Hi everyone!
The Audit Division has just wrapped up its 24th Annual ASQ Audit Conference in Reno, NV, and it was outstanding! The conference drew 287 attendees from five different countries. We always appreciate comments from the attendees and take them very seriously. Over the years we have incorporated many of the opportunities for improvement from our attendees, and this year is no exception. For example, we heard from several people that you preferred one keynote speaker with different options for breakfast and lunch as we had done in the past. Do you remember when we had Mark Twain and some of our “futuristic speakers?” Going forward, we plan to have one keynote speaker and incorporate different entertainment options for the remainder of the meal breaks.

You also told us that some of the descriptions of the presentations on the website and the brochure did not always accurately describe the session content, and some of you felt that you went into a session expecting something different from what you received. We plan to clarify this issue on our speaker abstract form that we sent to presenters to ensure potential presenters give an accurate description of their presentation.

We got a lot of positive feedback on the “Auditor Charm School” tutorial. It seems as though everyone liked the idea of a free tutorial, so this is something we will try to offer at future conferences.

Our sponsors were very pleased with their location in the pre-function ballroom area, and several of them mentioned that they received a lot of traffic. I want to thank all of our attendees for supporting our sponsors. Our sponsors are a large part of why we are able to offer such an enjoyable conference experience to our attendees.

This will be my final letter as chair, as my term will end December 31, 2015. It has been a great two years, and I have to say that it was a privilege to have the opportunity to serve the Audit Division and all of its members. These last two years have given me the opportunity to gain valuable experience in leading an organization whose number-one goal is to serve its membership.

My job as chair of the Audit Division would have been very difficult if not for the support and advice of the entire division management team. I want to thank each and every team member for the contributions they have made in enhancing the experience for our loyal Audit Division members. I also want to thank our members for the support they have given to me and the Audit Division.

Your new chair will be Cindy Bonafede, and I will now become immediate past chair. Many of you have met Cindy during our Audit Division conferences and at the World Conference on Quality and Improvement. I hope everyone is looking forward to the next two years, and many, many more years to come.

Thank you all,
Nancy Boudreau
2014–2015 Audit Division Chair
Letter From the Editor

Hello Everyone,

As we go into the holiday season, I am happy to look back on a fantastic 24th annual ASQ Audit Conference held October 29 – 30 at the fabulous Peppermill Resort and Casino in Reno, NV. We had 287 attendees from five countries, which was the highest attendance in five years. These attendees provided very positive feedback on the six preconference tutorials and 40 sessions that were offered. In 2016 we are looking forward to an even higher attendance when we celebrate our 25th anniversary October 20 – 21 at the historic Peabody Hotel in Memphis, TN. We also have some new and exciting aspects to our conference program planned that we will share throughout the year here in the newsletter as they are confirmed.

Included in this issue are conference highlights and articles from one of the keynotes and several presenters on the topics they addressed during the conference. The call for papers for our 2016 conference is also included. Though the call will close on April 1, this year we are doing a phased review so that those who submit their proposals early will receive a response within 30 days of submittal. The last papers submitted just before the April 1 deadline will hear by May 1.

Thanks as always for your support in reading our newsletter. I hope you continue to benefit from it and appreciate any feedback you care to give. I also appreciate the kind words shared by several of our readers during our recent audit conference in Reno. Please stop by our booth at the World Conference on Quality and Improvement—May 16 – 18, 2016, Milwaukee, WI—meet the Audit Division leadership team, and let us know how we are doing or if there are any topics you would like us to cover in the newsletter. I wish you and your families a safe and happy holiday season. Look forward to seeing you on the road sometime in 2016!

Warm regards and safe travels,

Lance B. Coleman

ASQ Audit Division Newsletter Editor

lance@fullmoonconsulting.net

---

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
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, or book reviews
• News Bytes – event coverage, announcements, and other audit profession-related news

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

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

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

Calendar/Main Theme(s)
Submit submittals relating to the main theme and from division members receive priority.
• March 1 Issue: Submit content by January 15 – Preview of ASQ WCQI and open topics
• June 1 Issue: Submit content by April 15 – Recap of ASQ’s World Conference and open topics
• September 1 Issue: Submit content by July 15 – training, certification, back-to-school, and Audit Conference
• December 15 Issue: Submit content by October 31 – Conference recap, year-end reflection, and looking ahead to next year

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

by Peter Holtmann, president and CEO, Exemplar Global Inc.

In my presentation at the ASQ Audit Conference in Reno, NV, in October, I shared findings from Exemplar Global’s latest survey, which aims to clarify facets of the global auditor population and provide insight into auditing as a viable career pathway alternative. For the “Auditing Profession Career Pathway,” Exemplar Global went straight to the source and invited auditors to take part in a study via LinkedIn. More than 1,000 responses were received, with the results published in the survey.

The survey presented the professional auditor as someone able to skillfully manage conflictual relationships through the establishment of strong interpersonal relationships across all levels of an organization. However, the skills of the individual auditor can shift auditees’ perception of the overall audit from feeling they are being “policed,” to viewing the experience as adding value. Two subcultures emerge as a result of this construct: one that applauds the process and one that pits the auditor against the auditee.

There are varied paths to entering the auditing profession, with respondents revealing varied experiences. Those originating from within companies that actively support the profession tended to find a career path easier to access and move through. Alternatively, those working within the quality profession experience their auditing career trajectory as a natural progression.

Regardless of their entrance point, many auditors underscore the value of access to on-the-job training, such that they could benefit from the expertise of more experienced professionals. However, difficulty accessing training opportunities or being a mother, young, or female were identified as barriers to entering the profession.

Experience emerged as a key theme in the survey, both for those looking to enter the auditing profession and for those already working as an auditor. Although experience is presented as being highly valued, exactly what the term entails remains unclear. Credibility is presented as being intimately entwined with the construct of experience, with many auditors expressing the belief that one cannot exist without the other.

The need for a clearly outlined, established career path is a key takeaway from the survey.

Key trends identified in the survey include:

- **Job satisfaction.** High industry retention rates and an overall desire to stay or grow within the auditing profession displayed by the general population signals that for the majority, auditing is an attractive, economically viable, and rewarding career.

- **Gender equality.** The data show increasing gender equality, reflected not only in terms of the changing proportion of male and female auditors over successive age ranges, but also in terms of the near equality of remuneration offered.

- **The need to attract a new generation.** There is a clear age imbalance, an aging auditor population, and an approximate 10-year window of opportunity to address this imbalance. Current challenges for the industry include leveraging job satisfaction and gender-neutral opportunities for career growth to attract personnel who possess the desired skills and personal attributes required to be successful auditors and leaders.

These people would then need to be trained and retained so they have the opportunity to continue the drive of the industry toward ever-improving service levels and bringing value to the wider community in the years to come.

With this in mind, where will the future population of auditors come from?

For detailed insight into the health of the auditing profession, how to source and train new auditors, and how to retain skilled auditors and utilize their knowledge for the benefit of the industry, visit www.exemplarglobal.org/who-we-are/reports-media-presentations to request a copy of the “Auditing Profession Career Pathway” survey white paper.

About the author: Peter Holtmann is the president and CEO of Exemplar Global Inc., the premium provider of personnel certification and credential management, and independent certification for training outcomes.

Holtmann has been passionately dedicated to the conformity assessment profession for 20 years, spending the last 10 years building Exemplar Global into a world-class certification organization. As the industry has changed so has his role, from a scientific professional to trainer and risk consultant, from auditor to business developer, and now as a strategist and leader of a global nonprofit organization.

Holtmann sees his role as an advocate for credentialing that helps drive career pathways to international recognition. He believes unilateral acceptance of a person’s capabilities across cultures, countries, and continents builds world trade and fosters global growth of human capital.

---

Attention Auditors!
You have options.

**Certification as an Auditor of QMS is a valuable credential to maintain.**

It does not need to be costly.
Consider TRACI as your choice for annual renewal or re-certification.
Enroll now and receive a 50% discount!

www.personnelcertification-tra.com
Audit planning is the first and crucial step in any audit program. Poor planning can lead to poor audit outcome. One key aspect in audit planning is the selection of departments to be audited. With sufficient resources (manpower and time), the ideal case would be to audit 100 percent of departments. But whether or not the audit plan would still be effective and efficient is questionable. The purpose of this article is to look at how departments are selected to be audited in a structured manner using risk management.

Challenges
Some of the challenges in audit planning include:
- Diversified and complex processes
- New processes or equipment, or changes to existing processes or equipment
- Limited number of auditors
- Audit fatigue faced by auditee
- Regulatory/Certification mandatory requirements
- Previous audit findings

Another factor to consider is the stress faced by the audit planner, who has the task to identify departments to be audited, including the stress of being challenged by the auditee on the selection criteria.

Selection Process
The selection of departments to be audited can be subjective, most of the time relying on one’s experience. There is a lack of selection tools available that show how to prioritize departments to be audited. When seeking a solution to this problem, I began by looking at translating my tacit knowledge into explicit knowledge: What was the experienced audit planner thinking? What was the decision process that led to selecting that particular department? The selection tool has to be structured with a predetermined criteria that anyone—regardless of experience—can use.

### Risk Management Used in Audit Planning

A risk assessment tool was adapted to allow selection of departments in a more structured manner.

The risk matrix is established based on identified “risk” factors:
- Environment, health, and safety (EHS) risk
- Level of readiness in terms of documentation and monitoring/ measurement of process parameters

The “risk” factors may be different, depending on the focus of the audit program or organization requirements.

To better understand the department, a department profiling was conducted (see Table 1).

#### Step #1. EHS Risk Level

The EHS risk level is determined based on regulatory and workplace hazards:
- **High:** Use a lot of hazardous materials; a registered factory
- **Medium:** Use some hazardous materials
- **Low:** Office of administration work environment

The preliminary audit frequency is determined for each EHS risk level (see Table 2).

#### Step #2. Level of Readiness

To establish this level of readiness (see Table 3), a workgroup composed of auditors is formed. Feedback is sought from auditors to rate the department that they have audited previously. One point to note is that this feedback exercise can be subjective, to a certain extent. Thus, it is

Continued on page 5
important to have a moderator to reach a consensus rating.

The preliminary audit frequency is then determined based on the level of readiness matrix table (see Table 4).

**Step #3. Other Factors**

Other factors to be considered that may change the preliminary audit frequency include:

- Management priorities
- New/Revised processes, equipment
- Changes to business environment, regulatory requirements

Continued on page 6

### TABLE 4. Level of Readiness Matrix Table – Preliminary Audit Frequency

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Not met</td>
<td>Every year</td>
<td>Every year</td>
<td>Every year</td>
<td>Every year</td>
</tr>
<tr>
<td>2. Minimal</td>
<td>Every year</td>
<td>Every two years</td>
<td>Every two years</td>
<td>Every two years</td>
</tr>
<tr>
<td>3. Met</td>
<td>Every year</td>
<td>Every two years</td>
<td>Every three years with option to extend one year</td>
<td>Every three years with option to extend one year</td>
</tr>
<tr>
<td>4. Exceed standard</td>
<td>Every year</td>
<td>Every two years</td>
<td>Every three years with option to extend one year</td>
<td>Every three years with option to extend one year</td>
</tr>
</tbody>
</table>

**Note:** The “year” in this context refers to preliminary audit frequency.
• Previous internal/external audit results
• Performance trends, e.g., complaints, incidents

A three-year audit plan is then established (see Appendix A). This audit plan is reviewed every year to incorporate other factors that may result in bringing forward an audit.

**Three-Year Audit Plan and Annual Audit Plan**

The three-year audit plan recommended audit frequency is established based on three criteria:
• EHS risk level
• Level of readiness
• Other factors

Usually, the “more stringent” preliminary audit frequency is selected. To ensure that the three-year audit plan stays relevant, review is conducted regularly (every two to three years) or when deemed necessary.

Based on the three-year audit plan, the annual audit plan (Appendix B) is developed. However, audit frequency may be affected by other factors that may not be known when establishing the three-year audit plan. Therefore, the leader of the audit program must consider other factors that may encourage the audit of a particular department.

**Appendix A. An Example of a Three-Year Audit Plan**

<table>
<thead>
<tr>
<th>S/N</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of Department</td>
<td>Kitchen</td>
<td>X-Ray</td>
<td>Call Center</td>
<td>QA Department</td>
</tr>
<tr>
<td>EHS Risk Levels</td>
<td>High: Use a lot of hazardous materials; registered factory</td>
<td>Medium: Use some hazardous materials</td>
<td>Low: Office/Administration</td>
<td></td>
</tr>
<tr>
<td>Preliminary Audit Frequency (refer Table 2)</td>
<td>1 year</td>
<td>2 years</td>
<td>3 years</td>
<td>3 years</td>
</tr>
<tr>
<td>EHS Risk Level</td>
<td>High</td>
<td>Medium</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Level of Readiness</td>
<td>Documentation and Records</td>
<td>3</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Monitor and Measure</td>
<td>1. Not met</td>
<td>3</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Preliminary Audit Frequency (refer Table 2)</td>
<td>3 years</td>
<td>3 years</td>
<td>1 year</td>
<td>3 years</td>
</tr>
<tr>
<td>Other Factors</td>
<td>Registered factory</td>
<td>New equipment in 2017</td>
<td>Mandatory by Certification Body</td>
<td></td>
</tr>
<tr>
<td>Recommended Audit Frequency</td>
<td>1 year</td>
<td>2 years</td>
<td>1 year</td>
<td>1 year</td>
</tr>
<tr>
<td>Year 2015</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Year 2016</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Year 2017</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**Appendix B. An Example of an Annual Audit Plan for Year 2016**

<table>
<thead>
<tr>
<th>S/N</th>
<th>1</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department to Be Audited</td>
<td>Kitchen</td>
<td>Call Center</td>
<td>QA Department</td>
</tr>
<tr>
<td>Location</td>
<td>Block 3</td>
<td>Block 1</td>
<td>Block 6</td>
</tr>
<tr>
<td>HOD</td>
<td>Ben Tan</td>
<td>Sherry Lim</td>
<td>Mark Chang</td>
</tr>
<tr>
<td>Standards Used</td>
<td>J, Q, E, H</td>
<td>Q</td>
<td>J, Q, E, H</td>
</tr>
<tr>
<td></td>
<td>3. Mark Chang</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Auditor Department</td>
<td>1. Infection Control</td>
<td>1. General Services</td>
<td>1. Service Quality</td>
</tr>
<tr>
<td></td>
<td>2. Operations</td>
<td>2. HR</td>
<td>2. Maintenance</td>
</tr>
<tr>
<td></td>
<td>3. QA</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. Q</td>
<td>2.</td>
<td>2.</td>
</tr>
</tbody>
</table>

* = lead auditor  J = Joint Commission International  Q = ISO 9001  E = ISO 14001  H = OHSAS 18001

**Conclusion**

Audit planning can be more transparent and less subjective through the use of a risk assessment tool. This allows a more structured and consistent approach in selection of departments for audits. The structured approach takes less time in planning an audit; and auditors are deployed more effectively and efficiently.

**About the author:** Sharon Tay has worked in the manufacturing and healthcare industries. She has experience in managing accreditation and licensing work in the healthcare industry for the past 17 years, pioneering the implementation and maintenance of the integrated management system in Singapore. She is an ASQ Certified Manager of Quality/Organizational Excellence (CMQ/OE) and a registered Workplace Safety and Health Officer. As part of her life-long learning, Tay has recently completed her bachelor of science degree in human factors in safety.
A frustrated auditor once asked me, “Is there anything in this factory that isn’t automated that I can audit?” The auditor was on the production floor of a highly automated factory with very few production line personnel. Those on the production floor were either performing machine maintenance or engineering experiments. Production was monitored from a central command center.

A typical auditor’s technique was to verify QMS requirements by interviewing production line personnel. This technique is commonly used to ensure personnel impacting product quality are competent, know work procedures, and are aware of the factory’s quality policy and how it related to their work.

But with no production personnel to interview, the auditor had no way to verify these requirements.

But with no production personnel to interview, the auditor had no way to verify these requirements.

The fact is, automation of production and support processes—from automobile assembly to order entry and delivery scheduling—is a fact of work life. Continually improving processes often use technology to reduce direct human involvement.

So how does an auditor verify that the processes are properly implemented, documented, controlled, and effective?

**Answer:** Verify the results of support processes in the QMS as indicators of the automated process’s effectiveness. The following are a few key areas to verify.

### Automated processes require a strong link to change control management.

How a process was initially automated and maintained will likely be managed by the change control process. Evidence of how the automated process will meet the product or service requirements should be part of the change control material. Frequency of process changes may be an indicator of the automation’s capability to capture product requirements.

Automation increases the occurrence of disruptions if not implemented effectively. Negative trends resulting from automation such as increased scrap rate or increased order processing time may indicate erroneous or noncompatible automation deployment. Release of any automation should include a thorough validation during the initial release and a structured change management methodology.

**Automated processes require process control.**

This sounds obvious, but sometimes “trust” in automated systems is not always verified. Most effective automated processes have some type of inline monitors to determine that the process is running effectively. These inline monitors may include attributes of the process not necessarily related to an end product requirement, such as metal sheet resistivity in a deposition process or cycle time for signature loop approval in an office process. Waiting on end-point measurements, feedback from downstream processes, or even customer acceptance are not effective process controls. Remember, automation without a control system increases the frequency and impact of a negative event such as expensive scrap trend or production shutdowns.

**Automated tools require training.**

Automation almost always relies on either software or hardware tools for continued effectiveness. The workforce’s understanding and implementation of these automation tools usually require extensive training. This, quite often, cannot be done on the job site, thus, documentation, acquisition of reference materials, or outside technical support sources need to be structured for future knowledge relay or cross-training, as needed.

**Effective automation improves overall performance.**

Optimum deployment of automation should include a measurement system monitored by properly trained personnel.

An optimized deployment should yield improvement and customer satisfaction. Gaining positive results for one process under the expense of other processes should be a consideration in the automation deployment program. The impact of automation should be evaluated to ensure a proper balance of benefits vs. risks associated with the processes involved.

Automating processes may reduce the need for production floor audits. Adapting to how the processes are implemented, maintained, and monitored, the auditor can verify the requirements of the QMS with minimum or no frustration.

**About the author:** Shawn Rogers is a Certified Quality Management Lead Auditor with more than 30 years’ experience in high-technology manufacturing and product development. He has extensive experience in technology startups, engineering, and business management, and in quality systems development in both small and large organizations. He has worked in all areas of the electronics industry, including: semiconductor wafer fabrication, semiconductor assembly operations, printed circuit board (PCB) manufacturing, and multifactory manufacturing logistics. In the last five years he has conducted more than 200 quality audits in all areas of the electronics industry. He has degrees in electrical engineering and business administration.
Larry Whittington presented “ISO 9001:2015 - Plan for the Changes” at the recent ASQ Audit Conference in Reno, NV. This article shares information from the transition guidance part of that presentation.

ISO 9001:2015 was issued on September 15, 2015. Organizations certified to ISO 9001:2008 have a three-year transition period to make their move to the new standard before ISO 9001:2008 is withdrawn.

As you plan for the transition, remember to obtain funding for your transition activities. You will need to arrange for training on the new and changed requirements, as well as possibly pay for extra audit days for your certification body to conduct the transition audit.

Context of the Organization

Understanding the context of your organization is a new requirement, although some organizations may already focus on their organizational environment. To transition to ISO 9001:2015, you’ll need to determine the internal and external issues that are relevant to your strategic direction, and that may affect your ability to achieve the intended results.

In addition, you need to determine the relevant requirements of relevant interested parties that may potentially affect your ability to consistently provide conforming products and services. You’ll have to consider these issues and interested parties when determining the risks faced by your organization.

Risk-Based Thinking

A key purpose of a quality management system (QMS) is to act as a preventive tool. ISO 9001:2015 requires an organization to apply risk-based thinking to the planning and implementation of its QMS.

You need to first determine your business risks and opportunities, and then plan the actions needed to address them. Understand your options for dealing with these risks. Plan how to integrate these actions into your processes for ongoing prevention.

The effectiveness of the actions taken to address the risks must be analyzed and evaluated, and then considered at management reviews. Guidance on risk management can be found in ISO 31000.

Transition Guidance

One of the first transition activities will be to document the scope of your quality management system, as well as the justification for any requirements that you determine are not applicable for that scope.

Be sure to advise top management of their expanded responsibilities. They may have to step up to demonstrate their visible leadership and accountability. They will need to align the quality policy and quality objectives with their business strategy. They may decide to hold more frequent management reviews to assess progress of the ISO 9001:2015 transition project.

The use of a management representative is not mentioned in ISO 9001:2015. You could decide to keep the management representative position, or disburse those duties among top management.

More Transition Guidance

After training on ISO 9001:2015, the organization should perform a gap analysis against the new requirements. The results can be used to develop your transition plan containing specific deliverables, assignments, and due dates.

Rely upon the transition guidance that will be provided by your registrar. Many certification bodies have already released transition white papers and made available transition checklists.

You will need to maintain conformity to ISO 9001:2008 until your transition audit to ISO 9001:2015 successfully completes. If you have another audit scheduled against ISO 9001:2008 before you are ready for the transition audit, you won’t be able to drop items no longer required by ISO 9001:2015, e.g., the quality manual and the required six procedures.

Additional Transition Guidance

If your current documents are working well, you may decide to keep them—even if they aren’t required by the new standard. There is value in having a documented process to capture knowledge, gain agreement, train staff, and provide operational control.

If your documents are numbered based on the old clause structure, will you stay with that numbering, although it will no longer be linked to the new clause numbers? Or, will you switch to the new numbers? Or, will you move to a generic numbering scheme that is independent of the standard clauses?

Scan for references to the old standard and its clauses in your existing documentation. Try to minimize these references and change any remaining references to the new standard and its clauses.

Further Transition Guidance

You don’t have to implement all the new and changed requirements of ISO 9001:2015 during the last few months leading up to the transition audit. Look for requirements that can be adopted early and be assessed by internal and external audits in the cycle before the transition audit.

Be aware that your internal audits may need additional planning, execution, and reporting time due to the introduction of the new and changed requirements.

Continued on page 9
Transition Starting Point

If your organization has invested time implementing ISO 9001:2008, and is almost ready for its certification audit, go ahead and complete the project in the next few months. Leave yourself plenty of time to then turn around and begin your transition to ISO 9001:2015.

If you are just starting your implementation of a quality management system, then skip the use of ISO 9001:2008 and begin with ISO 9001:2015. Save yourself the later transition effort.

Transition Timing

Registrars will suggest you schedule the transition audit for your next recertification audit. The transition audit will be a full system audit, so planning it for a recertification audit will add fewer audit days (and less cost) than if you synchronize it with a shorter duration surveillance audit.

However, if you decide the recertification audit date is too soon for you to complete the transition, you can convert the next surveillance audit to be the transition audit. And, if your recertification audit is too late in the three-year period, you can use the prior surveillance visit as the transition audit. Or, you can arrange a special visit to schedule the transition audit in your preferred timeframe.

If you are currently assessed twice a year by your registrar, you may want to shift to an annual audit for the period leading up to the transition audit so you have more time to complete all the changes.

As you move through the transition, use it as an opportunity to improve quality and your business.

Presentation Handouts

If you are interested in receiving a copy of the following handouts, send an email to larry@whittingtonassociates.com.
1. ISO 9001:2008 to ISO 9001:2015 Clause Map (2 pages)
2. ISO 9001:2015 to ISO 9001:2008 Clause Map (3 pages)
3. ISO 9001:2015 Clause Quick Reference (2 pages)
4. Required Documented Information (4 pages)
5. Quality Management Principles (4 pages)
6. Risk Assessment Worksheets (4 pages)

About the author: Larry Whittington is president of Whittington & Associates, located in Canton, GA, and Orlando, FL. He is a certified Exemplar Global and IRCA Lead Auditor. He has successfully completed the ISO 9001:2015 exam and transition requirements. His auditor scope now includes the new standard.

His monthly newsletter on quality and auditing topics has been published for more than 15 years and is read by thousands of subscribers.

Whittington has a bachelor’s degree in electrical engineering and a master’s degree in engineering from the University of Florida. He is an ASQ Certified Quality Auditor (CQA) and Software Quality Engineer (CSQE).
Effective Techniques for Auditing a Risk Assessment
(Key Attribute for Auditing ISO 9001:2015 Risk-Based Thinking Requirements)

January 7, 2016

Abstract

The ability to predict, evaluate, and mitigate potential failures is crucial. Whether you work in a complex engineering company, a manufacturing environment, or a process-oriented one, such as a hospital, laboratory, or school system, risk assessments are integral to meeting the requirements of ISO 9001:2015.

A sound approach to quality risk management utilizes the knowledge and experience of the entire team in your organization. The team includes the people participating in the risk assessment, the people executing the mitigation, as well as the internal auditors who need to evaluate the effectiveness of the process. Everyone needs to work together to ensure customer and business satisfaction.

Auditors continue to struggle with effective and efficient audit execution of risk assessments. Common deficiencies include an over-reliance on checklists and inadequate understanding of the documentation risk assessments, including linkage of audit procedures to the risks they are designed to address. So what exactly does that mean? In plain English, this means the auditor needs to:

• Understand where, within the company’s quality/business system, are the highest product/process risks
• Tailor his or her audit program to evaluate risk management effectiveness
• Understand the purpose and structure of FMEAs (or other risk assessment tools)
• Know how to audit the severity, occurrence, and detectability criteria
• Evaluate the effectiveness of the mitigations to reduce risk
• Audit for value

You’ll learn to:

• Determine the right time to audit risk assessments
• Identify the critical requirements for the product or process to be included in a risk assessment
• Identify and classify potential failure modes
• Evaluate potential failure mode severity
• Evaluate potential causes to the failures
• Evaluate potential probability
• Determine how to ensure the process is “living”

Please register for “Techniques for Effective Risk Assessment Audits. How Will You Audit ‘Risk-Based Thinking’?” on January 7, 2016, 11:00 a.m. EST at:

https://attendee.gotowebinar.com/register/1480160724929453569

After registering, you will receive a confirmation email containing information about joining the webinar.

About the Presenter: Angelo Scangas is president of Quality Support Group, Inc., an international consulting and training organization.

Scangas has worked in the automotive, aerospace, medical, and electronic industries for close to 30 years, holding positions in operations, quality, and engineering.

Scangas is a Six Sigma Black Belt and a lean instructor. He has led clients to TS 16949, AS9100, ISO 13485, and ISO 9001 certifications. Scangas is a Senior member of ASQ and the webinar chair of the ASQ Audit Division.

He has a BS in chemical engineering, MS in manufacturing engineering, and an MBA.

2016 25th Annual Audit Conference Call for Papers

We are recently returned from our 24th annual ASQ Audit Conference in Reno, NV, at the Peppermill Resort and Casino—and what an excellent conference it was! We had 287 attendees from five countries—the highest attendance in five years. Here’s what attendees said:

“… the topics/talks were useful. The venue was very good.”
–B.C. from California

“Awesome event. Very well done.”
–J.D. from Michigan

If you weren’t able to come, we missed you and hope you will make plans to attend our 25th anniversary event, which will take place in the historic Peabody Hotel in Memphis, TN, October 20 – 21, 2016.

http://www.peabodymemphis.com/

Planning has already begun for next year’s event, which we expect to be even bigger and better! The call for papers is below.

http://asqauditconference.org/2016_ASQAuditConference-CallForPapers.pdf

Exam Refresher Course

Prior to the Reno conference we had 22 CQA candidates take the CQA refresher course. The next public offerings of the refresher will take place May 2 – 4, in Covington, KY, and May 11 – 13, in Milwaukee, WI, as one of the World Conference on Quality and Improvement preconference workshops. Other public offerings in 2016 will take place:

• October 16 – 18, 2016, Memphis, TN (before the Audit Conference)
• November 7 – 9, 2016, Las Vegas, NV

We are very pleased that this course has a 95 percent pass rate for students who complete the course and then take the CQA exam. To register go to http://asq.org/training/certified-quality-auditor-certification-preparation_CQAR.html.
Managing Suppliers AND Clients

by Barry Craner

This article is for YOU. If your company buys from another company, builds for another company, or makes its own components or devices, you manage suppliers and need to think about the consequences of your operational decisions.

Your clients and suppliers have similar needs, whether they purchase your services and products or you purchase theirs.

- How do you select suppliers and even clients (you sign the contracts, so you have a choice)?
- Who do you trust and not trust (this is a topic we are loath to discuss, but it is important), and how can you be sure you can trust your clients and suppliers?
- How do you ensure you have the parts, subassemblies, and processes to meet client needs?
- How do you select pivotal contract suppliers, and when do you go outside for design or manufacturing?
- What are the needs of both contract design and manufacturing?

Choosing Clients

First, consider YOU have a “say” in who you say “yes” to. If you are aware of the need to consider a client to sell a major output of your production, you need to contribute to that discussion. You probably know facts that need to be said. For instance, are they hard to deal with? Do they pay on time? Are they flexible, reasonable? Does anyone you know well (or in your company) work(ed) there, and what do they know? Do you have a checklist in selecting clients? Use it!

Choosing Suppliers

You need parts/subassemblies to meet client (your) needs.

Again, consider YOU have a “say” in who you say “yes” to. If you are aware of the need to consider a supplier from which to buy a major input to your production, you need to contribute to that discussion. You probably know facts that need to be said: Are they hard to deal with? Do they deliver quality goods on time? Are they flexible, reasonable? Does anyone you know well (or in your company) work(ed) there, and what do they know? Do you have a checklist in selecting suppliers? Use it!

Who Do You Trust and Not Trust?

Why are we loath to discuss this? It might be we will miss some business or be ostracized by your peers/superiors for facts shared. However, if so and you have your facts straight, remember trust in your clients and suppliers is important, and that you have nothing if you don’t have trust. So, what do you have to lose to “check them out” first?

What is important when considering trust? First, working with clients and suppliers must be a mutual win-win. Second, you need to trust your partners in business because they must be confidential, reliable, and their word must mean something! They work with you during unforeseen circumstances and events. Also, don’t start dealing with a supplier or client without a mutual nondisclosure agreement (MNDA)—never. Trust but verify. I have seen companies almost fold because of misplaced trust—no MNDA, no relevant or even peripheral information given or taken.

What Is Contract Design/Manufacturing?

Contract design/manufacturing can range from the design of a device to full design control, or the design of component(s) of a final product, or even “feasibility” or process development, or to the manufacturing component, part, or all of the product.

Why Use Contract Design/Manufacturing?

One reason to use contract design/manufacturing is that a virtual company cannot afford long-term staff. Also, in-house design/manufacturing is a long-term salary commitment, and resources are limited—making contracting ideal for short-term needs and when fast and unfamiliar technology startup is needed. Lastly, this is when centers of competence are needed and can be contracted.

What about other considerations, such as performance cost of goods, or the look and feel of a device? Other considerations are time to market, feasibility only (no long-term design commitment); is this a single process/component/full product; is it after-market service; is it start-up cost concessions to supplier (part molds, process development, etc.)?

What About Due Diligence?

Here are some major considerations in choosing companies (big/little): nondisclosure, quality systems, audits, regulatory status, contractor selection and management, amount of contractor work (do you need a clean doc package?), subcontractor selection (one out of qualified group), negotiation with contractor (step or all at once), status of document package, and matching competencies with need (hardware, software, materials, goals, personnel, experience, culture considerations, cost, time, etc.). Remember, this list is not exhaustive! What are other concepts you need to consider?

Selecting Contractors: Due Diligence

One of the most important decisions you will make will come out of your due diligence process. If you have an acquisition checklist (a list senior managers use for mergers and acquisitions), considerations may include a visit to potential contractor site and documentation (this is a supplier selection). Supplier audit materials apply here—prepare for this supplier. Referencing can be a dominant tool using your previous medical device experience. Always consider the flavor for

Continued on page 12
your potential partnership feasibility personnel, competence in core technologies, team feasibility between major players, similar or complementary missions/visions between your company and your potential supply partner, and similar previous design experience.

Should You Use Big Companies or Little Companies?

Do you see any possible problems here? What about general compatibilities of cultures? This is important. You want to get real work done. You want to enjoy working with each other. Consider these several very relevant aspects requiring agreement and cooperation. Such concepts are procedural formatting, requirements, and documentation system/approval requirements differences. These aspects include the design history file—and who holds it—being wary of document systems burden and how much it really costs (your/their philosophy of validation—depth, reasonableness, requirements burden). What are reasonable expectations of each other regarding design cooperation (who, how much, impact)? What are your/their manufacturing process expectations, such as how much intrusion into each other’s processes? And what about long-term relationships or turnover of employees—especially those with knowledge of core competencies?

Nondisclosure History: Both Ways

You must have an attitude of confidentiality. Without it, many problems with key aspects of your relationship may be compromised, including protection of a company’s virtual intellectual assets and patents, and protection of your reputation and that of contract/client companies. Be sure your nondisclosure agreement restricts disclosure, but says no more than necessary. What if your potential contractor/client decides not to sign an NDA?

Your unwitting good will may be rewarded with a substantial theft of your business.

Purchase Order: Both Ways

You may not be thinking about this, but POs often have multiple requirements printed on the obverse, one of which allows no changes to parts, materials, and processes unless authorized in writing. Remember: A PO is a contract. This is paramount in the cases of regulated products. Other requirements should include order cancellation terms, meeting current specifications only, and what will happen in case of breach of contract (terms, patents, designs, IP disclosure, delivery, etc.). Also to be considered in your contracts are access into supplier production facilities, that the signed contract is binding (changes only in writing/approved), and that the material/supplies inspection are always an option for the client. One must also agree on who supplies or owns tooling, molds, machines, and processes.

Status of Contractor Quality Systems

In this area, provisions must be made to understand any supplier regulatory status. This can be accomplished with audits of their quality systems using predetermined checklists or audit formats, focusing on the specific quality system aspects relevant to your supplier products, such as focusing on design control, manufacturing processes, or secondary suppliers such as sterilization processors, or other critical secondary processors your supplier uses. Is the supplier required to comply with regulations by FDA, aerospace (AS1000), OSHA, and other agencies, and under scrutiny by international regulatory bodies, such as TUV-NORD, Megdev, Semko (EU notified bodies), FDA 21CFR820 (the quality system regulation), U.S. DoD, and others? Is there (should there be) a requirement to certifying for international (CE) marking?

Lastly, does the supplier have a site license for that (those) agency(ies)? What is the current status of agency inspections? And are there any outstanding regulatory actions (warning letters, consent decrees, noncompliance reports)? Are they relevant to your partnership?

Audits: Contractor Quality Systems

Briefly, you’ll need to determine how you will audit your supplier. Do you have a standard audit technique that works well enough to pick out potential problems for your supplier and you? Do you use a format based on the relevant regulation(s)? Do you use an auditing standard (e.g., ISO 11019)? Certainly, take care to focus on areas of product/process interest, such as looking at all phases of the supplier design control system, or manufacturing processes, or focusing on only those relevant to your mutual concerns. What about plans, inputs, specs, verifications, validations, and tests?

And concerning regulated product software, do you want to or need to evaluate their software development process? If you do, ensure they have an acceptable software development system that is well documented. What about tracking their development

Continued on page 13
history (validation, software development life cycle system)? Do they use a waterfall, a “V”, or an agile software development philosophy? Do they have adequate software configuration control (it should be mandatory)?

Do they have a good manufacturing history? Are they compliant where they need to be? Do they have experience developing similar devices? Are there past partnership references?

Remember to audit before you chose, and certainly before you sign the contract (a contract is a contract)!

**Design Control Management/Documentation: Big Issues**

Other very relevant concepts requiring agreement are who controls/approves changes? Who attends design reviews? Who assembles/retains the documented history of the design process? How do you ensure your activities/processes are compatible—both those of the contractor and client?

Also, what documents are turned over (when, what format)? Who is responsible for verification activities? Who is responsible for specification development? Are there other issues in design to consider?

**Risk Management Process: Now Key in All Major QMS Standards**

Is this emphasis needed for this product/part? Is there sufficient client risk management experience? Are risk management SOPs in place? Do they have the needed ISO 31000, or 14971:201, or AS9100c, experience? Is there a subject matter expert (SME) on site? When you review their risk management process, do you find it sufficient? Are there deficits to fill, or other risk management considerations?

**Third-Party Contractors**

Without going into further details on third-party contractors (those suppliers to your contractors), what quality system features are needed? Will audits by other second-party contractors suffice? What is the criticality of parts and/or processes? What are the third-party certifications to quality systems and certification history? Consider it important to be consistent in your process of handling these third-party suppliers with thoughts about suppliers, parts, materials, and process criticality.

**Acquisition of Standards (List)**

This is a simple area, but be sure to synchronize the organization’s and your standards, use only standards required (a starting place, enough to do to get and stay rolling, but not so many to tangle the effort). Be sure to keep the organization’s/your standards archived, easy to locate, and up to date.

**Checklists**

Here is an opportunity not to miss process actions in any process you or your suppliers use. Checklists are lists shared by all who want to reduce work/waste, and who are not in competition.

These lists have a wide variety of origins, including product questions and answers for/from focus groups, for regulatory/audit purposes, for various phases of product development to help in phase planning, for product specifications (to remember important, even minor aspects of the product), design reviews, manufacturing processes (again to remember before your process is fully developed and would require significant cost and time to revise). Do you know of other checklists you have and need to follow, or revise as they are used each time?

**Consultant Lists for Short-Term Contracting**

When engaging consultants for any reason, be sure to keep them in your approved supplier/contractor list, and if not engaged, at least a list of potential consultants. They can be acquired (created from focus group), from finders of esoteric consultants like Teltech (fee for finding who you need for hard-to-find experts on materials, alarms, nuanced regulatory issues, etc.). These consultants can be experts in reliability, safety, and electromagnetic compatibility (EMC), quality systems (design control, management reviews, etc.), clinical trials, good laboratory practices, software development process/procedure, software development resources, manufacturing (design for manufacturability), and other sources/lists for such expertise.

**Some Final Recommendations**

Remember to have MNDAs executed, engage contractors early, and invite them to design reviews, even if in early phases and to significant verification activities. Be sure to stipulate your expected timeframes for subcontractor corrective and preventive actions (CAPAs), your requirements for your product documentation specs, contractor approval requirements for major documents, agreements on specs and test methods (as practical and appropriate). Ensure you as a client have reasonable access to your contractor records. Don’t forget to add your client or contract design company to your design plans, and include appropriate interfaces.

You can have successful client/contractor relationships when you are purposeful and engage with your partners. These are very important affiliations, some of the most important you will have. Take them seriously and you will succeed.

**About the author:** Barry Craner has nearly 40 years of experience in the management of scientists and engineers in applications of aerospace, Internet technologies, medical devices, and medicine. He has written several design control systems for companies and has consulted in areas of reliability engineering, risk management, design control, and quality system development. He has audited many medical device companies from first-, second-, and third-party perspectives. His advanced degrees are in cardiac physiology and business management with a computer information systems emphasis, and he has the equivalent of an electrical engineering minor. He is an ASQ Certified Quality Engineer (CQE), Reliability Engineer (CRE), Quality Auditor (CQA), and Biomedical Auditor (CBA), was on the founding team to create the Body of Knowledge and examination questions for the new ASQ CQA-Biomedical Auditor certification program. In 2008, he was awarded the Simon Collier Quality Award by Los Angeles ASQ Section, and on the MDDI list of “100 Notable People in the Medical Device Industry.” In May 2010, Craner was awarded the Marvin Rosenbaum Distinguished Service Award by the ASQ Biomedical Division.
ISO 9001:2015 Implementing Risk-Based Thinking

by Denis J. Devos, PE

1. Requirements for Risk-Based Thinking in ISO 9001:2015

The most important new concept to emerge in quality management systems in the past 15 years is the risk-based thinking requirements of ISO 9001:2015. There are two definitions of risk in the ISO family of standards, and since they are very similar to each other, you can choose either one or use them both together.

ISO 9000:2015 at clause 3.7.9 defines Risk as “Effect of uncertainty,”

ISO 31000:2009 at clause 2.1 defines Risk as “Effect of uncertainty on objectives.”

ISO 9001:2015 at clause 5.1.2 describes top management’s role in risk-based thinking in the following way:

“Top Management shall demonstrate leadership and commitment with respect to customer focus by ensuring that … b.) Risks and opportunities that can affect conformity of products/services and the ability to enhance customer satisfaction are determined and addressed.”

ISO 9001:2015 at clause 4.4.1 describes the relationship between risk-based thinking and the process approach in the following way:

“The organization shall determine the processes needed for the Quality Management System and their application throughout the organization and shall … f) Address the risks and opportunities in accordance with 6.1 and plan and implement the appropriate actions to address them.”

ISO 9001:2015 at clause 6.1.1 describes risk-based requirements in the following way:

“When planning for the Quality Management System, the organization shall consider the issues referred to in 4.1 (Understanding the Organization and its context) and 4.2 (Understanding the Needs of interested parties) and determine the risks and opportunities that need to be addressed to:

a) Give assurance that the Quality Management System can achieve its intended results,
b) Enhance desirable effects,
c) Prevent, or reduce, undesired effects,
d) Achieve improvement.”

ISO 9001:2015 at clause 6.1.2 then continues:

“The organization shall plan:

a) Actions to address these risks and opportunities
b) How to integrate and implement the actions into its QMS processes and evaluate the effectiveness of these actions.

Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.

NOTE (6.1.2) Options to address risks/opportunities can include:

• Avoiding risk,
• Taking risk in order to pursue an opportunity,
• Eliminating the risk source,
• Changing the likelihood or consequences,
• Sharing the risk,
• Retaining risk by informed decision.”

ISO 9001:2015 at clause 9.3.1 describes the relationship between risk thinking and management review:

“Top Management shall review the organization’s Quality Management System at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. The Management Review shall be planned and carried out taking into consideration … e) The effectiveness of actions taken to address risks and opportunities (see 6.1)”

It is clear from the above requirements in ISO 9001 (clause 5.1.2) that risk-based thinking has to begin with top management. At the company level, risks to products/services and customer satisfaction have to be determined and addressed. After identifying risks at the company level, the risk assessment needs to be carried out at the individual process level. Risks are also to be considered within the framework of what the organization is all about (the context of the organization and needs of stakeholders).

2. Quantitative vs. Qualitative Risk Assessment

Two popular models to perform risk assessments are the failure mode and effects analysis and the risk matrix. The benefits of these tools are that they are rigorous and offer a numerically scored or ranked (quantitative) risk assessment. Although these tools are very powerful and can be very effective, they may not be suitable for the assessment of processes in a smaller organization. A much simpler result can be derived from a discussion between experienced employees without using numerical scoring. This approach to risk assessment is qualitative in nature because it is based on the learned observation and “gut feel” of process owners.

3. Conducting a Qualitative Process-Level Risk Assessment: Using a Flowchart

In order to fulfill the requirements of ISO 9001:2015 Clause 4.4, the organization needs to start with its key business processes and consider risks and opportunities within their context. Risks will then be selected for action based on their criticality to the product, the customer, and the business. A flowchart is the preferred method for modeling processes, and the reader is encouraged to use flowcharts whenever possible.

Continued on page 15
If the risk assessment includes creating a set of flowcharts, then any format, such as the “Risk is the Compass” model (Devos, 2006) can be easily adapted to fulfill this role. Risks are simply recorded beside each box on the existing flowchart.

When considering types of process risks or categories of risks, it can be helpful to consider those risks along the dimensions of the basic Ishikawa or fishbone diagram in its consideration of man, machine, materials, methods, and measurement (5M).

**FIGURE 1** The basic fishbone diagram

![Fishbone Diagram](image)

4. Conducting a Qualitative Process-Level Risk Assessment: Without a Flowchart

In many cases, the risk assessment team may choose not to list risks on the flowchart itself, but brainstorm a list of process risks instead. To do that, a simple table can be used to guide the thought process. The sheet could look like the example in Figure 2 below. Enter the name of the process, the internal and external customers for the process, and the stakeholders or “interested parties” in the header. Then the table can prompt for the name of the process step (which can be derived from the flowchart for that process) and allow space for risks to be collected from the group. The risk table can be broken up into the same 5M categories as suggested by the fishbone in Figure 1 above. Note that the risk categories can also be anything that the team desires. For example, in a production process, the risk categories might be parts inspection, paperwork/reporting, raw materials, packaging/labeling, etc.

In the chart above, the analysis is qualitative rather than quantitative. The quality of the risk analysis is dependent on the composition and rigor of the team performing the analysis. One will note that there is no scoring associated with this method as there would be with a failure mode and effects analysis (FMEA) or a risk matrix. In both an FMEA and risk matrix, the criticality/severity of the failure and the probability of occurrence are ranked on a scale between 1 and 10. Then these two scores can be added together or multiplied together to derive a combined risk index or risk priority number. If the group determines that a quantitative ranking of severity and probability is useful, then it would be very easy to add these thin columns to the risk table in Figure 3 above. However, since these numbers are derived largely as a result of educated guesses by group, it can be just as valid to skip this step and simply decide whether or not the risk warrants additional process controls.

5. Next Steps: Evaluation of Actions Taken During Management Review

As required by Clause 9.3.1 of ISO 9001:2015 (see Section 1.0 above), the effectiveness of actions taken as a result of the risk analyses will be brought forward for review by senior management.

Therefore, after the assessments are completed, one of two next steps can take place. The first course of action could be to take a list of proposed process improvement actions to management review for discussion and endorsement, after which the actions would be taken. The second half of this course would then be

---

**TABLE 1** A Risk Table for Capturing Outputs of the Team

<table>
<thead>
<tr>
<th>Process Name</th>
<th>Hiring and Orientation Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>Customers: External and Internal</td>
<td></td>
</tr>
<tr>
<td>Internal departments that have a need for a new employee</td>
<td></td>
</tr>
<tr>
<td>Needs of Other Interested Parties (owners, employees, community, etc.)</td>
<td></td>
</tr>
<tr>
<td>Owners have a need for the best talent at a reasonable wage. The community has a need for satisfying employment for its citizens. The new hire has a need for fair, challenging work.</td>
<td></td>
</tr>
<tr>
<td>Organizational Objectives Related to the Process</td>
<td></td>
</tr>
<tr>
<td>Hire the best employee at the best wage; achieve a low turnover; achieve a high degree of “fit” of the employee and a high level of job satisfaction.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Process Risks</th>
<th>Current Control</th>
<th>Additional Controls Required?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Step 1</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Man</td>
<td>Job requirements may be vague</td>
<td>Requisition form</td>
</tr>
<tr>
<td><strong>Hiring manager fills in a job requisition</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Material</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methods</td>
<td>The requisition form may not address the type of job being filled</td>
<td>Requisition form</td>
</tr>
<tr>
<td><strong>Machine</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Measurement</td>
<td>Timing may be too short to find a suitable candidate</td>
<td>None</td>
</tr>
<tr>
<td><strong>Step 2</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Man</td>
<td>Skills may be in high demand</td>
<td>None</td>
</tr>
<tr>
<td><strong>Requisition is reviewed and approved by HR manager</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Material</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methods</td>
<td>There may not be a sufficient budget or forecast for the position</td>
<td>Annual strategic plan and budget</td>
</tr>
<tr>
<td><strong>Machine</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Measurement</td>
<td>There is not a disciplined way to determine the veracity of the need</td>
<td>Manager provides a justification</td>
</tr>
</tbody>
</table>

Continued on page 16
to submit results of the actions to management review. The second course of action could be for the group to autonomously perform their actions to improve the processes (if they have sufficient empowerment and authority to do so) and then simply report results to management review. The minutes of management review will then show evidence of the review of those improvement actions and any follow-up actions that are required subsequent to those actions. This provision of the standard is a very effective way of making sure that the risk assessments of each process owner were performed in an honest way.

6. Conclusions

The long-awaited promise of including risk-based thinking in the ISO 9001 quality management standard has finally been realized in the new 2015 version of the standard. Risk, using the definitions from both ISO 9000 and ISO 31000, is a very straightforward concept. Organizations can assemble a cross-functional team to assess risks at the company level and at the process level. The goal of the risk assessment is to compare process risks to current process controls to determine if the level of control is sufficient, or if additional controls and contingency plans may be required. Practitioners can start with a flowchart whenever possible, and list the risks and controls (enablers) and each step of the process. If a flowchart is not available or not desired, a simple risk table using risk categories based on the fishbone diagram to assist in brainstorming can be used. For this type of qualitative risk assessment, it is not necessary to use the numerical rankings and scores as would be required by an FMEA or risk matrix. Once improvement activities are taken, the results of those improvements will be reviewed during an appropriate management review.

Endnotes

4. Ibid.
5. Ibid.
6. Ibid.
7. Ibid.

About the author: Denis Devos is a professional engineer with a long career in quality assurance. He is an ASQ Fellow, and is a recognized expert in the application of the ISO 9001 and TS 16949 standards. Devos was the developer of the “Risk is the Compass™” risk-based audit model in 2001. Over the past 15 years, Devos has been working throughout Canada and the United States leading clients through organizational design, technical training, and internal auditing. He practices in many industries, provides training and internal audit services, and coaches his clients in lean thinking. Devos is the vice chair global for the ASQ Quality Management Division and is a regular contributor to conferences for ASQ’s Audit Division and Management Division, and at the World Conference on Quality and Improvement.
As always, everything starts with booth assembly …

Passing of the torch—incoming membership chair David Wu with outgoing membership chair Lawrence Mossman.

Above: Executive panel discussing industry trends.

Right: Reno section after their section meeting held as one of the preconference events.

Crowds dancing during opening reception.

Fantastic turnout reflected in crowds attending the various keynotes.
Your Audit Division Contacts

Chair
Nancy J. Boudreau
nboudreau@tlcnh.com

Chair-Elect
Cindy Bonafede
bonafede_cindy@bah.com

Vice Chair (Technical)
Douglas L. Berg
dougberg@earthlink.net

Vice Chair (Communications)
Lance B. Coleman
lance@fullmoonconsulting.net

Treasurer
Mary Chris Easterly
mary.chris.easterly@merck.com

Secretary
Glenda West
gswest@uss.com

Immediate Past Chair
George Callender
callendg@bellsouth.net

Nominating Chair
Conference and Events Chair
Glenda West
gswest@uss.com

Membership Chair
Lawrence Mossman
mossman@netins.net

Education and Training
Kevin Posey
kevin.posey@yahoo.com

Newsletter Editor
Lance B. Coleman
lance@fullmoonconsulting.net

Social Media Chair and
Internet Liaison
Mark Tegart
mark.tegart@srs.gov

Photographer
Nancy R. Crenshaw
nancycrenshaw@ymail.com

Voice of the Customer Chair
Susanne L. Burke
susanne.burke@aseholdings.com

Digital Media Chair
Byron Mattingly
byronmattingly2013@yahoo.com

Financial Audit Chair
Bruce Knutson
bruce.w.knutson@boeing.com

Webinar Chair
Angelo Scangas
angelo@qualitysupportgroup.com

Division Administrator
Chris DeMartino
cdemartino@asq.org

Certification Liaison
Ann Azroff
adaasq@gmail.com

In The Next Issue:
Chair’s Message
Letter From the Editor
Feature Article: Why Executives Should Audit, by Paul Harding
Tips From the Trenches: Managing External Product and Service Providers, by Lance B. Coleman and Kirsten Wagner
Article 1: TBD
Division News Bytes – WCQI Preview and Other News
Article 2: TBD

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