Automotive QMS Update
IATF 16949:2016

September 2016

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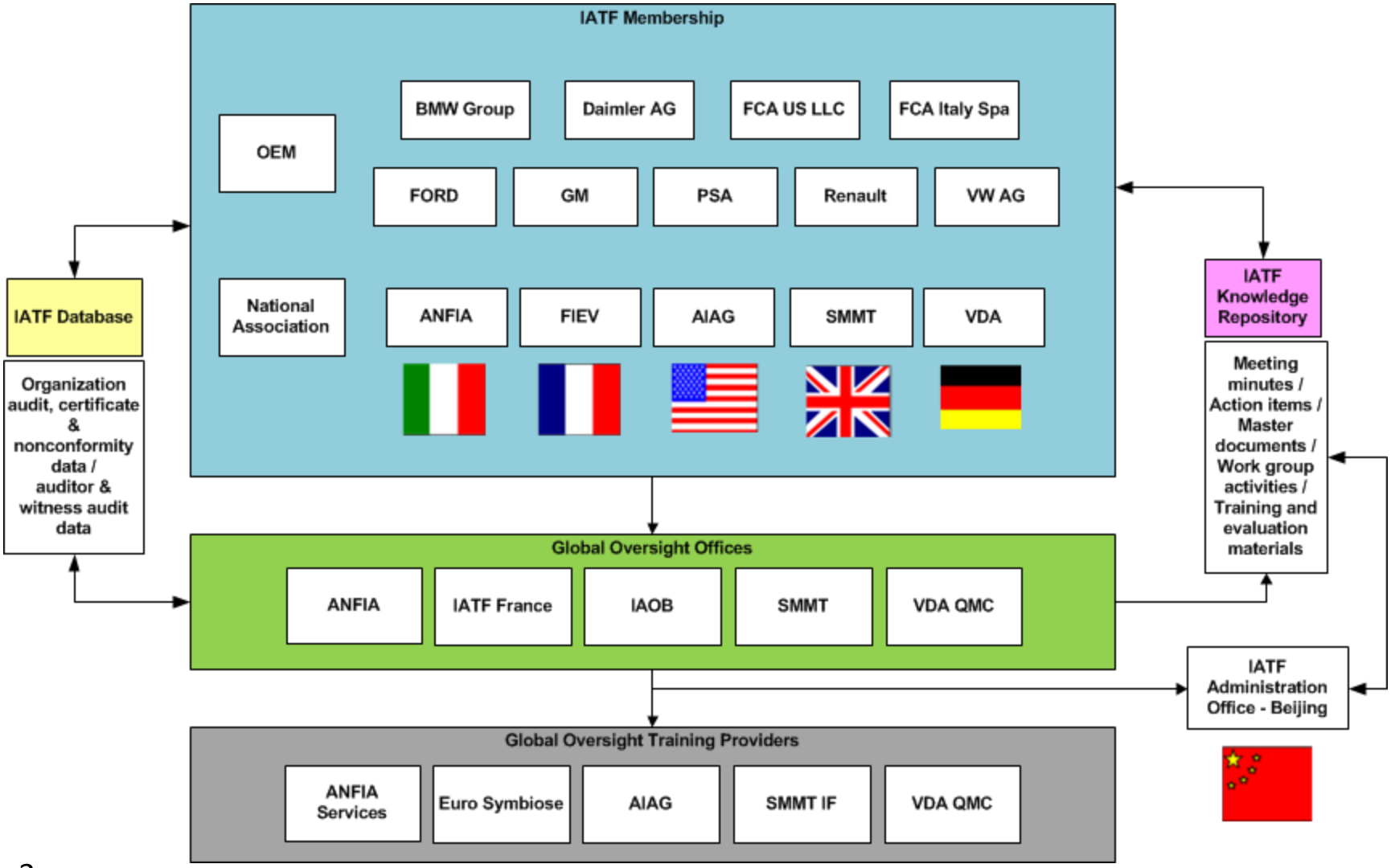
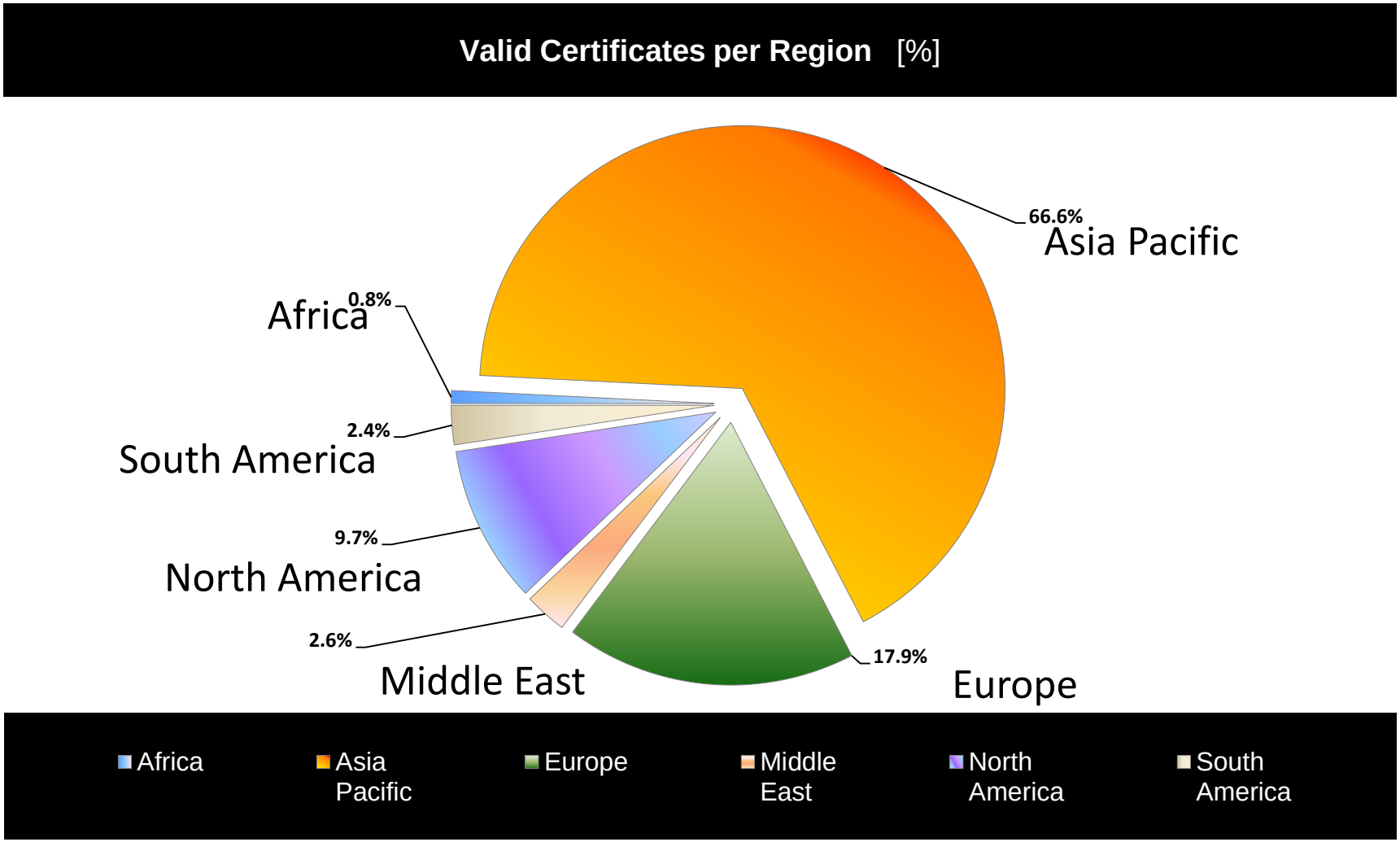
Ms. Cherie Reiche
International Automotive Oversight Bureau

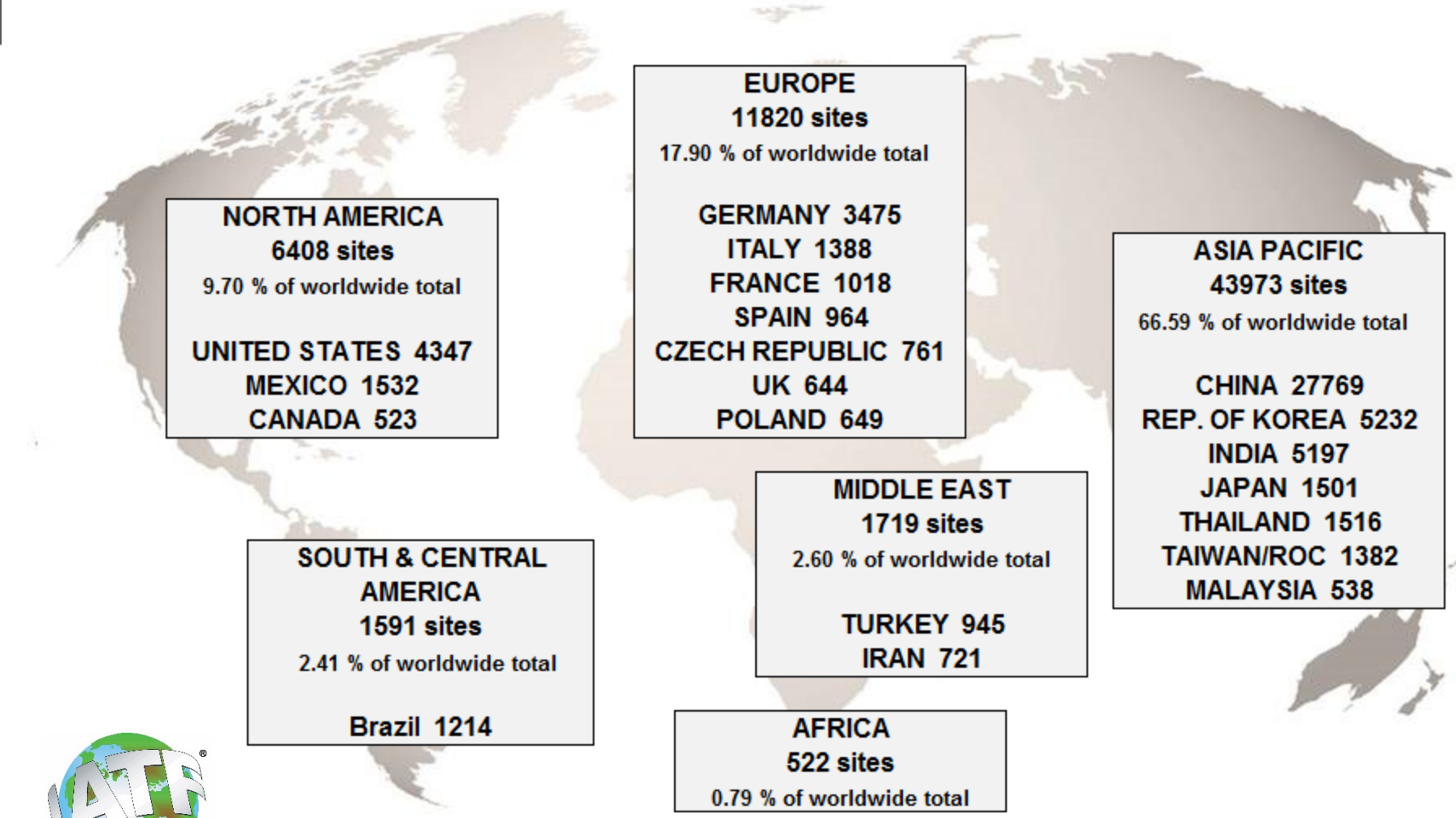
IATF Scheme Management Structure



Percent Regional Certificate Distribution



Distribution of 66,033 certificates (31 August 2016)



Note: only countries with greater than 500 certificates are listed on this slide

Oversight CBs & Certificates

31st August 2016

Oversight	No. CBs	Certificate Count	Percentage (%)
ANFIA (Italy)	2	1776	~2.7
IAOB (USA)	20	21,494	32.5
IATF France (France)	3	2022	~3.0
SMMT (England)	6	13,101	19.8
VDA QMC (Germany)	13	27,639	~42.0
Total	44	66,033	100

Disciplined development method for IATF 16949

- Revision work began in December 2014 and was completed in August 2016
- The team completed a 5-Phase approach to revising ISO/TS 16949 into IATF 16949
  - Pre-plan; Analyze; Build; Validate; and Deploy
- Revision Work Team consisted of 17 global partners from 14 organizations (IATF OEMs, IATF Global Oversight Offices, and others)

AIAG	**IAOB**
ANFIA	**IATF France**
BMW	**Jaguar Land Rover**
FCA US LLC (formerly Chrysler)	**PSA Group**
FCA Italy S.p.A. (formerly Fiat)	**SMMT**
Ford	**VDA QMC**
GM	**VW**

Changes from ISO/TS 16949 to IATF 16949

New automotive standard: IATF 16949:2016

- IATF 16949:2016 follows the high level structure of ISO 9001:2015
- IATF 16949:2016 must be used in conjunction with ISO 9001:2015
  - 2 separate documents must be used to have ***all*** requirements
  - IATF 16949 cannot be used as a stand-alone requirements document

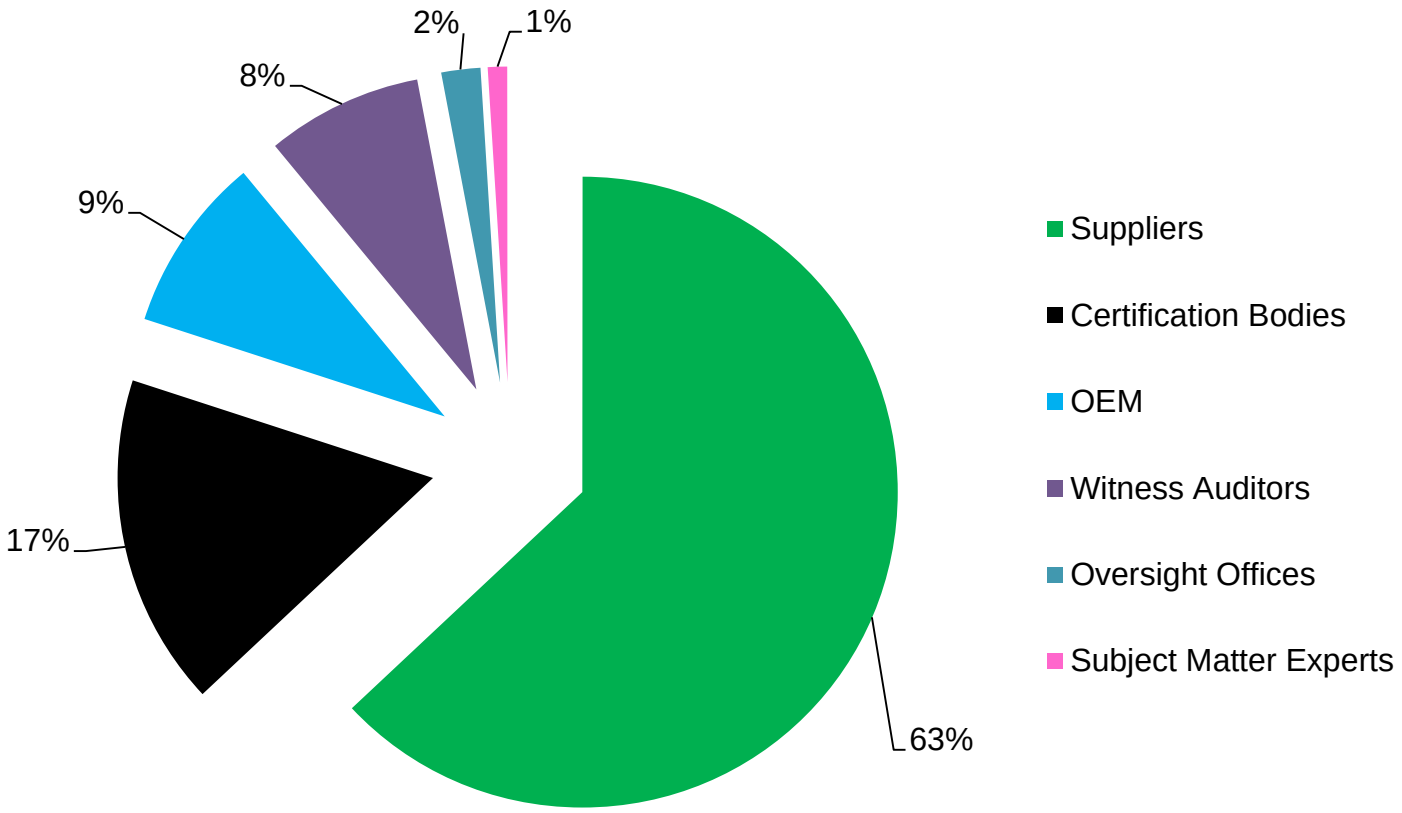
- 282 shalls / 16 shoulds in IATF 16949
  (292 shalls / 16 shoulds in ISO/TS 16949)

- IATF created a transition plan and communicated April 2016 (further revised in August 2016), which will be discussed in more detail later.

Unprecedented input from key stakeholders

- IATF launched a survey (via the National Associations) early June 2015 soliciting feedback from over 2,000 key stakeholders:
  - OEMs
  - Suppliers (all Tiers)
  - Certification Bodies
  - Witness Auditors
  - Subject Matter Experts
  - Oversight Offices
- Over 1,700 comments were received for consideration of updates to ISO/TS 16949.
- Additionally, the IATF conducted a face:face review of the draft IATF 16949 standard in Rome, Italy in April 2016 with CBs and supplier representatives.

Survey respondents



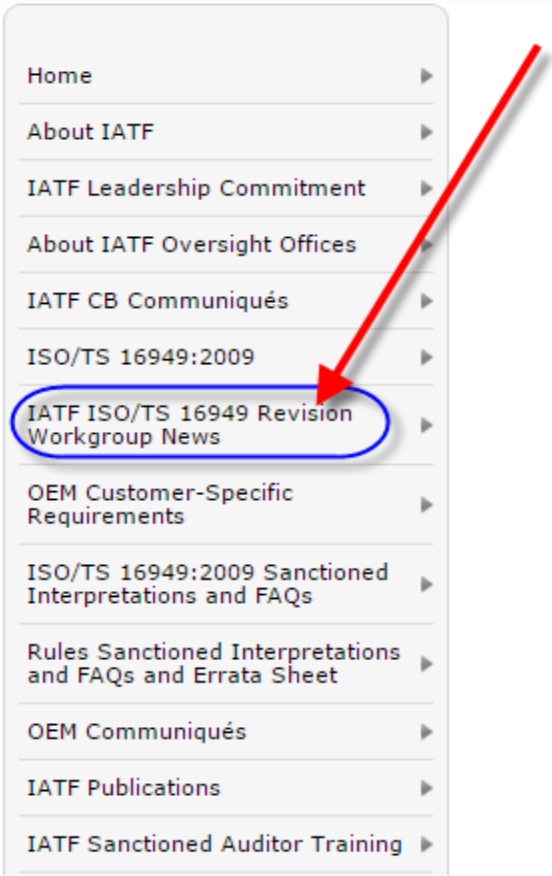
Value & Credibility

- IATF OEMs and Global Oversight members look at the linkage between ISO/TS 16949 Certification and Supplier/Client **quality performance**
  - Increased focus on operational performance and customer feedback (customer scorecards/metrics)
  - IATF 16949 contains many IATF OEM Customer Specific Requirements (CSRs)
  - OEMs are raising the bar regarding expectations for audits to reflect systemic weaknesses that affect supplier/client performance
- Goal = Prevent problems before they occur

Communication Process

International Automotive Task Force

The IATF felt it was important to keep everyone informed about project updates, so they posted regular updates to the IATF Global Oversight website:
http://www.iatfglobaloversight.org/content.aspx?page=IATF%20ISO/TS%2016949%20Revision%20Workgroup%20News



IATF ISO/TS 16949 Revision Workgroup News

10 August 2016

Guidance for the transition from **ISO/TS 16949:2009** to **IATF 16949:2016** is in the following document

IATF 16949 Transition Strategy

9 August 2016

The attached joint press release represents a win-win for IATF and ISO by communicating the IATF decision to publish the IATF 16949 standard as a separate document and maintaining a strong collaborative relationship between ISO and the IATF going forward

IATF Press Release

Additional information about IATF 16949 can be found in the following bulletin

IATF Supplemental Bulletin

Mr. Russ Hopkins
Ford Motor Company

IATF 16949 Project Lead

Legend of changes

NEW

MODIFIED

CARRYOVER

Changes

Section 4.3.1: Determining the scope of the quality management system – supplemental

- These requirements were originally included in ISO/TS 16949:2009 Sections 1.1 and 1.2. They have been moved to Section 4 within IATF 16949.
- The requirement relating to supporting functions was revised to ensure that supporting functions not only address the need to include support functions in the audit, but also to ensure that they are included in the scope of the QMS.
- In addition, any exclusion sought for design and development activities, now in Section 8.3, has to be preserved as documented information.

Changes

Section 4.3.2: Customer-specific requirements

- Although the need to fulfill and satisfy customer-specific requirements was already mentioned throughout the whole ISO/TS 16949 document, in IATF 16949 this requirement specifically addresses the need to evaluate the customer specific requirements and include them where applicable in the organization's quality management system.
- This means that the supplier would need some sort of process to evaluate each of their customer's customer-specific requirements and determine exactly how (and where) it applies to their organization's QMS, as applicable.

Changes

Section 4.4.1.1: Conformance of products and processes

- This requirement was adopted based on IATF survey feedback received
- It ensures two things:
  - that the supplier (organization) is responsible for the conformity of outsourced processes, and
  - that all products and processes meet all applicable requirements and expectations of all interested parties
- To ensure conformance of all products and processes, the organization would need to take a proactive approach to assess and address risks, and not rely only on inspection

Section 4.4.1.2: Product safety

- New section with enhanced requirements that address current and emerging issues the automotive industry is facing related to product and process safety.

- Organizations (suppliers) are required to have documented processes to manage product-safety related products and processes.

Section 4.4.1.2: Product safety

- This section includes identification of statutory requirements; identifying and controlling product-safety-related characteristics both during design and at point of manufacture; defining responsibilities, escalation processes, reaction plans, and the necessary flow of information including top management and customers; receiving special approvals for FMEAs and Control Plans; product traceability measures; and cascading of requirements throughout the supply chain.

Section 5.1.1.1: Corporate responsibility

- ISO 9001:2015 expanded the ISO 9001:2009 concept of management responsibility into a set of leadership behaviors to ensure an effective QMS.
- IATF 16949 includes the requirement for an anti-bribery policy, an employee code of conduct, and an ethics escalation policy to address increasing market and governmental expectations for improved integrity in social and environmental matters in the automotive industry.
- This implies responsibility and empowerment at all levels and functions of the supplier/organization to follow an ethical approach and report any observed unethical behavior without fear of reprisal.

Changes

Section 5.1.1.2: Process effectiveness and efficiency

- The requirement for a supplier/organization to review their processes to ensure effectiveness and efficiency was covered in ISO/TS 16949, Section 5.1.1.
- Based on survey feedback, the IATF strengthened the requirement to ensure that the results of process review activities will now be included in management review.
- Process review activities need to include evaluation methods and, as a result, implement improvements.
- The results of these steps would be an input to the management review process. Top management is thus performing a review of the process-specific reviews performed by the process owners.

Changes

Section 5.1.1.3: Process owners

- ISO/TS 16949:2009 addresses management responsibility and authority, but it does not explicitly mention that management ensure process owners understand their role and are competent.
- The IATF adopted this new requirement to ensure that management understands this expectation, by specifically identifying these process owners and ensuring they can perform their assigned roles.
- This requirement recognizes that process owners have the authority and responsibility for activities and results for the processes they manage.

Section 5.3.1: Organizational roles, responsibilities, and authorities – supplemental

- This requirement was already part of ISO/TS 16949:2009. However, based on IATF survey feedback, the IATF adopted some modifications to the requirement to address the need to document assigned personnel responsibilities and authorities.
- Additionally, this clause now clarifies that the goal is not just to address customer requirements but also to meet customer requirements fully.
- Personnel involved in capacity analysis, logistics information, customer scorecards, and customer portals now also need to be assigned and documented, per the requirements in this section.

Changes

Section 5.3.2: Responsibility and authority for product requirements and corrective actions

- Based on survey feedback, the IATF adopted some enhancements to the requirement originally included in ISO/TS 16949 to explicitly make Top Management responsible for ensuring conformity to product requirements and that corrective actions are taken.
- IATF 16949 clarifies that there must be a process to inform those with the authority and responsibility for corrective action in order that they ensure non-conforming product is identified, contained, and not shipped to the customer.
- This implies that the assigned personnel must be always available to take prompt action to prevent release.

Changes

Section 6.1.2.1: Risk analysis

- The need to identify, analyze, and consider actual and potential risks was covered in various areas of ISO/TS 16949.
- The IATF adopted additional requirements for risk analysis recognizing the continual need to analyze and respond to risk and to have suppliers/organizations consider specific risks associated with the automotive industry.
- Organizations would need to periodically review lessons learned from product recalls, product audits, field returns and repairs, complaints, scrap, and rework, and implement action plans in light of these lessons.
- The effectiveness of these actions should be evaluated, and actions integrated in to the organization's QMS.

Changes

Section 6.1.2.2: Preventive action

- The IATF enhanced the requirement found in ISO/TS 16949 by integrating what is considered to be a best practice in the automotive industry.
- Organizations would need to implement a process to lessen the impact of negative effects of risk, appropriate to the severity of the potential issues.
- Such a process would include: identifying the risk of nonconformity recurrence, documenting lessons learned, identifying and reviewing similar processes where the nonconformity could occur, and applying lessons learned to prevent such potential occurrence.

Changes

Section 6.1.2.3: Contingency plans

- The expanded requirement ensures the organization defines and prepares contingency plans along with a notification process to the customer or other interested parties.
- Organizations would first take a systematic approach to identifying and evaluating risk for all manufacturing processes, giving particular attention to external risk.
- Contingency plans would be developed for any of the outlined disruption conditions -- interruption of externally provided products, processes, and services, recurring natural disasters, fire, or infrastructure-related disruptions.
- Customer notification is a mandatory step in any contingency plan, unless there is no risk to deliver nonconforming product or affect on-time delivery.

Changes

Section 6.2.2.1: Quality objectives and planning to achieve them – supplemental

- ISO/TS 16949 included the importance of addressing customer expectations in the NOTE to Section 5.4.1.1. The IATF enhanced the requirement by requiring that it be done at all levels throughout the organization.
- In ensuring quality objectives meet customer requirements, these objectives need to consider customer targets.
- Personnel should be aware of, and committed to, achieving results that meet customer requirements.
- Quality objectives and related performance targets should be periodically reviewed for adequacy (at least annually).

Changes

Section 7.1.3.1: Plant, facility, and equipment planning

- This updated section includes an increased focus on risk identification and risk mitigation, evaluating manufacturing feasibility, re-evaluation of changes in processes, and inclusion of on-site supplier activities.
- Many operational risks can be avoided by applying risk-based thinking during planning activities, which also extends to optimization of material flow and use of floor space to control non-conforming product.
- Capacity planning evaluation during manufacturing feasibility assessments must consider customer-contracted production rates and volumes, not only current order levels.

Changes

Section 7.1.4.1: Environment for the operation of processes – supplemental

- This requirement for an organization to "maintain its premises in a state of order, cleanliness, and repair" was preserved from ISO/TS 16949 and transferred to IATF 16949.

Changes

Section 7.1.5.1.1: Measurement system analysis

- Records are now required for customer acceptance of alternative methods. The previous requirement to analyze variation in measurement results is now extended specifically to inspection equipment.
- IATF 16949 also clarifies that records of customer acceptance need to be retained along with results from alternative measurement system analysis.

Changes

Section 7.1.5.2.1: Calibration/verification records

- This updated section helps ensure that customer requirements are met through enhanced calibration/verification record retention requirements, including software installed on employee-owned or customer-owned equipment.
- IATF 16949 clarifies that a documented process is required to manage calibration/verification records in order to provide evidence of conformity, and this includes any on-site supplier-owned equipment.
- Inspection, measurement, and test equipment calibration/verification activities need to consider applicable internal, customer, legislative, and regulatory requirements in order to establish approval criteria.

Changes

Section 7.1.5.3.2: External laboratory

- This updated section allows the organization to conduct second-party assessments of laboratory facilities, but requires customer-approval of the assessment method.
- The clause also clarifies that internal laboratory requirements apply even when calibration is performed by the equipment manufacturer, and that use of calibration services may be subject to government regulatory confirmation.

Changes

Section 7.2.1: Competence – supplemental

- This section adds a requirement of “awareness,” which includes knowledge of an organization’s (supplier’s) quality policy, quality objectives, personnel contribution to the QMS, benefits of improved performance, and implications of not conforming with QMS requirements.
- It also further emphasizes the customer requirements for OJT (on-the-job training), not just quality requirements.
- Note that the use of the term "process" rather than "procedure" implies that these activities need to be managed (via the plan-do-check-act cycle), and not merely performed.

Changes

Section 7.2.2: Competence – on-the-job training

- IATF 16949 enhances the emphasis of on-the-job training and its importance in meeting customer requirements, including other interested parties.
- The process would consider any relevant interested party requirements as an input in determining the need for on-the-job training, and then consider the level of education and complexity of the tasks in determining the method used.
- This training must also include contract or agency personnel, and convey the consequences of nonconformity to customer requirements to all persons whose work affects quality.

Changes

Section 7.2.3: Internal auditor competency

- This section features greatly-enhanced requirements to the organization's internal auditor competency to ensure a more robust internal audit process.
- Organizations need to establish a documented process that considers the competencies required by this clause, take actions to address any deficiencies, assess the effectiveness of actions taken, and record a list of the approved auditors.
- The clause differentiates between quality management system auditors, manufacturing process auditors, and product auditors, and clarifies the competence requirements for each type of audit.

Changes

Section 7.2.4: Second-party auditor competency

- This new section outlines requirements for second-party auditors ensuring they are properly qualified to conduct those types of audits, with customer specific requirements being a main focus.
- The same core competencies that apply to internal auditors should, at a minimum, also apply to second-party auditors.

Changes

Section 7.3.1: Awareness – supplemental

- Includes additional requirements to ensure all employees are aware of their impact on the organization's (supplier's) product quality output, customer specific requirements, and risks involved for the customer with non-conforming product.

Changes

Section 7.3.2: Employee motivation and empowerment

- This section did not substantially change, but now requires "maintain[ing] a documented process(es)" for employee motivation and empowerment, instead of simply "having a process."

Changes

Section 7.5.1.1: Quality management system documentation

- The IATF retained the quality manual requirement that was removed in ISO 9001:2015; however, the quality manual can be one main document or a series of multiple documents (hard copy or electronic).
- This section also requires that the organization's processes and interactions are documented as part of their QMS.
- The quality manual needs to document where in the organization's QMS customer-specific requirements are addressed.

Changes

Section 7.5.3.2.1: Record retention

- This section now requires a record retention process that is defined and documented, and that includes the organization's record retention requirements.
- Specifically calls out production part approvals, tooling records, product and process design records, purchase orders, and contracts/amendments.
- If there is no customer or regulatory agency retention period requirements for these types of records, "the length of time that the product is active for production and service requirements, plus one calendar year" applies.

Changes

Section 7.5.3.2.2: Engineering specifications

- Added an engineering specifications requirement that the process is documented and agreed with the customer.
- This section also clarifies product design changes and product realization process changes, and the alignment to related sections.
- If there are no other overriding customer agreements, reviews of engineering standards/specifications changes should be completed within 10 working days of receipt of notification.

Automotive QMS Update
IATF 16949:2016

Mr. Fred Czubak
FCA US LLC

Changes

Section 8.1.1: Operational planning and control — supplemental

- This section features enhanced detail to ensure key processes are included and considered when planning for product realization.
- The required topics include customer product requirements and technical specifications, logistics requirements, manufacturing feasibility, project planning, and acceptance criteria.
- The section also clarifies the "resources needed to achieve conformity" encompasses all aspects of the development process, not just the manufacturing process requirements.

Changes

Section 8.1.2: Confidentiality

- Only a minor edit to clarify confidentiality "includes" related product information, instead of using the word "and." There is no change in intent.

Changes

Section 8.2.1.1: Customer communication — supplemental

- Added a requirement that the communication language (written or verbal) must be agreed with the customer.
- This should be considered when determining the necessary competence for roles that require customer communication.

Changes

Section 8.2.2.1: Determining the requirements for products and services – supplemental

- The IATF strengthened the standard by elevating Notes 2 and 3 of the former clause into requirements.
- This suggests current organizational knowledge regarding recycling, environmental impact, and product and manufacturing process characteristics should be standardized.
- This knowledge would be systematically reviewed and used when determining the requirements for the products and services to be offered to customers.

Changes

Section 8.2.3.1.1: Review of the requirements for products and services — supplemental

- IATF 16949 strengthens this requirement by requiring the organization to retain a documented customer authorization for waivers of formal reviews for products and services.

Changes

Section 8.2.3.1.2: Customer-designated special characteristics

- This section changes the action from "demonstrate conformity" to "conform," and clarifies that it refers to "approval documentation," rather than just "documentation.“
- There is no change in intent.

Changes

Section 8.2.3.1.3: Organization manufacturing feasibility

- Enhanced requirements for manufacturing feasibility analysis through the following changes:
- Requiring a multidisciplinary approach to analyze feasibility, considering all engineering and capacity requirements.
- Requiring this analysis for any new manufacturing or product technology, and for any changed manufacturing process or product design.
- The organization should validate their ability to make product specifications at the required rate. These should consider customer-specific requirements.

Changes

Section 8.3.1.1: Design and development of products and services – supplemental

- Strengthened the standard by elevating the NOTE in the former section to a requirement, and added a requirement for documentation of the design and development process.
- As the concept of the design and development process in the automotive industry includes manufacturing design and development, the requirements from other parts in Section 8 should be considered complimentary in the context of manufacturing and product design and development.

Changes

Section 8.3.2.1: Design and development planning – supplemental

- Clarifies when the multidisciplinary approach is to be used and who should be involved. Specifically, it must include all affected stakeholders within the organization and, as appropriate, its supply chain.
- Additional examples are provided of areas where such an approach may be used during design and development planning (including project management), and the note further clarifies that purchasing, supplier, and maintenance functions might be included as stakeholders.

Changes

Section 8.3.2.2: Product design skills

- This section adds a NOTE as an example of a product design skillset. There is no change in intent.

Section 8.3.2.3: Development of products with embedded software

- This new clause adds requirements for organization-responsible embedded software development and software development capability self-assessments.
- Organizations must use a process for quality assurance of products with internally developed embedded software, and have an appropriate assessment methodology to assess their software development process.
- The software development process must also be included within the scope of the internal audit programme; the internal auditor should be able to understand and assess the effectiveness of the software development assessment methodology chosen by the organization.

Changes

Section 8.3.3.1: Product design input

- This section expanded the minimum set of product design input requirements, emphasizing regulatory and software requirements.
- New and broadened requirements include: product specifications; boundary and interface requirements; consideration of design alternatives; assessment of risks and the organization's ability to mitigate/manage those risks; conformity targets for preservation, serviceability, health, safety, environmental, and development timing; statutory and regulatory requirements for the country of destination; and embedded software requirements.

Changes

Section 8.3.3.2: Manufacturing process design input

- Expanded the list of manufacturing process design inputs including: product design output data including special characteristics, targets for timing; manufacturing technology alternatives; new materials; product handling and ergonomic requirements, and; design for manufacturing and design for assembly.
- This could include consideration of alternatives from innovation and benchmarking results, and new materials in the supply chain that could be used to improve the manufacturing process capacity.
- This section also further strengthened the requirements by transforming the former NOTE regarding error-proofing methods into a requirement.

Section 8.3.3.3: Special characteristics

- Identify the source of special characteristics and including risk analysis to be performed by the customer or the organization.
- Expands the list of sources used to identify special characteristics, along with the requirements related to those special characteristics.
- Special characteristics need to be marked in all applicable cascaded quality planning documents; monitoring strategies should focus on reducing variation, which is typically done using statistical techniques.
- The organization must also consider customer-specific requirements for approvals and use of certain definitions and symbols, including submission of the symbol conversion table, if applicable and required.

Changes

Section 8.3.4.1: Monitoring

- These changes align the IATF 16949 standard with IATF OEM advanced quality activities and aim to reduce the number of customer-specific requirements.
- The requirement clarifies that measurements apply at specified stages during the design and development of both products and services, and that reporting must occur as required by the customer.
- This could include, for example, the periodic update of customer APQP schedule milestones, gate reviews, and open issues lists related to development activities.

Changes

Section 8.3.4.2: Design and development validation

- This section features a strengthening of the requirements for design and development validation, and also added embedded software.
- Customer specific requirements (CSRs), industry, and governmental agency-issued regulatory standards need to be considered when planning and performing design and development activities.

Changes

Section 8.3.4.3: Prototype programme

- The changes in this section strengthen the standard by focusing the organization on the quality management system for managing outsourced products and services.
- Regardless of whether the work is performed by the organization or by an outsourced process, the prototype programme and control plan are part of the scope of the QMS.
- This type of control should be considered a support process and be integrated into the design and development process.

Changes

Section 8.3.4.4: Product approval process

- These changes clarify approval requirements, with an emphasis on outsourced products and/or services and record retention required.
- The activities should be managed (with an effectiveness review and improvement actions applied) and not just performed.
- A part approval process for externally provided products and services needs to be performed prior to final product submission to customers.
- Product approval must be obtained when the customer requires it, and records retained.

Changes

Section 8.3.5.1: Design and development outputs – supplemental

- Product design output additions include a recognition of the use of 3D models, and inclusion of service parts and packaging.
- IATF 16949 clarifies that it requires product design error-proofing methods, such as DFSS, DFMA, and FTA. The application of GD&T tolerancing and positioning systems allows organizations to specify dimensions and related tolerances based on functionality relationships.
- Outputs include repair and serviceability instructions and service parts requirements that will be used by approved maintenance organizations.

Changes

Section 8.3.5.2: Manufacturing process design output

- Changes in this section strengthened verification requirements, process input variables, capacity analysis, maintenance plans and correction of process nonconformities.
- Clarifies that the process approach methodology of verifying outputs against inputs applies to the manufacturing design process.
- The list of manufacturing design outputs is also expanded

Changes

Section 8.3.6.1: Design and development changes – supplemental

- This section strengthens the requirement for change validation and approval prior to implementation, and also added embedded software.
- Design changes after initial product approval implies that products, components, and materials need to be evaluated and validated prior to production implementation.
- This validation needs to be done by the organization and the customer, when there is a customer-specific requirement.
- For products with embedded software, the change record needs to document the revision level of the software and hardware to help assure that product configuration is managed appropriately.

Changes

Section 8.4.1.1: General - supplemental (under Control of externally provided processes, products and services)

- The former NOTE about purchased products was broadened and elevated into a requirement.
- It now clarifies that all the requirements of section 8.4 apply to sub-assembly, sequencing, sorting, rework, and calibration services.

Changes

Section 8.4.1.2: Supplier selection process

- While ISO/TS 16949:2009 did address supplier selection in the ISO 9001:2008 boxed text via the Purchasing Process (see Section 7.4.1), the supplier selection process was not as detailed.
- This section now specifically calls out supplier selection process criteria, in addition to clarifying that it is a full process.
- The assessment used to select suppliers needs to be extended beyond typical QMS audits and include aspects such as: risk to product conformity and uninterrupted supply of the organization's product to their customers, etc.

Changes

Section 8.4.1.3: Customer-directed sources (also known as "Directed–Buy")

- This section features a clarification of the organization's responsibilities for customer directed sources, even for customer directed-buy suppliers.
- Unless otherwise defined by contract, all requirements of IATF 16949 Section 8.4 apply in this situation, except requirements related to the selection of the supplier itself.

Changes

Section 8.4.2.1: Type and extent of control – supplemental

- The changes in this section further strengthened the requirement for control of outsourced processes, including the assessment of risk.
- Internal and customer requirements are inputs that need to be considered during the development of methods to control externally provided products, processes, and services.
- Type and control needs to be consistent with supplier performance and an assessment of product, material, or service risk.
- This implies a constant monitoring of performance and assessment of risk based on the established criteria, triggering the actions to escalate (increase) or reduce the types and extent of control.

Changes

Section 8.4.2.2: Statutory and regulatory requirements

- The updates clarify the applicability of statutory and regulatory requirements and strengthen the requirements.
- Identification of applicable statutory and regulatory requirements needs to consider the country of receipt, shipment, and delivery.
- When special controls are required, the organization must implement these requirements and cascade those requirements down to their suppliers.

Changes

Section 8.4.2.3: Supplier quality management system development

- This section provides a method to strengthen ISO 9001 certification, aligns with customer-specific requirements, and clarifies the acceptable third-party certification bodies (which shall be recognized by the IATF).
- Instead of requiring organizations to simply "develop" the supplier QMS, this section outlines a progressive approach that goes from compliance to ISO 9001 via second-party audits all the way through certification to IATF 16949 through third-party certification.

Changes

Section 8.4.2.3.1: Automotive product-related software or automotive products with embedded software

- This new section added requirements for software development assessment methodology.
- These requirements align to those presented within Section 8.3, but are now cascaded down to suppliers.

Changes

Section 8.4.2.4: Supplier monitoring

- Organizations should continuously review inputs and introduce improvement actions regarding supplier monitoring data, as needed.
- Documented and non-documented yard holds and stop ships should be considered customer disruptions, and the number of premium freight occurrences need to be monitored.
- Performance indicators provided by the customer and from service need to be included within the organization's supplier monitoring process.

Changes

Section 8.4.2.4.1: Second-party audits

- This new section aligns customer-specific requirements into the IATF 16949 standard.
- Second-party audits should consider issues relevant to the organization beyond simply the maturity of their QMS development.
- Examples of situations that could trigger a second-party audit include: input from supplier performance indicators; risk assessment results and follow-up of open issues from process and product audits; and new development launch readiness.
- The organization's criteria for determining the need, type, frequency, and scope of second-party audits must be based on a risk analysis.

Changes

Section 8.4.2.5: Supplier development

- This section adds an emphasis on performance-based supplier development activities.
- Supplier monitoring process should be considered an input to the supplier development activities. These development activities should consider both short term and long term goals.
  - Short term efforts would generally focus on supplier products, and would require defining suitable methods to assure the quality of purchased product from each supplier.
  - Long term efforts would generally focus on supplier QMS and manufacturing processes on the whole, and consider audits, training, and enhancement efforts that implement and enhance quality assurance agreements between suppliers and the organization, and further reduce risk.

Changes

Section 8.4.3.1: Information for external providers – supplemental

- The organization is required to provide key information to their supply chain through this new requirement.
- This information includes all applicable statutory and regulatory requirements and special product and process characteristics.

Changes

Section 8.5.1.1: Control plan

- This section strengthened the control plan requirements and aligned IATF OEM customer-specific requirements into the IATF 16949 standard. It also elevated a NOTE regarding customer approval to a requirement, and strengthened the control plan review and update criteria and linked to the PFMEA updates.
- Control plans are needed for the relevant manufacturing site and all product supplied, and not just for the final product or final assembly line, as an example.
- Although family control plans are acceptable for bulk material and similar parts using a common manufacturing process, care should be given to identify the degree of difference that is acceptable to apply this common control.

Changes

Section 8.5.1.2: Standardized work – operator instructions and visual standards

- Through this section, IATF 16949 strengthens the requirements for standardized work, including the requirement to address specific language needs.
- Standardized work documents need to be clearly understood by the organization's operators and should include all applicable quality, safety, and other aspects necessary to consistently perform each manufacturing operation.

Changes

Section 8.5.1.3: Verification of job set-ups

- The changes in this section elevate a NOTE to a requirement, and clarify record retention.
- Clarify that the organization shall verify job changes that require a new set-up; maintain documented information for set-up personnel; perform first-off/last-off part validation, as applicable, including retention and comparison; and retain records of process and product approval following these validation actions.

Changes

Section 8.5.1.4: Verification after shutdown

- Defines a new requirement for verification after shutdown, integrating industry lessons learned and/or best practices.
- The necessary actions after the shutdown period should be anticipated in the PFMEA, control plans, and maintenance instructions, as appropriate.
- A multidisciplinary approach should be used to identify any additional actions needed to address unexpected shutdown events.

Changes

Section 8.5.1.5: Total productive maintenance

- Strengthens the requirement for equipment maintenance and overall proactive management of the Total Productive Maintenance (TPM).
- TPM is a system for maintaining and improving the integrity of production and quality systems through machines, equipment, processes, and employees that add value to the manufacturing process. TPM should be fully integrated within the manufacturing processes and any necessary support processes.

Changes

Section 8.5.1.6: Management of production tooling and manufacturing, test, inspection tooling and equipment

- IATF 16949 features strengthened tooling and equipment marking and tracking requirements.
- This requirement extends the scope to production and service materials and for bulk materials, as applicable, and clarifies that requirements apply whether tooling is owned by the organization or by the customer.
- The updates clarify that the system for production tooling management must include tool design modification documentation and tool identification information.
- Customer-owned tools and equipment need to be permanently marked in a visible location.

Changes

Section 8.5.1.7: Production scheduling

- This section emphasized the importance of planning information and integrated IATF OEM customer lessons learned.
- Ensure that customer orders/demands will be achieved.
- This suggests the organization needs a robust feasibility review process regarding production scheduling. The production scheduling activities also need to include all relevant planning information as inputs to their feasibility review and make any necessary adjustments.

Changes

Section 8.5.2.1: Identification and traceability — supplemental

- Strengthened the requirements for traceability to support industry lessons learned related to field issues.
- Requirement of clear start and stop points for product received by the customer is aligned with the definition of traceability in ISO 9000:2015.

Changes

Section 8.5.4.1: Preservation – supplemental

- Adds specificity to preservation controls and includes application to internal and/or external providers.
- Preservation activities are expanded in two ways: first, activities that are considered preservation controls, and second, locations where preservation controls apply.
- Preservation controls include the preservation of identification during the product shelf life; a contamination control program appropriate to identified risks; design and development of robust packaging and storage areas; adequate transmission and transportation considerations; and measures to protect product integrity.

Changes

Section 8.5.5.1: Feedback of information from service

- Requirements for this section feature an expanded scope to include material handling and logistics.
- The new second NOTE also clarifies that "service concerns" should include the results of field failure test analysis where applicable
  - the intent of this addition is to ensure that the organization is aware of nonconformities that occur outside of its organization.

Changes

Section 8.5.5.2: Service agreement with customer

- This section clarifies that service centers need to comply with all applicable requirements when there is a service agreement with the customer.

Changes

Section 8.5.6.1: Control of changes – supplemental

- IATF 16949 strengthens the control of changes requirements in the standard to align with existing IATF OEM requirements.
- The changes clarify that "any change" includes those caused by the organization and/or the customer, in addition to those by any supplier.
- The process to control and react to changes needs to include risk analysis and to retain records of verification and validation.
- FMEAs should be reviewed for any manufacturing or product changes, prior to implementation. Production trial run activities should be planned based on the risk and complexity of the changes.

Changes

Section 8.5.6.1.1: Temporary change of process controls

- This new requirement for temporary control of process changes addresses issues experienced by the IATF OEM customers.
- The organization must identify, document, and maintain a list of process controls that includes both the primary process control (example: automated nut driver) and the approved back-up or alternate methods (example: manual torque wrench). The list must be updated regularly to reflect the current and approved process controls.
- The use of alternative control methods is considered a process; therefore, the organization is expected to manage these activities appropriately.

Changes

Section 8.6.1: Release of products and services — supplemental

- While ISO/TS 16949:2009 did mention product and delivery of service in the ISO 9001:2008 boxed text via the Monitoring and Measurement of Product section (see Section 7.4.1), the product and delivery of service process is further detailed in IATF 16949.
- These updates strengthen the standard to ensure process controls align with the control plan.
- To achieve coherence between the control plan and the planned arrangements to verify product and service conformity, the organization should conduct a regular control plan audit that compares the current approval status of the product and process with the actual controls applied in the manufacturing process.

Changes

Section 8.6.2: Layout inspection and functional testing

- An added note clarifies that frequency of layout inspections is determined by the customer.

Changes

Section 8.6.3: Appearance items

- This section requires organizations to provide masters for haptic technology, as appropriate. Haptic technology recreates the sense of touch by applying forces, vibrations, or motions to the user.

Changes

Section 8.6.4: Verification and acceptance of conformity of externally provided products and services

- Changes in this section align with ISO 9001:2015 terminology and clarify the source of statistical data as that provided by the supplier to the organization.

Changes

Section 8.6.5: Statutory and regulatory conformity

- Strengthens the standard for statutory and regulatory conformity to require evidence of compliance.
- "Prior to release" means that the organization should implement a process and/or agreements with its suppliers requiring sufficient prevention and detection controls to ensure that products meet all applicable statutory, regulatory, and other requirements.
- These requirements must consider both the countries where products are manufactured and the destination countries.

Changes

Section 8.6.6: Acceptance criteria

- This section clarifies "where required" to be "where appropriate or required," and updates the clause reference to align with the new structure.
- There is no major change in the intent of this section.

Changes

Section 8.7.1.1: Customer authorization for concession

- Changes in this section are for the alignment of terminology, and the clarification of concessions applied to rework of nonconforming product and sub-component reuse.
- The changes clarify that the organization must obtain customer authorization prior to further processing for "use as is" and rework disposition of nonconforming products, and sub-component reuse must be clearly communicated to the customer.
- Appropriate internal verification and validation activities of any rework or reuse of sub-components should be approved prior to customer submission.

Changes

Section 8.7.1.2: Control of nonconforming product – customer specified process

- This section ensures customer controlled shipping requirements are followed, and that these customer-specific requirements are integrated into the organization's internal activities for the control of nonconforming product.

Changes

Section 8.7.1.3: Control of suspect product

- The updates in this section augment the requirements for control of suspect product by ensuring containment training is implemented.
- Appropriate training should consider, for example, awareness about special characteristics, customer-specific requirements related to nonconforming product control, product safety, escalation processes, storage areas, and related roles.

Changes

Section 8.7.1.4: Control of reworked product

- This update increases the scope of control of reworked product requirements to include: customer approval, risk assessment, rework confirmation, traceability, and retention of documented information.
- The risk analysis and customer approval requirements are interrelated; FMEAs should identify and address risks related to each possible rework of the characteristics stated in the control plan.

Changes

Section 8.7.1.5: Control of repaired product

- The changes in this section clarify the requirement and the need for follow-up with detailed information for reworked product.

Changes

Section 8.7.1.6: Customer notification

- This new section features a new automotive requirement to address modifications in ISO 9001 requirements and address customer issues for IATF OEM concerns.
- While customer notification is mentioned twice in ISO/TS 16949:2009 (see Section 7.4.3.2 and Section 8.2.1.1), it did not address customer notification in a standalone section.
- The organization is required to immediately notify the customer if they ship nonconforming product, and follow up with detailed documentation.

Changes

Section 8.7.1.7: Nonconforming product disposition

- Strengthen the requirement of disposition of nonconforming product by clarifying that organizations must also have a documented process for disposition of nonconforming product not subject to rework or repair.
- Planned activities need to be managed and the results considered to improve this process.
- Contamination control practices should be applied to avoid any risk of unintended use of this type of nonconforming products.
- Customer approval is required before nonconforming products in this category can be diverted for service or any other use.

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Changes

Section 9.1.1.1: Monitoring and measurement of manufacturing processes

- Clarifies the requirement for targeting process effectiveness and efficiency (not just “having” a process, but monitoring it)
- Further ensures that organizations support the manufacturing process through defined roles, responsibilities, and effective escalation processes to drive process capability and stability.
- The NOTE clarifies that it may not be possible or feasible to measure product or manufacturing process characteristics through process capability assessments. In such cases, a rate or index of lot conformity may be acceptable.

Changes

Section 9.1.1.2: Identification of statistical tools

- Requirements for the identification of statistical tools feature clarifications regarding the documented deployment of the use of statistical tools from DFMEA, PFMEA, and the APQP (or equivalent) process.
- The tool chosen in the APQP (or equivalent) process must be included in design/process risk analysis and the control plan.

Changes

Section 9.1.1.3: Application of statistical concepts

- This section features a clarification regarding requirements for those involved in capturing and analyzing data; previously, this was driven across all employees regardless of relevance.
- These concepts should be included in the competencies required for "employees involved in the collection, analysis, and management of statistical data."

Changes

Section 9.1.2.1: Customer satisfaction – supplemental

- Clarify customer satisfaction monitoring criteria and introduction of additional focus on warranty management.
- Additional focus to ensure all customer performance measures are regularly reviewed to reduce the risk of failure to achieving customer satisfaction.
- The organization has a responsibility to access, review, and take appropriate action about information published in customer portals.
  - When identifying the need for correction or improvement actions, customer scorecard deficiencies should be given priority.

Changes

Section 9.1.3.1: Prioritization

- The emphasis of the requirement changed from the ISO/TS 16949 standard's “Analysis of data" to the prioritization of actions based on performance and risk management.
- Actions to improve customer satisfaction need to take precedence as the organization considers trends and drives towards improvement.

Changes

Section 9.2.2.1: Internal audit programme

- Strengthened the need to drive a risk-based approach to the development and deployment of an organization-wide internal audit programme.
- Internal audit activities are considered a process, which require a clear definition of expected inputs, planned activities, intended outputs, and monitored performance.
- The process needs to identify and evaluate the level of risk related to each QMS process, internal and external performance trends, and process criticality.
- Then, the process would need to continuously monitor this information to trigger special internal audits and/or to plan periodic internal audits.

Changes

Section 9.2.2.2: Quality management system audit

- Strengthen the quality management system audit and the use of process approach, which further drives process improvements organization-wide.
- The audit programme is continuously monitoring information that could trigger the need for an unplanned internal audit.
- The use of the automotive process approach, including risk-based thinking, needs to be applied during the audit.
- The internal audit must also sample customer-specific QMS requirements for effective implementation.

Changes

Section 9.2.2.3: Manufacturing process audit

- Strengthens the formal approaches to ensure organizations achieve the benefits of effective manufacturing process audits.
- Shift handover should be considered a significant process event; internal auditors should look for objective evidence of an effective process to communicate and address relevant information.
- The audit must also evaluate the effective implementation of the process risk analysis, control plan, and associated documents.

Changes

Section 9.2.2.4: Product audit

- The strengthened product audit requirements now require the use of customer-specified approaches, when applicable.
- If not applicable, the organization shall define their process.

Changes

Section 9.3.1.1: Management review – supplemental

- Strengthens management review requirements to include an assessment of risk and compliance to customer requirements.
- The one-year frequency is a minimum, as the process is driven by the continuous assessment of the risks related to internal and external changes and performance-related issues.
- As changes and issues increase, the frequency of management review activities should increase in turn, preserving the minimum of at least an annual review.

Changes

Section 9.3.2.1: Management review inputs – supplemental

- Enhanced details for management review input requirements, including those related to cost of poor quality, effectiveness, efficiency, conformance, feasibility assessments, customer satisfaction, performance against maintenance objectives, warranty performance, review of customer scorecards, and the identification of potential field failures through risk analysis.
- The above should be considered the minimum information that should be covered during management review; a monitoring system should be in place, with criteria that trigger special unplanned management review activities.

Changes

Section 9.3.3.1: Management review outputs – supplemental

- Enhanced section ensures action is taken where customer requirements are not achieved, and supports the continual analysis of process performance and risk.
- Even though process owners should address customer performance issues related to the processes they manage, this requirement gives top management the clear and ultimate responsibility to address customer performance issues and ensure the effectiveness of corrective actions.

Changes

Section 10.2.3: Problem solving

- Updates to this section are to facilitate the consolidation of IATF OEM customer specific minimum requirements.
- The organization's defined process(es) for problem solving must consider: various types and scales of problems; control of nonconforming output; systemic corrective action and verification of effectiveness; and review/updates to documented information.
- In addition, CSRs related to nonconformity and corrective action need to be used and integrated within the internal corrective action process.

Changes

Section 10.2.4: Error-proofing

- This section, which previously only mentioned the use of error-proofing methods in corrective action, includes new requirements to strengthen the approach to error proofing and consolidate customer-specific requirements.
- The organization needs a process that both identifies the need or opportunity for an error-proofing device/method, and designs and implements the device/method.
- The FMEA would document whether the method impacts occurrence (a prevention control) or impacts detection (a detection control).
- The control plan needs to include the test frequency of the error-proofing devices, and records must be maintained for the performance of these tests.

Changes

Section 10.2.5: Warranty management systems

- This is a new requirement based on the increasing importance of warranty management and consolidates IATF OEM customer specific requirements.
- The warranty management process should address and integrate all applicable customer-specific requirements, and warranty part analysis procedures to validate No Trouble Found (NTF) decisions should be agreed by the customer, when applicable.

Changes

Section 10.2.6: Customer complaints and field failure test analysis

- Includes a new requirement regarding embedded software and identification of preferred approaches.
- The organization's analysis is extended beyond parts to the customer complaints and field failures themselves, and the results must be communicated to the customer and also within the organization.

Changes

Section 10.3.1: Continual improvement – supplemental

- Changes in this section clarify the minimum process requirements for continual improvement: identification of methods, information and data; an improvement action plan that reduces variation and waste; and risk analysis (such as FMEA).
- Use of TPM, Lean, Six Sigma, and other manufacturing excellence programs or methodologies should follow a structured approach that continuously identifies and addresses opportunities for improvement.

Summary

- There are many enhancements to the Automotive QMS requirements within IATF 16949, which further increases the value and credibility of certification
- We have integrated many common CSR requirements into IATF 16949
- IATF 16949 further strengthens the performance linkage among OEMs, Suppliers (all tiers), CBs, and Oversight Offices
- We obtained extensive stakeholder input to make the new standard – ***thank you for your support!***

Q&A

Thank you!