TRANSITIONING from

ISO/TS 16949:2009 to IATF 16949:2016







A NEW EVOLUTION

FIRST DEVELOPED IN 1999, ISO/TS 16949 HAS
BECOME ONE OF THE MOST WIDELY USED
INTERNATIONAL STANDARDS IN THE AUTOMOTIVE
INDUSTRY TODAY. IN 2016, THE INDUSTRY IS SET TO
EVOLVE WITH THE PUBLICATION OF A NEW GLOBAL
INDUSTRY STANDARD BY THE INTERNATIONAL
AUTOMOTIVE TASK FORCE (IATF).

ISO/TS 16949 was first developed by the IATF in conjunction with ISO's technical committee for quality management, ISO/TC 176. As a result, ISO/TS 16949 integrated with ISO 9001 by including specific requirements from the automotive sector.

In October 2016, the IATF will publish a revised automotive industry standard, and the first edition will be referred to as "IATF 16949."

This new standard will supersede and replace the current ISO/TS 16949:2009, defining the requirements of a quality management system for organizations in the automotive industry.

IATF 16949 is aligned with and refers to the most recent version of ISO's quality management systems standard, ISO 9001:2015, fully respecting its structure and requirements. IATF 16949 is not a standalone quality management standard, but is implemented as a supplement to, and in conjunction with, ISO 9001:2015. This means that an organization in the automotive sector seeking IATF 16949 certification must also comply with ISO 9001:2015.

HIGH RISK, HIGH COST

The automotive industry produces high-risk, high-cost products and services and has tightly controlled industry requirements; therefore, IATF 16949 better aligns with the needs of its stakeholders. According to the IATF 16949 Revision Team, the goal of this standard is the development of a quality management system that provides for continual improvement, emphasizing defect prevention, and the reduction of variation and waste in the supply chain.

A SMOOTH TRANSITION

IATF 16949 plays an essential role in ensuring quality requirements are met, thus reducing the risk of product and service failure for automotive production, service and/or accessory parts organizations. Certification to IATF 16949 is mandatory for organizations who wish to manufacture parts for the automotive industry.

To get you pointed in the right direction, this whitepaper will cover the following topics:

- Transition Guidance
- Transition Timeline
- New High Level Structure
- Preview of IATF 16949 changes



INTENT BEHIND THE REVISION

ISO standards are reviewed every five years to determine what changes, if any, are required to keep the standards up-to-date and relevant. Since the ISO 9001:2008 revision, business needs and expectations have changed significantly. The new ISO 9001:2015 better meets customer requirements, adapts to new technologies, better integrates with complex supply chains, and addresses the need for more sustainable development initiatives. This is accomplished through a better understanding of the organization's context and relevant interested parties, and by taking appropriate actions to address risks and opportunities at every level.

IATF 16949 fully supports these changes in ISO 9001:2015 with additional requirements that better meet automotive industry needs. Alignment with the ISO 9001:2015 structure makes it easier for organizations that need to implement more than one quality management system standard. If IATF 16949 is implemented and properly managed, an organization will:

- Receive recognition from regulatory authorities
- Produce safer and more reliable products
- Meet or exceed customer requirements
- Improve processes and documentation system



TRANSITION TIMELINE

ISO 9001:2015 **PUBLICATION**

ISO's flagship quality management systems standard published on September 23, 2015. September 2015

RULES 5TH EDITION

Rules for Achieving and Maintaining IATF Recognition 5th Edition projected to publish in October 2016

IATF 16949 **PUBLICATION**

IATF 16949:2016 projected to publish in October 2016.

PUBLICATION

November 2016.

November 2016

> June 2017

September

2018

AUDITOR REGISTRATION COMPLETE

By June 30, 2017, all active third-party auditors registered in the IATF ADP must pass the IATF 16949 and Rules 5th training and quiz modules or they will be subject to deactivation.

FUTURE AUDITS TO IATF 16949

Beginning October 1, 2017, all audits must be to IATF 16949 using Rules 5th Edition, and all organizations seeking initial certification can no longer certify to ISO/TS 16949.

October 2017

IATF 16949 TRANSITION COMPLETE

Transition to IATF 16949 must be complete by September 14, 2018. All ISO/TS 16949 certificates will no longer be valid.



TRANSITION GUIDANCE: SUPPLIERS

The IATF has communicated that there will only be one transition option for organizations: *Transition in line with the organization's current ISO/TS 16949* audit cycle.

Organizations transitioning from ISO/TS 16949:2009 to IATF 16949 must transition to the new standard through a transition audit in line with the organization's current regularly scheduled recertification audit or surveillance audit, as defined in the IATF Rules, section 5.1.1. Review the IATF 16949 Transition Strategy and requirements guide here.

For organizations currently certified to ISO/TS 16949, here is a recommended action plan for transitioning:

- 1. Familiarize yourself ISO 9001:2015 and IATF 16949.
- 2. Perform an **organizational gap analysis** against ISO 9001:2015 and IATF 16949 to identify the differences that need to be addressed to ensure your organization's QMS meets all the new requirements, including those related to external providers.
- 3. Based on the results of the gap analysis, develop an **implementation plan** specific to your organization.
- 4. Provide **appropriate training** for all individuals involved in implementing ISO 9001:2015 and IATF 16949 at your organization.
- 5. Update your existing system and **provide evidence** that your organization meets the new requirements.

NEW HIGH LEVEL STRUCTURE

ISO 9001 embraces a new structure by switching from eight clauses to ten clauses in the 2015 revision. This change allows the standard to better align with business strategic direction, become more compatible with other management system standards, and incorporate the Plan-Do-Check-Act approach, as shown below.

- 1. Scope
- 2. Normative references
- 3. Terms and definitions

4. Context of the organization

- 4.1 Understanding the organization and its context
- 4.2 Understanding needs and expectations of interested parties
- 4.3 Determining the scope of the quality Management system
- 4.4 Quality management system and its processes

5. Leadership

- 5.1 Leadership and commitment
- 5.2 Policy
- 5.3 Organizational roles, responsibilities and authorities

6. Planning

- 6.1 Actions to address risks and opportunities
- 6.2 Quality objectives and planning to achieve them
- 6.3 Planning of changes

7. Support

- 7.1 Resources
- 7.2 Competence
- 7.3 Awareness
- 7.4 Communication
- 7.5 Documented information

8. Operation

- 8.1 Operational planning and control
- 8.2 Requirements for products and services
- 8.3 Design and development of products and services
- 8.4 Control of externally provided processes, products and services
- 8.5 Production and service provision
- 8.6 Release of products and services
- 8.7 Control of nonconforming outputs

9. Performance evaluation

- 9.1 Monitoring, measurement, analysis and evaluation
- 9.2 Internal audit
- 9.3 Management review

10. Improvement

- 10.1 Genera
- 10.2 Nonconformity and corrective action
- 10.3 Continual improvement

PLAN:

Set objectives and build processes necessary to deliver results.

D0:

Implement what was planned.

CHECK:

Monitor and measure processes and results against the objectives, including effectiveness, efficiency and risk.

ACT:

Take actions to improve results.



IMPLEMENTATION CONSIDERATIONS

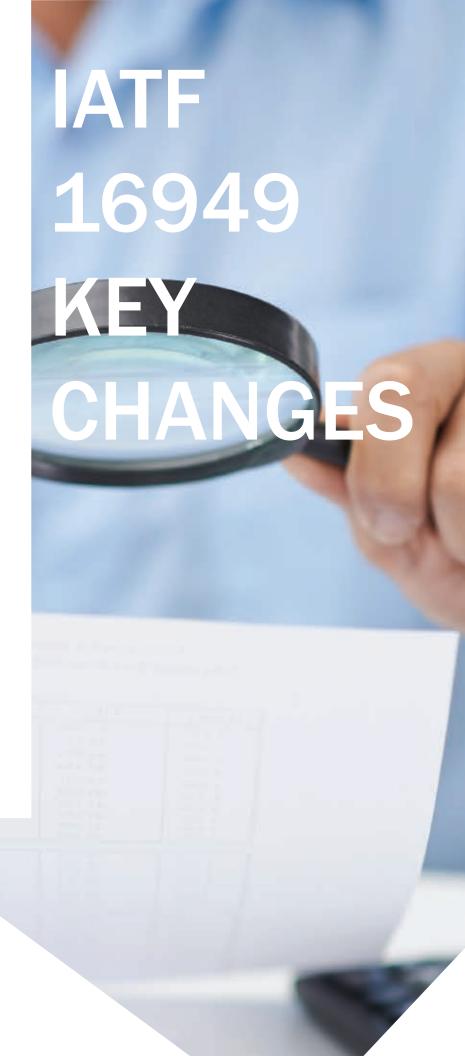
An organization is not required to reflect the new ten-clause structure and terminology in the documentation of their organization's quality management system. The purpose of the new structure is to provide a clear presentation of the requirements; it is not to intended to be a model for documenting an organization's policies, objectives and processes.

If an organization's quality system documentation is currently aligned based on the structure of a previous standard, you are encouraged to consider realigning your documentation according to your organization's value stream instead. Aligning the QMS with the business structure allows organizations to customize their documentation based on their unique business needs.

Too many organizations impose a structure tied to the standard that is neither natural nor easy to understand within the organization.

Unlike ISO/TS 16949 and some other industry-specific standards, IATF 16949 does not contain the ISO 9001:2015 text. The document contains only the automotive-specific additional requirements; however, the organization is still required to comply with ISO 9001:2015. IATF 16949 clarifies that it is a supplement to be used in conjunction with ISO 9001:2015.

IATF 16949 shares the same general section headings and clause structure as ISO 9001:2015, without reciting the text. This ensures all IATF 16949 requirements are fully aligned with the ISO 9001:2015 high level structure.



RISK-BASED THINKING

Risk mitigation takes center stage in IATF 16949, as it does in ISO 9001:2015. IATF 16949 adds a number of specific risk-related requirements to minimize the likelihood of failure during new program development and to maximize the potential realization of planned activities. These additions are the result of industry best practices intended to make businesses safer and more stable by identifying and mitigating risk.

To ensure risk-based thinking is pervasive throughout the organization, top management needs to be actively engaged. Responsibilities include:

- Conducting contingency planning reviews
- Identifying and supporting of process owners
- Participating in the escalation process related to product safety
- Ensuring achievement of customer performance targets and quality objectives
- Implementing <u>corporate responsibility</u> initiatives including an anti-bribery policy, an employee code of conduct, and an ethics escalation policy ("whistle-blowing policy")

IATF 16949 requires that "organizations shall ensure conformance of all products and processes, including service parts and those that are outsourced." This use of the word "ensure" implies that the organization needs to establish and maintain a system that mitigates the risk of nonconformance throughout the supply chain. The organization is ultimately responsible for all conformity and must cascade all applicable requirements down the supply chain to the point of manufacture.

The standard reinforces the concept of a "multidisciplinary approach" throughout the product lifecycle, and particularly during design and development planning activities. IATF 16949 adds additional controls for the management of development projects throughout the cycle, which eventually concludes with a product approval process.

As well, the automotive standard adds a large number of requirements to specifically address the development of manufacturing processes. Manufacturing processes may have the same output requirements as those specified for the product;

however, customers often require the use of specific Automotive Core Tools, such as capturing and analyzing risk via a PFMEA. These sorts of considerations are included in IATF 16949 in an attempt to mitigate risk even before manufacturing the product or installing machinery.

Survival in the automotive industry requires continuous change to address internal and external issues. Organizations need to adopt a process to assess the risk of changes and take appropriate action. IATF 16949 requirements to manage changes include:

- Assessing manufacturing feasibility for changes to existing operations.
- Evaluating design changes after initial product approval.
- Reviewing control plans for changes affecting product, manufacturing process, measurement, logistics, supply sources, production volume changes, or risk analysis.
- Controlling and reacting to changes that impact product realization, including changes caused by the organization, the customer, or any supplier. This includes both permanent and temporary changes.
- Adjusting the frequency of internal audits based on occurrence of process changes.

Other sources of risk, such as how to deal with nonconforming outputs, are covered in more detail to ensure suppliers are aligned with their customers.



INTEGRATION OF CUSTOMERSPECIFIC REQUIREMENTS

IATF 16949 integrates many common industry practices previously found in customer-specific requirements. Integrating these common practices as requirements encourages commonality throughout the industry and aims to reduce the need for extensive customer-specific requirements in these areas.

Also important is the clear distinction between *customer* requirements and *customer-specific requirements (CSRs)*. In IATF 16949, these two terms are defined as follows:

- Customer Requirements: All requirements specified by the customer (e.g., technical, commercial, product and manufacturing process-related requirements, general terms and conditions, customer-specific requirements, etc.)
- Customer-Specific Requirements: Interpretations of or supplemental requirements linked to a specific clause(s) of this Automotive QMS Standard.

The new standard more clearly defines these two terms to reduce misunderstandings, and to facilitate the sampling of customer-specific quality management system requirements for effective implementation.

For example, the organization needs to review and agree with customer requirements such as packaging manuals and manufacturing process guidelines. However, for customer-specific requirements, organizations need to review and agree after considering the impact on their entire QMS.

Here are some examples of areas that were previously customerspecific requirements that are now included in more detail in IATF 16949:

- Manufacturing feasibility
- Warranty management
- Temporary change of process controls
- Supplier quality management system development
- Second-party audits
- Control plan
- Problem-solving methodologies
- Control of changes
- Total productive maintenance
- Standardized work



FIRST AND SECOND PARTY AUDITOR COMPETENCY

IATF 16949 adds additional requirements for both first and second-party auditors, which include:

- Organizations shall have a documented process to verify internal auditor competency.
- When training internal auditors, documented information shall be retained to demonstrate trainer's competency with the additional requirements.
- Organizations shall demonstrate the competency of second-party auditors, and second-party auditors shall meet customer-specific requirements for auditor qualification.

This standard also outlines the minimum competencies for auditors, which include:

- Automotive process approach for auditing, including riskbased thinking
- Applicable core tools requirements
- Applicable customer-specific requirements
- Software development assessment methodologies, if applicable

These changes may require a competence gap analysis followed by additional auditor training and development activities.

PRODUCT SAFETY

Product safety is an entirely new section in the IATF standard, and a transitioning organization must have documented processes for the management of product-safety related products and manufacturing processes. New requirements related to product safety include, where applicable:

- Special approval of control plans and FMEAs
- Training identified by the organization or customer for personnel involved in product-safety related products and associated manufacturing processes
- Transfer of requirements with regard to product safety throughout the supply chain, including customerdesignated sources

This clause highlights the fact that a product should perform to its designed or intended purpose without causing unacceptable harm or damage. Organizations must have processes in place to ensure product safety throughout the entire product lifecycle.

FEASIBILITY

In the new standard, an organization is required to assess if they are capable of achieving the performance and timing targets MANUFACTURING specified by the customer, otherwise known as manufacturing feasibility. While ISO/TS 16949 did require this kind of manufacturing feasibility analysis, it did not impose specific requirements. The new standard's specific requirements include:

- Using a multidisciplinary approach
- Performing the analysis for any new manufacturing or product technology and for any changed manufacturing process or product design
- Validating their ability to make product specifications at the required rate through production runs, benchmarking studies or other appropriate methods



WARRANTY MANAGEMENT

Based on the increasing importance of warranty management, a new requirement has been added to IATF 16949. When an organization is required to provide warranty for their product(s), the warranty management process must address and integrate all applicable customer-specific requirements and warranty party analysis procedures to validate No Trouble Found (NTF). Decisions should be agreed upon by the customer, when applicable.

DEVELOPMENT OF PRODUCTS WITH EMBEDDED SOFTWARE

IATF 16949 requirements for products with embedded software reflect the additional challenges as we move toward more of a drive-by-wire world. The standard references embedded software in the requirements for product validation, warranty and troubleshooting of issues in the field. A product requiring embedded software may need to comply with sourcing-from-origin requirements established by a customer. OEM requirements for sourcing and materials change frequently, and early changes to a program may negatively affect timing and increase risk.

Embedded software is here to stay and the new version of the standard may require companies to look at their purchased parts (now called outsourced components) and identify risks in their current system based on this new focus.

TRAINING OPPORTUNITIES

AIAG and Plexus work together to design, develop, and deliver training and certification for automotive third-party auditors, OEMs and suppliers worldwide.

Plexus is proud to be recognized as the global AIAG-certified training partner in automotive quality.

Collaboratively, AIAG and Plexus will be offering a variety of transitioning, understanding, and auditor training courses aligned with key expectations of OEMs and the automotive industry. Training will be available both online and face-to-face, including on-site.

Visit the <u>AIAG</u> website to discover what training meets your needs.

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