuals, procedures, reports, studies, specifications, and other documents.

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FIGURE 3 Management systems are controls



Once the plans are developed and approved, they need to be implemented. We need to apply resources, including machines, tools, and personnel. This is the “do” part of PDCA.

There is natural entropy (chaos) in the universe. Things do not always happen as planned. We need to check on actual implementation to see if it is proceeding as designed.

When variances are detected, they must be addressed. This is the “act” part of PDCA. Sometimes the variance is small and needs little attention. Sometimes corrective action on underlying causes is necessary. Risk management principles of probability, consequences, and tolerance are used, although they are seldom recognized as such. Supervisors will say, “That’s just the way I manage my group.”

Types of Audits

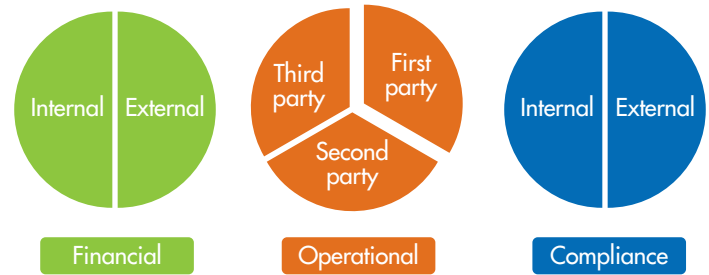
As stated above, the third component of PDCA is “checking,” also called monitoring. It comes in many sizes and shapes, from the informal “management by walking around” to the formal accident investigation. Inspection and audit are common forms of checking. Monitoring is an important part of all modern management systems. From quality to finance to sustainability, monitoring reduces risk. Monitoring improves performance while reducing failure. It is a fundamental component of managing all resources.

Auditing had its start in the 1930s, as the world was recovering from the Great Depression. We needed some oversight on the implementation of newly developed financial controls. So we used specially trained accountants to gather data (called observations), analyze those data (called findings), and present the conclusions to senior executives. These new auditors were from the outside, and were independent of the accounting department.

When these new audits started, we were still in the first era of management: control. The tools used by financial auditors were inspection and test. They measured and reported compliance. We continue to use and benefit from financial audits:

- External financial auditors, hired from outside the entity, look for the truthfulness of financial statements.
- Internal financial auditors are employees of the organization. They look at accounting practices, fraud controls, and truthfulness of financial reports.

FIGURE 4 Many different audits



Things got complicated during the second half of the 20th century. Internal financial auditors did a good job. They earned the trust of senior managers in the organization. They were asked to examine additional parts of business: operations, controls, risk, and performance. They became known as “operational auditors.” The Institute of Internal Auditors became their professional home. The organization started in the United States and is now international. It is highly respected. Operational auditors apply both compliance and consulting tools for performance of their work.

As organizations got larger and global, the risk of noncompliance with laws, regulations, treaties, and accords increased. Auditors from operations and accounting became “compliance auditors.” They focused on the legal aspects of the organization.

We now had financial auditors, operational auditors, and compliance auditors. Their reports generally went to C-level managers and the board of directors.

Things were getting messy. But wait, there’s more!

[Continued in our September 2014 issue](#)

About the author: Dennis Arter is an international author, consultant, and trainer from Kennewick, WA. He received his bachelor’s degree in chemistry from the University of Illinois and became a nuclear submarine officer. After military service, he joined the ASQC and the Quality Audit Technical Committee. He published the first newsletter of the committee and then division. Arter wrote Quality Audits for Improved Performance, a best seller published by ASQ Quality Press. He teaches and publishes on auditing, management systems, and risk. More than 10,000 people have learned to audit from his teachings. Arter is an ASQ Fellow, Certified Quality Auditor (CQA), and former member of the board of directors. He was awarded the ASQ Distinguished Service Medal in 2014. Arter plans to fully retire from professional life at the end of the year.

Thinking about taking exams?

- Certified Quality Auditor (CQA)
- Certified Biomedical Auditor (CBA)
- Certified Quality Engineer (CQE)
- Certified Manager of Quality/Organizational Excellence (CMQ/OE)

All ASQ certification exams—except the Certified Master Black Belt—will all be offered on **Sunday, May 4**, at the World Conference on Quality and Improvement. The next date for some exams is **Saturday, June 7**, at local ASQ sections in the United States and internationally.

Tips From the Trenches— Audit Planning: A Condensed Guide

by John F. Mascaro

The audit process is made up of the following general steps:

- Audit preparation
- Conduct the audit
- Report the findings

Proper preparation is crucial to effectively conducting the audit.

When an audit is well planned, it becomes easier to keep the audit on schedule. You can structure the size of the audit scope not to be too wide or specific; it will be easier to get full cooperation from the auditee; and your audit will produce more usable and effective results.

Audit preparation activities should include initial audit planning activities, audit scope definition, audit dates and logistic arrangements, identifying the audit criteria and reference documents, allocating the appropriate resources to the critical areas to be audited, and defining the roles and responsibilities of the audit team members (if appropriate) as well as the auditee.

Preparation activities are detailed in the following four major steps:

- Plan the audit, identify the timeframe, select the lead auditor, select the audit team, select a subject matter expert (SME) if necessary.
- Determine the scope based on the audit request, scope of service, previous audits, topics on audit checklist, and uncovered issues.
- Schedule the audit and send notification to the auditee, schedule the actual dates, and ensure agreement with the auditee.
- Review documentation and plan logistics: Obtain documents in advance, coordinate entrance and exit meeting dates and time, send out audit notification to all concerned, make copies of checklists for participants, create a flexible schedule of audit activities, create a tentative list of persons to be interviewed, inform auditee of reference documents.

Summary:

- Preparing for the audit before it starts will result in an easier, more effective, and more efficient audit.
- Take time to prepare the audit scope.
- Tailor the audit checklist to be an effective audit tool.
- Identify the lead auditor and audit team.
- Ensure the logistics and arrangements are made.
- Thorough preparations help lead to a successful audit.

UPCOMING EVENTS

WCQI Certified Quality Auditor Certification Preparation

April 30 – May 2, 2014

The CQA refresher training will be held from April 30 – May 2, prior to this year's WCQI.

2014 ASQ World Conference on Quality and Improvement

May 5 – 7 in Dallas, TX

There will be more than 100 sessions and workshops pertaining to the theme, "The Global Impact of Quality." The theme will be explored through sub-themes in five focus areas.

Video recordings will be available for most sessions. If you attend the conference, please stop by our booth, introduce yourself, and pick up a free gift. The five sub-themes are:

- Customer relationships
- Risk management
- Building and sustaining a culture of quality
- Making the case for quality
- Quality fundamentals

For more info go to:

wcqi.asq.org/2014/member-units/

Audit Division Conference

October 27 – 29 at the Wyndham Hotel, Orlando, FL

Find more details on the conference including tutorial and exam dates on the next page.

Where Will the Audit Division Conference Be Held in 2014?

The conference will be at the Wyndham Hotel, Orlando, FL. Tutorials will be held Monday – Wednesday, October 27 – 29; the conference will be held Thursday and Friday, October 30 – 31; and exams will be held Saturday, November 1.

Hi everyone. My name is Nancy Boudreau and I am the Audit Division chair. Some of you may know me from teaching the CQA refresher or from being conference program chair. I would like to share some information with you regarding the Audit Division conference in 2014.

The Technical Communities Council (TCC) (formerly known as the Division Affairs Council) held its biannual meeting in November 2013 and presented division member leaders from all divisions with new and interesting information that affects all of us as members.

One of the items of importance presented was the proposed 2014 TCC joint conference to be held in Orlando, FL. This is the first time a conference has been proposed where any division can participate for a nominal sponsorship fee! It is a cooperative effort open to any ASQ division interested in participating in a conference. You may be asking yourself, “What’s the difference between this and WCQI?” ASQ will be running the administrative, logistics, and registration portion of this conference, but the content is completely controlled by the divisions! As you may know, at WCQI the divisions may submit speakers for their division but ultimately it is ASQ that makes the decision as to who the speakers will be. In the TCC joint division conference, a division will be given a track or a designated number of sessions based on its sponsorship contribution and the number of divisions that participate.

As you know from last year’s joint Audit Division/Quality Management Division conference, the Audit Division has already successfully partnered with both the Quality Management Division and the Design and Construction Division to put on a diverse conference that offered many different perspectives from various subject matter experts.

One of the great things about this conference is it gives smaller divisions, and/or divisions that may not have had the greatest success with conferences in the past, a chance to participate in a conference and limit their risk. Any division’s financial risk is limited to the amount of sponsorship money it contributes. The idea is not to make money but to give a division and its members a chance to participate in a conference.

All conference goers, especially those who belong to multiple divisions, are well aware there are multiple conferences each year—some crossing over others. We may want to participate in a conference, but may be limited to only one or two a year, which forces us to choose between several division conferences. By having multiple divisions join together for a single conference, it is easier to select one conference that covers all of your interests!

I want to thank all our devoted Audit Division members for the great support you have given to our Audit Division conferences. Rest assured, we are not going to let you down in 2014 either. We will be giving the highest sponsorship amount requested in order to ensure we have control over an entire track for our members. Additionally, there will be several other industry and interest groups represented, and all of the sessions are open to all attendees!

The conference theme is: Celebrate the Gift of Quality

Provide the visibility, influence, understanding of, and access to quality both locally and globally. Experience the growth of quality through strategy, innovation, partnerships, and measured results.

Audit Division themes are:

Auditing: Establish Your Personal Brand While Supercharging Your Audit Program. We challenge you to create a new era in auditing. Will it be easy? No. Do you have the desire and determination to transform your audit program, preparing your organization for a constantly changing business environment? Change the way your organization views audits and show them how audits that truly add value can help with decision making and even protect investments. Be a driving force in leading your organization into the future.

Audits That Really Add Value. Understand what really makes an audit value added in a business environment that is being driven in part by risks associated with an unpredictable global economy and cyber threats experienced by small and large corporations alike, and acquire the tools you need to make a difference now.

Show Me the Data. Understand the right data for the right situation. What are performance-based metrics and how do you effectively collect, analyze, and present them.

Money Talks. No matter how good your audit program is, if your organization doesn’t get it, it doesn’t matter. Learn how to successfully communicate with executive-level management using their language.

And of course we will still offer the CQA refresher for those members taking the CQA exam who would like help preparing. The CQA exam preparatory course is a great tool for exam preparation or even if you aren’t planning to take the exam. The CQA exam will also be offered at this conference.

Once you attend the conference, we will be anxious to get your feedback on this new format.

Can’t wait to see you in Orlando!

Risk Is the Compass™: A New Approach to Auditing Processes Based on Process Risks

by Denis Devos

Introduction

Historically, ISO 9001 and its sister standards, have not been looked upon as a value-adding and strategically important activity by the organizations that adopt them. As a matter of fact, many quality management system (QMS) implementations are not performed voluntarily, but as a means to achieve market-place recognition through the third-party registration audit.

It is a pity organizations do not see (or rather, demand) that the quality management system, and their attendant internal audits, can be a key part of their overall operations strategy. Instead, adhering to standards such as ISO 9001 is considered a necessary evil, and as long as no overly disturbing or challenging findings result during audits, senior managers are content to perform this dance with their internal and external auditors to maintain their registration, and thereby continue to placate their customers.

The QMS is often seen as intrusive, and interrupting the “real” work of organizations. As a result, senior managers can’t wait to delegate all responsibility for the system to their quality managers. There are several reasons for this fact, all of which have to do with the traditional implementation of a QMS, and the emphasis placed on certain interpretations of systems by the audit community.

1. Early quality manuals and procedures were written as a series of 20 chapters, each one aligned with a clause of ISO 9001:1994. The new emphasis on “process approach” has promised to solve this, but many organizations still don’t understand how to align requirements with their key business processes.
2. Internal audits are seen as fulfilling a requirement. We perform internal audits to meet the requirements of clause 8.2.2, but expect no more from our audits than that. Senior managers often don’t realize they have every right to expect findings that will expose areas of *risk* and move operational performance to a higher level. Audits may also be infrequent. Many organizations perform internal audits only once per year.
3. Quality professionals are seen as intrusive and out of touch. When the quality manager and others focus the QMS on adding value, and aligning the system with the strategic needs of the organization, the quality management system instantly becomes more relevant.

Much has been written about aligning the QMS with the key objectives of the senior management team and the organization. The highest-priority concerns center around such things as market share, customer satisfaction, cost control, profitability, and overcoming obstacles to success. For that reason, quality professionals

must align themselves with these high-priority concerns, and be prepared to deliver conclusions regarding the suitability of the quality management system to support these goals.

Risk Is the Compass™

The process approach teaches us to not only audit for compliance, but also to audit for effectiveness and efficiency. The definition of effectiveness from ISO 9000:2005 (at clause 3.2.14) is as follows:

“extent to which planned activities are realized and planned results achieved.”

The definition of efficiency from ISO 9000:2005 (at clause 3.2.15) is as follows:

“relationship between the result achieved and the resources used.”

In the past, QMS auditors were taught to audit for compliance to procedures. As time went on, this approach evolved to include the effectiveness of procedures and processes and the efficiency with which these are executed. In the view of this author, we still have one more step to take. Auditing a process within the context of its targets and current performance is good, but not sufficient to fully critique its suitability or optimization. Superior auditing is about conducting a total critique of a process, and *risk* is the lens through which this examination should occur.

Often, procedures are poorly defined and unclear. Many organizations try to “overlay” the process approach onto their current structure of ISO 9001:1994-era procedures. Although this isn’t wrong *per sé*, the task falls to auditors to try to make the linkage between the key business processes of the organization and the various disconnected procedures of the quality management system. The emphasis on measures of effectiveness and performance targets helps us to add context to the audit, but are we always sure we are measuring the right things? On the other hand, reporting that a process is not meeting its performance targets and expecting the auditee to take corrective action is not very helpful. Our audit should bring back objective evidence of weakness so an organization’s senior management can take action to improve the process.

When it comes to auditing for effectiveness and efficiency, it is not sufficient to focus on measurables, but we must focus on the ability of a process to anticipate and manage the risks that stand in the way of success. This is the basis for a total examination of process effectiveness.

If “Risk Is the Compass™,” we accept that it points us in the best direction to pursue our audit trails. Perhaps the most difficult aspect of performing an audit is the up-front planning. It

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FIGURE 1 The evolution of the focus of quality management system (QMS) auditing



is during the planning phase that we determine which aspects of a process we’re going to examine, along with who we need to speak with, and what samples would best represent the total process for us. Since auditors understand they can’t possibly ask everything, or see everything, there is a need to derive the maximum impact from the minimum of amount of time. One of the best considerations for maximizing audit effectiveness is to ask questions and pursue audit trails that best reflect the ability of the process to mitigate characteristic risks while, of course, fulfilling requirements.

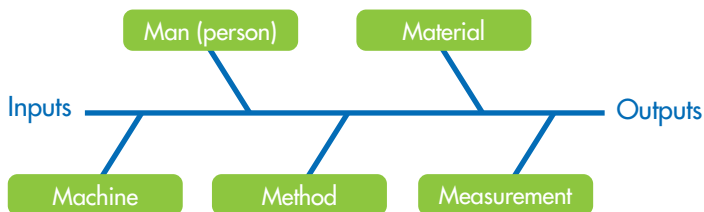
Risk is the perfect context to frame hypothetical questions and to test processes’ ability to manage infrequent or unexpected circumstances. Audit trails and findings related to process risk (when chosen well) will be seen as insightful and relevant by the auditee, and by the senior management team.

Risk and the Fishbone Diagram

The process approach teaches us to look at a process in three dimensions, and not just take the one-dimensional view that auditing only a procedure affords. The process approach is also all about the *context* of an activity; understanding customer needs and why activities need to be performed in a certain way.

It is helpful to consider the three dimensions of a process along the dimensions of the basic Ishikawa or fishbone diagram in its consideration of man, machine, materials, methods, and measurement.

FIGURE 2 The basic fishbone diagram



The Risk Is the Compass Audit Model

This model now combines the fishbone diagram with a basic flowchart. The first step is for the audit team to create a simple flowchart that begins with the inputs to the process and ends with the outputs of the process. Because a QMS audit should focus on the big picture, the model works best when no more than about six to eight process steps are recorded. Simplicity is important, too. Keep the flowchart linear, without feedback loops and other complicating branches.

For the purposes of this model, we combine the five aspects of a process (man, material, machine, method, measurement) into one broad category called enablers. Enablers, simply, are those aspects of a process that enable it to function and be successful.

There are a variety of enablers such as skill sets, procedures, machines, specifications and standards, approval signatures, etc. Enablers are listed next to the flowchart block where they apply, and are aligned with the process at every step.

Risks, similarly, are listed in a column next to their corresponding process steps and enablers. In this way, risks are aligned with the process at each step, and it becomes very easy to generate audit questions.

There is a very important operational difference between enablers and risks. Process risks are characteristic for that process; they are what they are, and cannot ever be completely removed by process design. Risks can be mitigated, but this is a function of the controls, or enablers, that we put in place in response to these risks. The only way to completely eliminate a risk is to undertake a completely different process. For example, driving a car carries with it the risk that the car will break down. This risk will always exist, unless we choose to walk, which is a completely different process for achieving the same purpose. We can reduce the risk that our car will break down by driving a late-model car and performing regular maintenance, but we can never completely eliminate it.

Enablers, on the other hand, are at the discretion of the engineer or process designer, and are completely a function of process design. Enablers should be those mitigation strategies that we put in place to manage and reduce risk, and the impact of a failure event.

As auditors, it is our role to assess the proper balance between enablers and risks, and critique the effectiveness of our enablers at mitigating process risk. Process risks should have corresponding enablers to manage them. Auditors should always focus on those risks that do not have appropriate enablers in place to produce a robust process. But just as too few enablers are evidence of under-control, too many enablers for a corresponding risk is over-control, and is a waste of resources. Consider the balance between enablers and risks in the following simple example of a hiring and orientation process in Chart 1 on the next page.

Flowcharts as an Organizational Model

Advocating the use of flowcharts to represent processes and procedures is not new, but a flowchart such as the one used in Chart 1 serves to bridge the gap between processes and auditing. A single flowchart can serve both as a procedure and as an audit checklist. By adding key requirements and process measures to the flowchart, we have a very complete representation of the entire process with a level of clarity that will allow effective audit preparation. This single-page flowchart becomes the basis for audit questions and a strategy that will enable the auditor to have a clear and concise list of requirements, procedures, and forms, along with risks that can inhibit the successful outcome of the process.

Many companies have found it useful to create a set of flowcharts such as these to serve as documented procedures *and* audit checklists. This serves the dual purpose of making documented systems less cumbersome and more aligned with reality, and designing the architecture of their quality management

Continued on page 10

CHART 1: Hiring process example considering enablers and risks

INPUT: Department needs a staff member	ENABLERS:	RISKS:
Manager completes a personnel requisition	Requisition form #123, Requires a complete justification and full job description	Job requirements may be vague Timing may be too short to react
Requisition is reviewed/approved by human resources	Business plan projects staffing needs: budgets in place HR reviews the requisition for completeness	No forecast for new hiring Skill may be in high demand
HR posts the job opening and recruits outside the company	Job posting boards Succession plans HR staff has experience and a network of contacts	Not reaching the right target group Outside recruiters not fully understanding our needs
Résumés are received and reviewed; interviews conducted	Hiring procedure 18-01 Skill of the HR interviewer Department manager participates HR knowledge of governing employment law	Candidates do not always tell the truth Experience may not be applicable to this job HR interviewer may not understand the technical requirements of the job
Offer made and candidate is hired		
Orientation and training during probationary period	Orientation package #18-02 Employee handbook #18-03 Training procedure #18-04 Training procedure #18-04 Job description Employee training plan	Employee is a poor "fit" Employee doesn't perform duties the "company way" Employee may not have all the skills that he/she said Manager may not conduct training
Evaluation and acceptance as full-time employee	Performance evaluation Form #18-abc Skill of department manager HR follow-up to ensure the evaluation is completed	Lack of objective criteria or standard method for evaluation Training ineffective Employee not treated fairly Evaluation may be late: unsuitable employee not fairly dealt with
OUTPUT: Fully trained, effective, productive employee		

system to be more audit-friendly. In this way, we create a series of “procedures” based on the actual processes of the organization, instead of such unwieldy subjects as *inspection and test status*. Constructing the QMS along these lines also incorporates aspects of the business that would not typically emerge in a typical QMS. As an organization begins to list its key business processes, scheduling, for example, is often identified as a very important business process. Anyone who has ever managed a manufacturing plant knows how critical the *scheduling* process is to their business, yet many quality systems barely consider it. Identifying scheduling as a key business process automatically gives it importance and emphasis in the QMS. At this point it would be expected to create a process map (procedure) and block out the key steps associated with scheduling, along with associated enablers and risks. Now, scheduling becomes a key process, subject to all of the tools and controls of the quality management system, including measures of performance, linkage with other processes, and internal audit.

Conclusions

There is still a concern that quality management systems such as ISO 9001:2008 and ISO/TS 16949:2009 have not yet lived up to their full potential as important sources of feedback and performance data for senior managers. Although the process approach to auditing has improved this fact a great deal, there is

still a lot of room for improvement when we actually construct our QMS using the concepts of the process approach. Our focus on performance and measurable results has increased the credibility of the QMS, but we are not yet fully aligned with what is important to business owners and executives. Risk is an important consideration that is too often neglected when planning and implementing a quality management system.

“Risk Is the Compass” that leads us in the right direction during an audit. Findings based on risk will be relevant, and aligned with what is important to senior management. Findings based on risk will seldom seem nitpicky, or the result of an auditor with their own agenda. Experience has shown that good audit findings, those that expose operational risks, will solicit a sincere thank-you from senior managers.

Using the flowcharting approach described here, auditors and their client organizations will benefit from using a tool that will deliberately and visually emphasize risk as an important focus of their quality management system.

About the author: Denis Devos is the principal advisor at Devos Associates, providing training and advisory services to a variety of industries. He is a professional engineer and an ASQ Fellow. Devos is a long-time member of the ASQ Audit Division and a regular contributor at the annual Audit Division conferences. For questions or comments, email Denis@DevosAssociates.com.

Annual Audit Division Conference Wrap-up: Tucson 2013

By Glenda S. West

We had a great time in Tucson, AZ, during our 2013 ASQ Audit Division annual conference. The conference offered a significant learning experience for auditors having diverse levels of experience and skill, with five keynotes, 36 sessions, and four workshops. It was truly an international event with the 214 attendees representing four countries. The El Conquistador Resort provided a scenic backdrop for the activities, as you will see by our photos. When the conference concluded, those who remained golfed together.

2013 AD-QMD Joint Conference Bookstore

Once again, the bookstore was a big attraction during the conference. I believe most attendees stopped in at least once to soak in the atmosphere, grab some refreshments, chat, browse available books and merchandise, pick up a free book, and/or get an autographed copy of one of our book-signing authors' books. We had more than \$2,500 in book sales.

We had a lot going on in the store this year. We were privileged to have three of our conference speakers graciously agree to come to our bookstore and participate in our book signing: J.P. Russell, Russell Westcott, and Denise Robitaille. A huge thanks to them.

The three participating divisions—Audit Division (AD), Quality Management Division (QMD), and Design and Construction Division (DCD)—were able to offer every attendee a complimentary copy of their choice from a nice

selection of brand-new, out-of-print ASQ books. Everybody loves free stuff! This will probably be repeated in the future. We also had someone bring some slightly used books, merchandise, and a couple of pieces of new merchandise from their personal collection to give away as well. Thanks, John Mascaro! At the close of the bookstore, we donated the remainder of books on the complimentary table to the local section and to one of our sponsors. The sponsor's daughter's school has begun to introduce quality methodologies. Both the school and the local section are working to communicate and support quality methodologies.

Last, but by no means, least, the bookstore co-chair, Cindy Bonafede, and I discovered a new talent. He came into the bookstore Wednesday afternoon with his mom and dad. He has a huge personality. His name is Alex Juhasz! Alex's father was one of the session speakers in the DCD track. Those who attended the reception on Thursday night at the Last Frontier got to see Alex in action. He stole the show with his impressive dance moves, and he danced the night away. The next day some of the Conference Committee received requests to bring Alex to Reno, NV, in 2015 as part of the reception entertainment. Thanks to his mom and dad for sharing Alex with us.

As always, Cindy and I were privileged to network with many of the conference attendees. Thanks to all the attendees who stopped in the bookstore.



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News Bytes

By Lawrence Mossman

Membership Update: We continue to have positive membership numbers in renewals and new members joining the Audit Division (AD). We face the same challenges as ASQ, but involving members in the overall division leadership and various activities has produced positive results. Our membership wants to feel like they are important to the Audit Division, not just another membership number! We have started and are maintaining a volunteer database to draw upon when volunteers are needed. If you haven't had the opportunity to volunteer for a division activity or event, please do so. You can gain recertification units (RUs) for the involvement! And the networking opportunities are tremendous. As stated during our DMC meeting, Audit Division membership is a very important asset of the division makeup and offers leadership opportunities. I challenge you to get involved and see how your talents can be utilized!

Regional Councilors: Audit Division regional councilors (RCs) continue to address the needs of the division as they reach out to members during monthly section meetings and training sessions. Opportunities to join this exciting group exist; so feel free to contact a DMC member to get the entry process started. The Audit Division is one of the few divisions that have RCs to assist the division and overall membership. The latest RC activity is the development of student branches at local colleges and universities in their individual regions. Join the group; it's exciting!

By Lance Coleman

CQA Exam Refresher Course: In 2013 the AD completed development of an exam refresher, begun in the 1990s, to help experienced auditors become better prepared for the Certified Quality Auditor (CQA) exam. The basis for the exam is the new, recently revised CQA Body of Knowledge (BoK), which has an increased emphasis on lean and Six Sigma methods as well as risk management. Class discussion will include an overview of the CQA BoK—offering participants a better understanding of the basic principles and applications that will appear on the exam. All course participants will receive the recently published course text, *The ASQ Auditing Handbook, Fourth Edition*, which can be used as a reference and can be taken into the exam. For more information on taking the course or having it taught at your organization, contact Nancy Boudreau, education/training chair at nboudreau@tlcnh.com.

Continuous Improvement: In lieu of a standalone conference this year, the AD is participating in the Fall Technical Conference Committee (TCC), and will have its own track. We are skipping this year to allow us to buy new equipment, look at new conference formats, and seek out new presenters so we can continue to provide you with the best conference experience possible. The division will once again have its standalone conference in Reno, NV, in 2015.

ISO 9001: As everyone knows, a major revision is coming to ISO 9001 in 2015. It is not too late for interested parties to get

involved. Those who wish to become involved in the final stages of the revision process can contact ASQ headquarters at 1-800-248-1946 and ask how to apply to become a member of U.S. Technical Advisory Group (TAG) to ISO/TC 176. This is the group that develops and provides the U.S. position on all work related to ISO 9001. For more information on the process read the "Standards Outlook" column in the February 2014 issue of *Quality Progress*.

Authors Wanted: *The Audit Report* 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.

Newsletter Publishing Guidelines

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

1. Not too similar to something recently done
2. Desired subject matter – how timely is material?
3. Well written (not requiring extensive editing)
4. 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, and book reviews
- News Bytes: event coverage, announcements, and other audit-related news

Length

Desired length for tips, book reviews, articles, and case studies is 400–800 words. Tips and book reviews would be in the 400–600 range, articles anywhere from 400–800 words, and case studies

Continued on page 14

500+. 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.

February Issue: Submit content by December 1 – Theme open

May Issue: Submit content by March 1 – Preview of ASQ's World Conference on Quality and Improvement; open

September Issue: Submit content by July 1 – Training, certification, back-to-school, and audit conference

December Issue: Submit content by October 15 – Conference recap, year-end reflection/looking ahead to next year

Book Review:

Auditing Beyond Compliance: Using the Portable Universal Quality Lean Audit Model

Author: Janet Bautista-Smith

Publisher: Quality Press

ISBN-13: 978-0-87378-840-9

Review by Lance Coleman

How do I become a better auditor? How can my audit program provide more value to my company? These are questions often asked by audit professionals, and they have many possible responses—most of them appropriate. I would like to add one more suggestion to the litany of responses for how to become a better auditor and bring more value to an organization. That suggestion would be to read *Auditing Beyond Compliance: Using the Portable Universal Quality Lean Audit Model*, by Janet Bautista-Smith.

In *Auditing Beyond Compliance*, Bautista-Smith deftly covers the expansive topics of the eight wastes of lean and improving performance through the elimination of these wastes. As part of that process, she takes auditors on a journey to the “hidden factory,” wherein resources are diverted to create waste alongside the goods and services the parent organization is paid to produce.

Auditors who read this book will be taught how to use powerful analytical tools such as value stream mapping and supplier-input-process-output-customer (SIPOC) diagrams that will complement the strategies and tools they currently employ as part of the audit process. They will also learn how to spot inefficiencies in the areas audited, in addition to items of noncompliance. However, this book is not just for auditors. Lean practitioners will also benefit from learning the auditing methodologies explained in the book along with learning the unique deployment of Lean Six Sigma tools, heretofore used only during lean and Six Sigma projects.

Bautista-Smith provides many examples from her own extensive experience to clearly illustrate key points, as well as examples of completed audit forms and reports using her Portable Universal Quality Lean Audit Model (PUQL). There is also a training DVD that comes with the book, containing a PowerPoint presentation along with a template for her PUQL. It should be noted that this book is not for the professional new to quality. Experienced auditors and lean practitioners will get the most benefit out of this work.

Although Bautista-Smith gives many reasons why auditing beyond compliance is a good idea, I would have appreciated some discussion about *how* to advocate for this change in practice when you aren't the decision maker. Something else that should be included is advice on rolling out an auditing beyond compliance program incrementally. Also, I would like to have seen blank templates of the various audit checklists, reports, and other forms from her book included on the DVD as well.

All in all, *Auditing Beyond Compliance* provides a clear road map, including useful tools for those organizations that would like to reap the benefits of implementing the strategies and techniques discussed therein. It is particularly timely considering the increased emphasis on lean and Six Sigma methods in the new Certified Quality Auditor Body of Knowledge, and should be included in the library of anyone serious about the auditing profession.

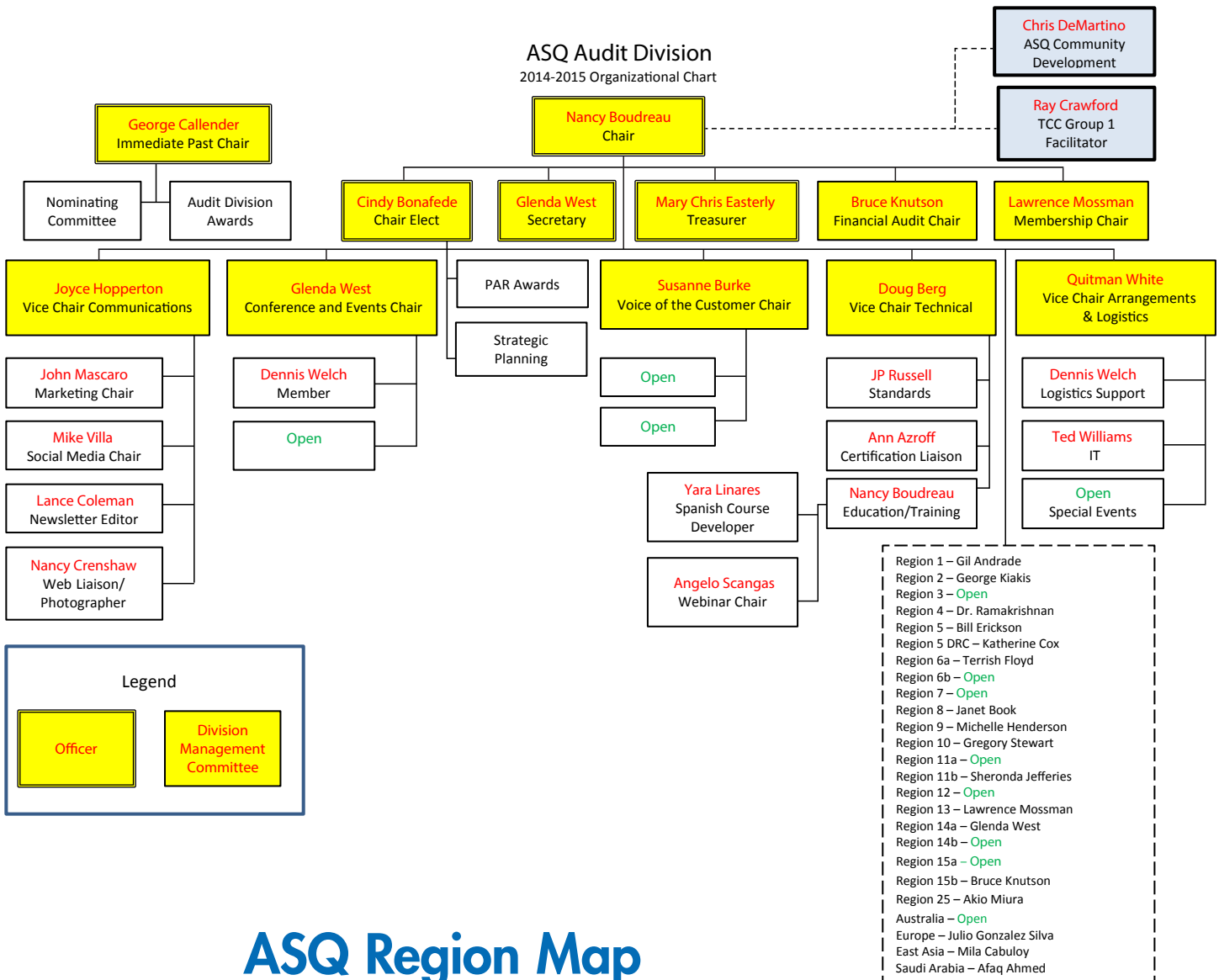
About the Reviewer: Lance Coleman is a quality engineer and lean leader in Tempe, AZ, who has worked in the medical device, aerospace, and other regulated industries for more than 15 years. Coleman has a degree in electrical engineering technology from Southern Polytechnic State University in Marietta, GA, and is an ASQ Senior member, Certified Quality Auditor (CQA), Biomedical Auditor (CBA), Six Sigma Green Belt (CSSGB), and a RABQSA QMS Provisional Auditor. Coleman currently serves as the ASQ Lean Enterprise Division Publications Committee chair and newsletter editor, and is a candidate to become an instructor for the new ASQ CQA refresher course. He can be reached with comments or questions at lance.b.coleman@gmail.com or via www.fullmoonconsulting.net.

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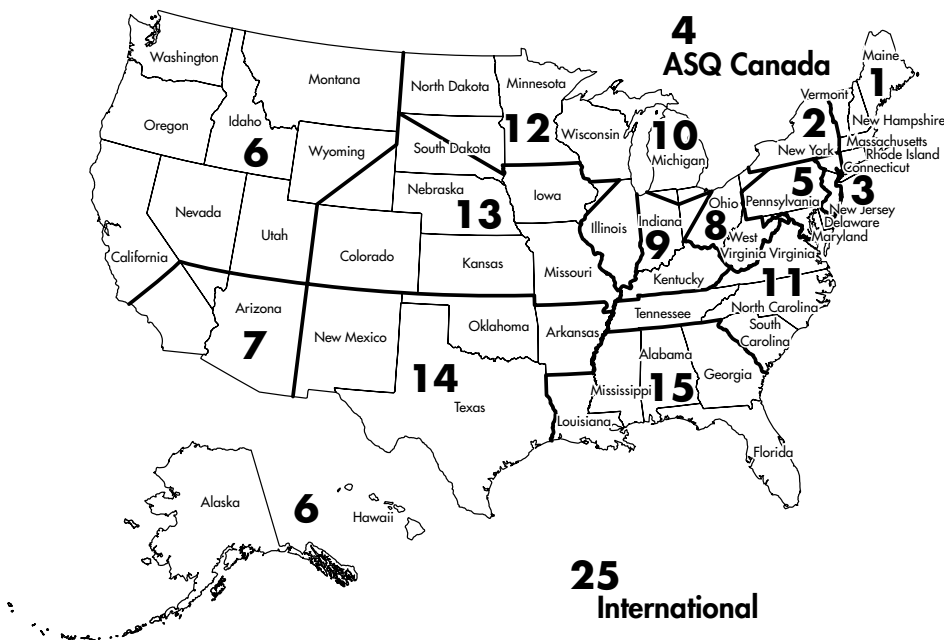
**For submissions or questions, contact Lance Coleman,
lance@fullmoonconsulting.net.**

ASQ Audit Division
2014-2015 Organizational Chart



February 22, 2014

ASQ Region Map





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