The Road Ahead

How ISO 9001:2015 could affect ISO/TS 16949 and automotive supply chains

by Roderick A. Munro, David Butler and Michael Willadsen

In 50 Words Or Less

- The new ISO 9001:2015 will affect how ISO/TS 16949—which covers automotive quality system standards—is revised.
- Changes to ISO/TS 16949 will have implications for management, internal auditors and members of the supply chain.
- Just as ISO 9001:2015 emphasizes risk, leadership and documentation requirements, so will the revised ISO/TS 16949.

EDITOR’S NOTE: This article was finalized in September before the release of the final, published version of ISO 9001:2015. Information presented here was based on the final draft international standard (FDIS) version.
REVIEWING THE FINAL draft international standard (FDIS) version of ISO 9001:2015 after its release in early July, a team of ASQ Automotive Division members have considered how this could and will likely affect the pending release of the new ISO/TS 16949—an International Organization for Standardization (ISO) technical specification, scheduled for release in 2016.

This specification aligns existing U.S., German, French and Italian automotive quality system standards in the global automotive industry, including throughout automotive supply chains.

Likely impacts to ISO/TS 16949 include the new overall structure of the standard and the elimination of the mandatory quality manual, mandatory documented procedures and the management representative.
We agree ISO/TS 16949 should eliminate the management representative requirement; however, we do not expect the ISO/TS 16949 to eliminate the requirements for a quality manual and selected document procedures. We expect risk-based thinking to be a key focus in the updated ISO/TS 16949, and we expect ISO/TS 16949 to emphasize demonstrated leadership and commitment requirements with documented information (the new code words that replace documented procedure and records) requirements.

The Annex SL and the overlay of the quality (ISO 9001—Quality management systems—Requirements), environment (ISO 14001—Environmental management systems—Requirements with guidance for use) and safety (ISO 45001—Occupational health and safety management systems—Requirements) standards are similar. The ISO/TS 16949 revision could include more environmental and safety aspects, and quality professionals will need to start using the term “quality aspects” as it is used in the environmental and safety areas.

Overview of the FDIS
The ISO/FDIS 9001:2015 has the typical introduction and clauses one to three as seen in past versions (see Table 1). Besides a section on the process approach and risk-based thinking, ISO/FDIS 9001:2015 includes a graphic that depicts how to think about the process approach and a figure that illustrates the new structure of the management system in a plan-do-check-act style, which looks very different from the ISO 9001:2008 graphic.

Let's review clauses four to 10 of ISO/FDIS 9001:2015 and consider some of the implications for management, internal auditors and members of the supply chain when ISO/TS 16949 is revised.

### Clause 4. Context of the organization
Contains four subclauses, with 13 shalls (requirements) and three documented information statements. Internal and external issues shall be identified as they relate to the purpose and direction of the organization. Documented lists of relevant requirements and relevant interested parties shall be maintained and updated. The quality management system (QMS) shall be established with appropriate parameters with identified boundaries, scopes and a process-approach structure. Other requirements are carried over from ISO 9001:2008.

**Implications for management:** Executives are in business to make a profit for their organizations and must document how this money-making process has been put into place with the end goal of satisfying the customers and meeting regulatory requirements. In lieu of the difficulties the automotive industry has faced (such as General Motors’ ignition switch recall in 2014 and the massive Takata air bag recall earlier this year), it is expected the new requirements for risk-based thinking will be greatly expanded and magnified in the next version of ISO/TS 16949. Other high-risk industries—such as aerospace, defense and electronics—also could see tighter and more difficult requirements.

**Implications for internal auditors:** Auditors will be retrained to think differently and fully understand the differences the new standard will make to scoring. This could present challenges for ISO/TS 16949 auditors because the risk depends on the product.

Large variations in requirements in industry or customer-specific guidance documents will create confusion and compliance issues for suppliers. Auditors must understand the fundamentals of finance and economics. Nonautomotive and subtier suppliers also will need to train internal auditors in process-approach auditing.

**Implications for the supply chain:** The new ISO 9001:2015 should make it easier for subtier suppliers to qualify for certification to the standard. It will likely

### ISO/FDIS 9001:2015 overview / TABLE 1

<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>0. Introduction</td>
<td>0. Introduction</td>
</tr>
<tr>
<td>1. Scope</td>
<td>1. Scope</td>
</tr>
<tr>
<td>2. Normative references</td>
<td>2. Normative references</td>
</tr>
<tr>
<td>3. Terms and definitions</td>
<td>3. Terms and definitions</td>
</tr>
<tr>
<td>4. Context of the organization</td>
<td>4. Quality management system</td>
</tr>
<tr>
<td>5. Leadership</td>
<td>5. Management responsibility</td>
</tr>
<tr>
<td>7. Support</td>
<td>7. Product realization</td>
</tr>
<tr>
<td>8. Operation</td>
<td>8. Measurement, analysis and improvement</td>
</tr>
<tr>
<td>9. Performance evaluation</td>
<td></td>
</tr>
<tr>
<td>10. Improvement</td>
<td></td>
</tr>
</tbody>
</table>

FDIS = final draft international standard
widen the gap, however, between ISO 9001 and ISO/TS 16949 because of a few structural changes.

Compliance with the current mandate from some North American original equipment manufacturers (OEM) that requires subtier supplier certification or a second-party audit will be difficult, if not impossible. Many small subtier suppliers cannot afford the cost of ISO/TS 16949 registration and cannot support multiple second-party assessments.

Many OEMs and some tier-one suppliers still behave as if the documentation is what drives the processes—and not that the processes drive the documentation. This is also a common issue in healthcare organizations.

**Clause 5. Leadership**

**New section with three subclauses, six shalls and one documented information statement.** This new section requires that top managers demonstrate leadership and commitment. The top person at each site shall demonstrate how they have taken accountability for the performance of the organization and how they are developing, coaching and monitoring staff. Roles and responsibilities shall be defined for all supporting organization functions, with top leaders taking much more active roles in the overall QMS management and effectiveness.

**Implications for management:** Many managers believe they are leaders, and based on the new requirements, they may not be. Few senior leaders get involved to the level that this new standard will require. Being able to demonstrate they are consistently involved—for instance, on the shop floor or in problem-solving meetings—is going to be a challenge for many. There must be evidence their leadership is effective and demonstrates clear improvement and continued positive results. One benefit may be that the revised standard will force organizations to look at developing effective leaders.

**Implications for internal auditors:** Much more interaction will be needed between auditors and senior leadership. This may require training auditors to learn the business language used by leaders. Determining whether the processes are effective may be a challenge for internal and external auditors—that is, does effective leadership always translate into improved metrics? Or, are there some subjective determinations to be made?

**Implications for the supply chain:** The ISO/TS 16949 customer addendums help ensure tier-one suppliers, registrars and auditors understand requirements for risk and customer focus. Subtier suppliers, however, may not fully understand the customer requirements because many come from an OEM that is one, two or three levels up the supply chain.

**Clause 6. Planning**

**Three subclauses that introduce the risk approach, with nine shalls and one documented information statement.** Documented information will be needed to demonstrate the planning for quality, and how quality objectives and relevant functions are to be monitored for satisfying customer requirements and regulations. Communication to interested parties shall be demonstrated, along with an ongoing change process to update the systems as needed. Also, the organization shall evaluate the effectiveness of these actions.

**Implications for management:** Barriers that currently exist for sharing technical information must be removed for all parties to fully understand the risk. Considering the unique customer-specific requirements, automotive tier suppliers must put additional emphasis on this section. There must be discussion regarding organizations that supply to multiple OEMs with their own specific requirements. Down the line, this may force U.S. OEMs and others to agree on what they expect from their suppliers.

**Implications for internal auditors:** Auditors will have to make certain advanced product quality planning, or APQP, is robust to verify that risk is properly identified, transparent and understood among the tier suppliers. An additional challenge for auditors would be assessing the effectiveness of how the risks are managed.

**Implications for the supply chain:** We expect tier-one suppliers to manage this requirement fairly well because it is already a focus of many OEM customers. Subtier suppliers have not been exposed to this way of planning (far more than submitting a production part approval process, or PPAP). ISO/TS 16949 should have clear expectations defined for this item.

Because change management has always been a weakness in the automotive industry, and in lieu of the recent automotive recalls, we can expect those requirements to be enhanced in the next revision of ISO/TS 16949. Suppliers could benefit because it will
force organizations to expand their thinking about how change affects their customers.

Clause 7. Support
Five subclauses that carry over many ISO 9001:2008 requirements, with 24 shalls and 10 documented information statements. Resources—both people and infrastructure—will be needed to achieve the desired outcomes with all interested parties.

Competency at all levels of the organization—not just production workers—shall be demonstrated as related to the outcomes of the quality performance. This includes everyone coming under the control of the QMS—contractors and truck drivers, for example. Documentation controls similar to those in ISO 9001:2008 shall be in place and updated to ensure accurate information is at the point of use.

Implications for management: This should not be a problem for larger tier-one organizations, but it could be a serious challenge for some small organizations with limited staff. Many organizations are looking to increase value-add employees and limit the number of employees in support functions.

Implications for internal auditors: Because this section may lead to more subjective findings or observations, auditors will need to be trained to recognize whether resources are sufficient when managing a variety of different risk levels at organizations.

Implications for the supply chain: Not all suppliers have been exposed to or are required to comply with environmental standards. With the focus on managing risk in this new standard, lot control and traceability may need improvement. Response time and lot size may be a greater concern due to risk. Measurement traceability also could potentially be applied to training processes, surveys and other nonmechanical measurement devices.

Clause 8. Operation
Seven subclauses with numerous subclauses specific to the quality side of the business, with 55 shalls and 16 documented information statements. Many things in this clause are similar to the current process, including: plan, implement and controls for processes needed to meet requirements; communicating with customers; design and development of products and services; externally provided products and services; production and service provisions; release of products and services; and nonconforming outputs, products and services.

Without the exclusion clause in the new standard, organizations will need to think a little differently about how they set acceptance and compliance levels on their products and services.

Implications for management: The more specific and different the customer or industry guidance is, the more difficult it will be for an organization to satisfy those requirements. It is already very difficult to generate multiple varieties of process failure mode and effects analysis (PFMEA) documents when customers don’t use the Automotive Industry Action Group (AIAG) format. For this to be effective, all of the OEMs will need to agree on how the supplier chain needs to address risk.

Implications for internal auditors: Auditors will have to understand the product and processes enough to enable assessment based on risk and unique customer requirements. This could add to the workload of auditors due to additional requirements developed with the roll-out of the updated standard and ongoing changes to the OEM, and thus tier-one supplier changes on customer-specific requirements.

Implications for the supply chain: The automotive industry is already familiar with using turtle diagrams and the process approach as defined in ISO/FDIS 9001:2015. This, however, is not a common practice for subtier suppliers. These suppliers will likely have difficulty with this fairly simple update if there is no clear definition or a reference document specifically for this requirement, such as a management or leadership guideline for how the turtle diagram or process flow should be organized.

Assessing risk has been a challenge for tier-one suppliers. In many cases, failure mode and effects analyses (FMEA) end up in a file cabinet somewhere. This addition will test some of these organizations.

Clause 9. Performance evaluation
Three subclauses, with 16 shalls and three documented information statements. Much in this clause
is similar to the current process, including: monitoring, measurement, analysis and evaluation; gather and analyze information from customers and the process; maintain an effective internal audit process; and use of an effective management review process of the system. The document information is focused on the internal audit process.

Implications for management: Suppliers that adhere to multiple ISO standards will have a common framework, which will be this new version of ISO 9001. That will help greatly with alignment. There is a potential for a ISO/TS 16949 industry management risk standard to be developed, or customer requirements may be modified in a way to make risk management more difficult than before.

We suggest ASQ should help influence ISO/TS 16949 and standards from other groups—such as Verband Der Automobilindustrie, Germany's automotive industry association, and ANFIA, Italy's National Association of Car Building Industries—to mitigate these concerns and call for more collaboration.

Implications for internal auditors: Auditors will need additional training in business systems to recognize whether resources are sufficient when managing a variety of different risk levels in organizations.

Implications for the supply chain: It will be important for industry groups (such as ASQ's automotive, aerospace and healthcare divisions) to help suppliers become familiar with this new standard.

ASQ divisions should consider drafting guidelines to help members and leaders understand how these standards affect them. Quality professionals in each division have been in the middle of implementing changes to the standard in the past. Top management at each plant will need to pay more attention now because the focus will be on them (plant-level vs. corporate-level focus).

Clause 10. Improvement

Three subclauses, with eight shalls and one documented information statement. Much in this clause is similar to the current process, including: determining and selecting opportunities for improvement, maintaining an effective corrective action process, and continually improving the overall QMS process.

Implications for management: Systems shall be in place to ensure the review of processes, products and services as they relate to the entire QMS (process approach). When nonconformities are found in the system, the organization will now need to determine whether similar issues can occur in other parts of the organization and take steps to prevent such occurrences in the future.

A documented procedure is not required; however, documented information shall show the nature of the nonconformances and any subsequent actions taken. Automotive organizations already should be doing this.

Implications for internal auditors: Automotive auditors should continue conducting audits because they have been trained about the additional need to ask about the risk to the organization when nonconformities are noted. Nonautomotive auditors must include reviews for root cause analysis, and provide evidence that other systems have been reviewed to prevent recurrence of the issue and ensure there are accurate records of actions taken with any future updates.

Implications for the supply chain: There is a possibility OEM customers will take the opportunity to use ISO/TS 16949 to bolster adherence to the Chartered Quality Institute (CQI) standards and other customer-specific requirements that are not currently pushed through the entire supply chain.

We will have to watch closely to see how ISO/TS 16949 and other standards interpret this clause. Subtier suppliers are already balking at supporting the second-party audits, especially if they have a lot of customers.

A simpler way to qualify smaller subtier suppliers will be essential. The challenge will be determining what level of improvement is acceptable. Will the OEMs dictate what that should look like? Or, will the level of improvement be compared to internal company objectives?

Common-sense thinking

These are just some of the beginning thoughts and discussions that have started at ASQ's Automotive Division council level as we look for ways to add value to our members and leaders throughout the automotive supply chain.

The expanding, and sometimes conflicting OEM customer-specific requirements could be incorporated more
fully into the new ISO/TS 16949. One-size-fits-all requirements (that is, bulk deliveries recorded in a parts per million reporting structure, paint standards used for powdered-coat applications, and brazing operations being evaluated using heat-treat specifications) are yet to be addressed.

Another area where we see a huge risk to tier-one suppliers is in deploying OEM requirements for second-party audits to ISO/TS 16949, and AIAG and CQI guidance manuals. Without a commonized approach through ISO/TS 16949, the tier-one suppliers and registrars will have tough decisions to make in the near future. Grandfathering some organizations under contract while enforcing new rules will lead to many issues and could even lead to lawsuits for the OEMs.

The ASQ Automotive Division will continue efforts to instill common-sense thinking into any new requirements. We look forward to future discussions with OEMs, tier suppliers and subtier suppliers to create an even more robust automotive supply chain. QP

MICHAEL WILLADSEN is quality manager at Mueller Water Products in Decatur, IL. He has a bachelor’s degree in business management from Cleary University in Ann Arbor, MI. A senior ASQ member, Willadsen is an ASQ-certified manager of quality/organizational excellence, quality auditor and quality engineer. He is also an IR0 quality management systems lead assessor. He is the author of Lean Six Sigma for the Healthcare Practice (ASQ Quality Press, 2009) and co-author of the Certified Six Sigma Green Belt Handbook, second edition (ASQ Quality Press, 2015).

DAVID BUTLER is global director of corporate quality at Ti Automotive in Auburn Hills, MI. He holds a bachelor’s degree in business administration from the University of Phoenix. A senior ASQ member, Butler is an ASQ-certified quality engineer and Six Sigma Black Belt. He is also chair-elect for ASQ’s Automotive Division Council and is a member of ASQ’s Customer-Supplier Division and Quality Management Division.

RODERICK A. MUNRO is business improvement coach at Ram Q Universe Inc. in Suttons Bay, MI. He holds a doctorate in instructional technology from Wayne State University in Detroit. A fellow of the Chartered Quality Institute and ASQ, Munro is an ASQ-certified manager of quality/organizational excellence, quality auditor and quality engineer. He is also an IR0 quality management systems lead assessor. He is the author of Lean Six Sigma for the Healthcare Practice (ASQ Quality Press, 2009) and co-author of the Certified Six Sigma Green Belt Handbook, second edition (ASQ Quality Press, 2015).