Standard	Element	Is this a new requirement?	ISO 9001:2015 / IATF 16949:2016 Requirements	Correlation	Commentary	Level of current implementation	Level of difficulty to implement	Level of complexity to implement	Action / Resources Required
		New/Modified/ Carryover	**Bolded text indicates new to ISO 9001:2015 and IATF 16949:2016**	ISO/TS 16949:2009		1 = Fully implemented	1 = Not difficult	1 = Not complex	
						5 = Nothing in place	5 = Very difficult	25 = Very complex	
4.0 Context									
4.1 Unders									
								0	
4.2 Understanding the needs and expectations of interested parties									
								0	
4.3 Determining the scope of the quality management system									
								0	
4.3.1 Determining the scope of the quality management system - supplemental									
								0	
4.3.2 Customer-specific requirements									
								0	

The 3 areas above have been populated in the following sections.

All requirements have been populated in the following sections.

Correlation to the previous version ISO/TS 16949:2009 standard.

All commentary areas have been populated in the following sections. However, feel free to modify based on your

Removed.

Removed

In the action and/or resources required box, identify what activities and resources are needed

You can add or subtract columns and re-format this spreadsheet based on your own preferences.

Consider additional columns to assign responsibility and completion dates for follow-up activity.

Removed

Cells with a white background represent elements from **ISO 9001:2015**.

Cells with a light blue background represent elements from **IATF 16949:2016**.

Standard	Element	Is this a new requirement?	ISO 9001:2015 / IATF 16949:2016 Requirements	Commentary	*Action / Resources Required	**Objective Evidence**	Responsible	Planned Start Date	Planned Completion Date	Status Open/In Progress/Closed/ Overdue
		New/Modified/ Carryover	**Bolded text indicates new to ISO 9001:2015 and IATF 16949:2016**							
4.0 Context of the organization										
4.1 Understanding the organization and its context										
ISO 9001	**4.1**	New	**The organization shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system.** **The organization shall monitor and review information about these external and internal issues.** **NOTE 1: Issues can include positive and negative factors or conditions for consideration.** **NOTE 2: Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local.** **NOTE 3: Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization.**	This was not specifically mentioned in the previous standard and is now an explicit requirement. The organization must now be able to demonstrate they have identified, monitored and reviewed all external and internal issues.		SWOT Management Review Customer surveys Customer Feedback	Team			Open
4.2 Understanding the needs and expectations of interested parties										
ISO 9001	**4.2**	New	**Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine:** **a) the interested parties that are relevant to the quality management system;** **b) the requirements of these interested parties that are relevant to the quality management system.** **The organization shall monitor and review information about these interested parties and their relevant requirements.** **The organization shall monitor and review information about these interested parties and their relevant requirements.**	The intent of this requirement is to ensure that the organization considers the requirements of relevant interested parties beyond just those of the customer. The intention is to focus on the interested parties which are relevant to the Quality Management System (QMS).		Interested Parties Matrix Management Review Board Meeting Notes	Team			Closed
4.3 Determining the scope of the quality management system										
ISO 9001	**4.3**	Modified	**The organization shall determine the boundaries and applicability of the quality management system to establish its scope.** **When determining this scope, the organization shall consider:** **the external and internal issues referred to in 4.1;** **the requirements of relevant interested parties referred to in 4.2;** the products and services of the organization. **The organization shall apply all the requirements of this International Standard if they are applicable within the determined scope of its quality management system.** **The scope of the organization's quality management system shall be available and be maintained as DOCUMENTED INFORMATION.** The scope shall state the types of products and services covered, and **provide justification for any requirement of this International Standard that the organization determines is not applicable to the scope of its quality management system.** Conformity to this International Standard may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.	The new revision to the standard now explicitly requires that before you set the scope of the QMS, you must have previously considered and demonstrated that the issues within 4.1 and interested parties within 4.2 are completed, prior to setting the scope and boundaries of the QMS. It is important to note that ISO 9001:2015 requires that all requirements within the standard are to be met unless they do not apply. This scope must be documented and include the products and services provided as well as any justification for any requirements that the organization has determined do not apply.		Scope included with Context procedure	Team			Closed

4.3.1 Determining the scope of the quality management system - supplemental										
IATF 16949	**4.3.1**	Modified	Supporting functions, whether on-site or remote (such as design centers, corporate headquarters, and distribution centers) **shall be included in the scope of the quality management system (QMS).** The only permitted exclusion for this **Automotive QMS Standard relates to the product design and development requirements within ISO 9001, Section 8.3. The exclusion shall be justified and maintained as documented information (see ISO 9001, Section 7.5).** Permitted exclusions do not include manufacturing process design.	Originally included in ISO/TS 16949:2009, Sec. 1.1 and 1.2. The first requirement relating to supporting functions was revised to not only address the need to include them in the audit, but also to ensure that they are included in the scope of the QMS. Any exclusion(s) must now be documented.	Review procedure to be sure Manufacturing process design is included	only 1 site included in the scope.Exclusion is included in the 4 procedure.	**QMS Supervisor**	April	April	Open
IATF 16949	4.3.2	Carryover	Customer-specific requirements shall be evaluated and included in the scope of the organization's quality management system.	This suggests the organization would need a process to evaluate each customer-specific requirement and determine exactly how and where it applies to their QMS.	Needs updated		Team	April	April	Open
4.4 Quality management system and its processes										
ISO 9001	**4.4.1**	Modified	The organization shall establish, implement, maintain **and continually improve** a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard. The organization shall determine the processes needed for the quality management system and their application throughout the organization, and shall: **a)** determine the **inputs required** and the **outputs expected** from these processes; **b)** determine the sequence and interaction of these processes; **c)** determine and apply the criteria and methods **(including monitoring, measurements and related performance indicators)** needed to ensure the effective operation and control of these processes; **d)** determine the resources needed for these processes and ensure their availability; **e) assign the responsibilities and authorities for these processes;** **f) address the risks and opportunities as determined in accordance with the requirements of 6.1;** **g) evaluate** these processes and **implement any changes needed to ensure that these processes achieve their intended results;** **h)** improve the processes and **the quality management system.**	This further reinforces the need for risk to be considered throughout the QMS. The requirement for ownership within the processes are now required. Sec. 4.4.1 is a paraphrase of the entire standard. If you think about the standard as a living organism, 4.4.1 would be the skeleton. the specifics for 4.4.1 can be found throughout the remainder of the standard. The outputs of the activities listed may include process flow maps, interrelationships, authority and responsibilities, quality performance data, etc.,	Need Quality Manual	Process Sequence and Interactions Matrix	**QMS Supervisor**	April	April	Open
4.4.1.1 Conformance of products and processes										
IATF 16949	**4.4.1.1**	New	**The organization shall ensure conformance of all products and processes, including service parts and those that are outsourced, to all applicable customer, statutory requirements (see section 8.4.2.2)**	This ensures 2 things: that the 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.	Need to generate a procedure	Suppliers listed in the Process Sequence and Interaction Matrix				closed
4.4.1.2 Product safety										
			The organization shall have documented processes for the management of product-safety related products and manufacturing processes, which shall include but not limited to the following, where applicable:	This is a new section with new and enhanced requirements that address current and emerging issues the automotive industry is facing related to product and process safety. Organizations are specifically required to have documented processes to manage product-safety related products and processes.						
			a) identification by the organization of statutory and regulatory product-safety requirements;		Should address in a procedure in case a customer would have a requirement	Procedure	**Team**	April	April	Open
			b) customer notification of requirements in item a);							
			c) special approvals for design FMEA;							
			d) identification of product safety-related characteristics;							

IATF 16949	**4.4.1.2**	New	**e) identification and controls of safety-related characteristics of product and at the point of manufacture;**							
			f) special approval of control plans and process FMEAs;							
			g) reaction plans (see section 9.1.1.1);							
			h) defined responsibilities, definition of escalation process and flow of information, including top management, and customer notification;							
			i) training identified by the organization or customer for personnel involved in product-safety related products and associated manufacturing processes;							
			j) changes of product or process shall be approved prior to implementation, including evaluation of potential effects on product safety from process and product changes (see ISO 9001, Section 8.3.6);							
			k) transfer of requirements with regard to product safety throughout the supply chain, including customer-designated sources (see Section 8.4.3.1);							
			l) product traceability by manufactured lot (at a minimum) throughout the supply chain (see Section 8.5.2.1);							
			m) lessons learned for new product introduction.							
			Note: Special approval is an additional approval by the function (typically the customer) that is responsible to approve such documents with safety-related content.							
ISO 9001	**4.4.2**	Modified	To the extent necessary, the organization shall:	The intent is to allow an organization to tailor the documentation around their own value streams. Documented information is defined as maintained = documents and procedures & retained = records.		Records Matrix				Closed
			a) maintain DOCUMENTED INFORMATION to support the operation of its processes;			Manual - Procedures - forms - turtles, management review				
			b) retain DOCUMENTED INFORMATION to have confidence that the processes are being carried out as planned.			Purchasing Prints contract review and amendments process and product inspection records				

Standard	Element	Is this a new requirement?	ISO 9001:2015 / IATF 16949:2016 Requirements	Commentary	*Action / Resources Required	Objective Evidence	Responsible	Planned Start Date	Planned Completion Date	Status Open/In Progress/Closed/ Overdue
		New/Modified/ Carryover	**Bolded text indicates new to ISO 9001:2015 and IATF 16949:2016**							
5 Leadership										
5.1 Leadership and commitment										
5.1.1 General										
ISO 9001	**5.1.1**	Modified	Top management shall **demonstrate leadership** and commitment with respect to the quality management system by: **a) taking accountability for the effectiveness of the quality management system;** **b)** ensuring that the quality policy and quality objectives are established for the quality management system and **are compatible with the context and strategic direction of the organization;** **c) ensuring the integration of the quality management system requirements into the organization's business processes;** **d) promoting the use of the process approach and risk-based thinking;** **e)** ensuring that the resources needed for the quality management system are available; **f)** communicating the importance of effective quality management and of conforming to the quality management system requirements; **g) ensuring that the quality management system achieves its intended results;** **h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;** **i) promoting improvement;** **j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.** NOTE: Reference to "business" in this International Standard can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence, whether the organization is public, private, for profit or not for profit.	There are now specific requirements for Top Management to: - Take accountability for the effectiveness of the QMS - Promoting process approach and risk - Integration with business system This will assist in the integration of the QMS within the business system and to keep the QMS from being thought of as a a stand-alone system. The intent of this requirement is to establish the roles and responsibilities of top management in relation to the effectiveness of the quality management system, and the achievement of planned results.		Procedure 5				Closed
5.1.1.1 Corporate responsibility										
IATF 16949	**5.1.1.1**	New	**The organization shall define and implement corporate responsibility policies, including at a minimum an anti-bribery policy, an employee code of conduct, and an ethics escalation policy ("whistle-blowing policy").**	The IATF supplemented the ISO requirements by adopting a Corporate Responsibility requirement to address increasing market and governmental expectations for improved integrity in social and environmental matters.	Policy Template or separate template implementation		Team	May	May	Open
5.1.1.2 Process effectiveness and efficiency										
IATF 16949	**5.1.1.2**	Modified	Top management shall review the product realization processes and support processes to **evaluate and improve** their effectiveness and efficiency. **The results of the process review activities shall be included as input to the management review (see Section 9.3.2.1).**	The IATF strengthened the requirement to ensure that the results of process review activities are now to be included in the management review.		Identified in process sequence and interaction map				Closed
5.1.1.3 Process owners										
IATF 16949	**5.1.1.3**	New	**Top management shall identify process owners who are responsible for managing the organizations processes and related outputs. Process owners shall understand their roles and be competent to perform those roles (see ISO 9001, Section 7.2)**	The IATF adopted this new requirement to ensure that management understands this expectation, by specifically identifying the process owners and assuring that they can perform their assigned roles.		Identified in process sequence and interaction map				Closed
5.1.2 Customer focus										
ISO 9001	**5.1.2**	Modified	Top management shall **demonstrate leadership and commitment with respect to customer focus** by ensuring that: **a)** customer and applicable statutory and regulatory requirements are determined, **understood and consistently met;**	Customer requirements must be known and met with the aim of increasing and improving customer satisfaction. Top management to visibly demonstrate leadership	update to include the statutory and regulatory requirements of customer in the quote.	Procedure job descriptions, Management Review records,KPI charts and org charts				Open Closed

ISO 9001	5.1.2	Modified	**b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;**	and commitment.		Customer Satisfaction Index				Closed
			c) the focus on enhancing customer satisfaction is maintained.			Customer score cards and internal customer satisfaction index				Closed
5.2 Policy										
5.2.1 Establishing the quality policy										
ISO 9001	**5.2.1**	Modified	Top management shall establish, implement and maintain a quality policy that:	The intent of this requirement is to ensure that top management aligns the quality policy with the organization's strategic direction.		Procedure				Closed
			a) is appropriate to the purpose **and context** of the organization **and supports its strategic direction;**			Customer Satisfaction Index				Closed
			b) provides a framework for setting quality objectives;			Procedure				Closed
			c) includes a commitment to satisfy applicable requirements;			Procedure				Closed
			d) includes a commitment to continual improvement of the quality management system.			Procedure				Closed
5.2.2 Communicating the quality policy										
ISO 9001	**5.2.2**	Modified	The quality policy shall:	The quality policy must be documented. Associates need to understand the quality policy and what it means to them.	Post on website?					Closed
			a) be available and be maintained as documented information;			Procedure				Closed
			b) be communicated, understood and **applied** within the organization;			Posted objectives				Closed
			c) be available to relevant interested parties, as appropriate.			Part of management review				Closed
5.3 Organizational roles, responsibilities and authorities										
ISO 9001	**5.3**	Modified	Top management shall ensure that the responsibilities and authorities **for relevant roles are assigned**, communicated **and understood** within the organization.	Responsibility and authority and their interactions must be defined and communicated. When changes are made, consider the impact of that change on the system, not simply the local impact.						closed
			Top management shall assign the responsibility and authority for:							
			a) ensuring that the quality management system conforms to the requirements of this International Standard;			Process Sequence and Interaction matrix				
			b) ensuring that the processes are delivering their intended outputs;			Contingency Plan				
			c) reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to top management;			management review				
			d) ensuring the promotion of customer focus throughout the organization;			objectives posted				
IATF 16949	**5.3.2**	Modified	**Top management shall ensure that:**	The IATF adopted some enhancements to explicitly make Top Management responsible for ensuring conformity to product requirements and to corrective actions taken. The standard clarifies that there must be a process to inform those with the authority and responsibility for corrective action in order that they ensure nonconforming product is identified, contained, and not shipped to the customer.						
			a) personnel responsible for conformity to product requirements have the authority to stop shipment and stop production to correct quality problems:			Procedure				closed
			Note: Due to the process design in some industries, it might not always be possible to stop production immediately. In this case, the affected batch must be contained and shipment to the customer prevented.			Procedure				closed
			b) personnel with authority and responsibility for corrective action are promptly informed of product or processes that do not conform to requirements **to ensure that nonconforming product is not shipped to the customer and that all potential nonconforming product is identified and contained.**			Postings				closed
			c) production operations across all shifts are staffed with personnel in charge of, or delegated responsibility for, ensuring conformity to product requirements.			One shift at this time but procedure in plaqce				closed

Standard	Element	Is this a new requirement?	ISO 9001:2015 / IATF 16949:2016 Requirements	Commentary	*Action / Resources Required	Objective Evidence	Responsible	Planned Start Date	Planned Completion Date	Status Open/In Progress/Closed/ Overdue
		New/Modified/ Carryover	**Bolded text indicates new to ISO 9001:2015 and IATF 16949:2016**							
6.0 Planning										
6.1 Actions to address risks and opportunities										
ISO 9001	**6.1.1**	New	**When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:**	Determine risks and opportunities, considering the issues raised and requirements identified. Then plan appropriate actions to reduce undesired effects on the QMS and evaluate effectiveness.		6 Planning procedure				closed
			a) give assurance that the quality management system can achieve its intended result(s);			FMEA risk assesment				
			b) enhance desirable effects;			corrective actions				
			c) prevent, or reduce, undesired effects;			meetings				
			d) achieve improvement.			Management Review				
ISO 9001	**6.1.2**	New	**The organization shall plan:**	Having identified the risks and opportunities that may impact the quality management system, the organization should plan actions to address each item.						Closed
			a) actions to address these risks and opportunities;			Procedure				
			b) how to:							
			1) integrate and implement the actions into its quality management system processes (see 4.4);			Process Sequence and interaction Matrix				
			2) evaluate the effectiveness of these actions.			Risk FMEA				
			Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.							
			NOTE 1: Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.							
			NOTE 2: Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.							
6.1.2.1 Risk analysis										
IATF 16949	**6.1.2.1**	Modified	**The organization shall include in its risk analysis, at a minimum, lessons learned from product recalls, product audits, field returns and repairs, complaints, scrap, and rework.**	The IATF adopted additional requirements for risk analysis recognizing the continual need to analyze and respond to risk and to have organizations consider specific risks associated with the automotive industry.		Risk FMEA				Closed
			The organization shall retain DOCUMENTED INFORMATION as evidence of the results of risk analysis.			Risk FMEA				
6.1.2.2 Preventive action										
IATF 16949	**6.1.2.2**	Modified	The organization shall determine and implement action(s) to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the **severity** of the potential **issues**.	The IATF enhanced the requirement found in ISO/TS 16949. Organizations 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 towards prevention.	Add lessons learned update preventive turtle	PPAP FMEA	QMS Supervisor	May	May	Closed
			The organization shall establish a process to lessen the impact of negative effects of risk including the following:			Preventive Turtle				Open
			a) determining potential nonconformities and their causes;			8-D Analysius				Closed
			b) evaluating the need for action to prevent occurrence of nonconformities;			Continual Improvement				Closed
			c) determining and implementing action needed;			Effectiveness review of corrective actions				Closed
			d) documented information of action taken;							
			e) reviewing the effectiveness of the preventive action							
			f) utilizing lessons learned to prevent recurrence in similar processes (see ISO 9001, section 7.1.6)							
6.1.2.3 Contingency plans										
IATF 16949	**6.1.2.3**	Modified	The organization shall:	The expanded requirement ensures the organization defines and prepares contingency plans along with a notification process to the customer or other interested parties. Customer notification is a mandatory step in any contingency plan, unless there is no risk to deliver nonconforming product or affect on-time delivery. The effectiveness of these contingency plans would be tested periodically and reviewed by a multidisciplinary team that includes top management. Contingency plans would be updated as necessary.	Update Contingency Plan	Contingency Plan	**QMS Supervisor**	May	May	Open
			a) identify and evaluate internal and external risks to all manufacturing processes and infrastructure equipment essential to maintain production output and to ensure that customer requirements are met;			Give a risk number				Open
			b) define contingency plans according to risk and impact to the customer;			customer risk and impact				Open
			c) prepare contingency plans for continuity of supply in the event of any of the following: key equipment failures (also see section 8.5.6.1.1); interruption from externally provided products, processes, and services; recurring natural disasters; fire; utility interruptions; labor shortages; or infrastructure disruptions;			C. is on contingency plan				Closed
			d) include, as a supplement to the contingency plans, a notification process to the customer and other interested parties for the extent and duration of any situation impacting customer operations;			Notification to customer and other interested parties				Open

			e) periodically test the contingency plans for effectiveness (e.g. simulations, as appropriate);			Test for effectiveness				Open
			f) conduct contingency plan reviews (at minimum annually) using a multidisciplinary team including top management, and update as required;			add contingency review to Management Review				Open
			g) document the contingency plans and retain DOCUMENTED INFORMATION describing any revision(s), including the person(s) who authorized the change(s);			Document and document revision changes				Open
			The contingency plans shall include provisions to validate that the manufactured product continues to meet customer specifications after the re-start of production following an emergency in which production was stopped and if regular shutdown processes were not followed.			add process to validate product meets customer specification after a re-start.				Open
6.2 Quality objectives and planning to achieve them										
ISO 9001	**6.2.1**	Modified	The organization shall establish quality objectives at relevant functions, **levels and processes needed for the quality management system.**	Although the objectives are still reviewed by top management in management review, this requirement has been driven down more to the organization to determine and, evaluate the results. Top management oversees the establishment of quality objectives at these relevant functions and levels. The quality objectives must be documented. These objectives must be measurable and consistent with the quality policy. It is important to communicate the objectives throughout the organization, as appropriate.		Procedure				Closed
			The quality objectives shall:							
			a) be consistent with the quality policy;			Management Review Records				
			b) be measurable;			Process repors				
			c) take into account applicable requirements;			Customer score cards				
			d) be relevant to conformity of products and services and to enhancement of customer satisfaction;			Internal customer satisfaction Index				
			e) be monitored;			KPI results are posted				
			f) be communicated;			Monthly				
			g) be updated as appropriate.							
			The organization shall maintain DOCUMENTED INFORMATION on the quality objectives.							
ISO 9001	**6.2.2**	Modified	**When planning how to achieve its quality objectives, the organization shall determine:**	The organization should identify who is responsible for achieving specific objectives and ensuring sufficient resources are made available (see clause 7) and how results will be evaluated.						
			a) what will be done;		Review for necessary updates	Procedure				closed
			b) what resources will be required;			Management Review Inputs				
			c) who will be responsible;			Management Review Outputs				
			d) when it will be completed;							
			e) how the results will be evaluated.							
6.2.2.1 Quality objectives and planning to achieve them - supplemental										
IATF 16949	**6.2.2.1**	Modified	Top management shall ensure that quality objectives **to meet customer requirements are defined, established, and maintained for relevant functions, processes, and levels throughout the organization.**	The IATF enhanced the requirement of customer expectations to include a note in Sec. 6.2.2.1 and to require that it be done at all levels throughout the organization.	update procedure and Management Review Agenda	Update Procedure				
			The results of the organization's review regarding interested parties and their relevant requirements shall be considered when the organization establishes its annual (at a minimum) quality objectives and related performance targets (internal and external).			Management Review, customer scorecards, meetings	QMS Supervisor	May	May	Open
6.3 Planning of changes										
ISO 9001	**6.3**	Modified	When the organization determines the need for changes to the quality management system, the changes shall be carried out in a planned manner (see 4.4).	The term 'organization' is now used in lieu of just Top Management. The application of risk-based thinking can be helpful in identifying the actions necessary in planning changes to the quality management system.						
			The organization shall consider:			Records of change management				
			a) the purpose of the changes and their potential consequences;			Managemernt review records				closed
			b) the integrity of the quality management system;			communication boards				
			c) the availability of resources;			customer notifications				
			d) the allocation or reallocation of responsibilities and authorities.							

Standard	Element	Is this a new requirement?	ISO 9001:2015 / IATF 16949:2016 Requirements	Commentary	Action / Resources Required	Objective Evidence	Responsible	Planned Start Date	Planned Completion Date	Status Open/In Progress/Closed/ Overdue
		New/Modified/ Carryover	**Bolded text indicates new to ISO 9001:2015 and IATF 16949:2016**							
7 Support										
7.1 Resources										
7.1.1 General										
ISO 9001	**7.1.1**	Modified	The organization shall determine and provide the resources needed for the **establishment**, implementation, maintenance and continual improvement of the quality management system. **The organization shall consider:** **a) the capabilities of, and constraints on, existing internal resources;** **b) what needs to be obtained from external providers.**	A focus on the organization to consider internal capabilities, resources and constraints. Also, what needs to be obtained from external sources. Resources may include people, suppliers, equipment, etc.,	7.0 Support Procedure					Closed
7.1.2 People										
ISO 9001	**7.1.2**	Carryover	The organization shall determine and provide **the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.**	No impact. Resources needed to maintain the QMS must be determined and provided.	procedure and floor walk thru with questions					Closed
7.1.3 Infrastructure										
ISO 9001	**7.1.3**	Carryover	The organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services. NOTE: Infrastructure can include: **a)** buildings and associated utilities; **b)** equipment, including hardware and software; **c)** transportation resources; **d)** information and communication technology.	No impact. The organization must identify, provide and maintain the infrastructure necessary to ensure conformance of product including: - Building, workspace and utilities - Process equipment - Supporting services (i.e., transportation, communication)	Procedure Contingency Plan Contingency Plan Contingency Plan Contingency Plan					Closed Closed Closed Closed Closed
7.1.3.1 Plant, facility, and equipment planning										
IATF 16949	**7.1.3.1**	Modified	The organization shall use a multi-disciplinary approach **including risk identification and risk mitigation methods** for developing **and improving** plant, and equipment plans. **In designing layouts, the organization shall:** **a)** optimize material **flow**, material handling, and value-added use of floor space **including control of nonconforming product and;** **b) facilitate synchronous flow, as applicable.** Methods shall be developed and implemented to evaluate manufacturing feasibility for new product or new operations. **Manufacturing feasibility assessments shall include capacity planning. These methods shall also be applicable for evaluation proposed changes to existing operations.** **The organization shall maintain process effectiveness, including periodic re-evaluation relative to risks, to incorporate any changes made during process approval, control plan maintenance (see section 8.5.1.1) and verification of job set-ups (see section 8.5.1.3).** **Assessments of manufacturing feasibility and evaluation of capacity planning shall be inputs to management reviews (see ISO 9001, Section 9.3).** Note 1: These requirements should **include the application of** lean principles. **Note 2: These requirements should apply to on-site supplier activities, as applicable.**	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.	Update Procedure Improve current process Improve current process Improve current process Improve current process Improve current process Improve current process Improve current process		Team Team Team Team Team Team Team **Team**	June June June June June June June June	June June June June June June June June	Open Open Open Open Open Open Open Open
7.1.4 Environment for the operation of processes										
ISO 9001	**7.1.4**	Modified	The organization shall determine, provide and **maintain** the environment necessary **for the operation of its processes** and to achieve conformity of products and services. **NOTE: A suitable environment can be a combination of human and physical factors, such as:** **a) social (e.g. non-discriminatory, calm, non-confrontational);** **b) psychological (e.g. stress-reducing, burnout prevention, emotionally protective);** c) physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise). **These factors can differ substantially depending on the products and services provided.**	Key focus on addition of human and physical factors. The organization must identify and manage conditions of the work environment. This may include ergonomics, cleanliness, heat, noise, light, etc.	7.0 Procedure		**Team**			closed
IATF 16949	**7.1.4**	New	**Note: Where third-party certification to ISO 45001 (or equivalent) is recognized, it may be used to demonstrate the organization's conformity to the personnel safety aspects of this requirements.**	No equivalent note	N/A	OSHA rules				Closed
IATF 16949	**7.1.4.1**	Carryover	The organization shall maintain its premises in a state of order, cleanliness, and repair that is consistent with the product and manufacturing needs.	This requirement was preserved from ISO/TS 16949.	Company neat and orderly should document and include employees and customer product		Team	June	June	Open
7.1.5 Monitoring and measuring resources										
7.1.5.1 General										

ISO 9001	**7.1.5.1**	Modified	The organization shall determine and provide the resources needed to ensure valid and **reliable results** when monitoring or measuring is used to verify the conformity of products **and services** to requirements. The organization shall ensure that the resources provided: **a) are suitable for the specific type of monitoring and measurement activities being undertaken;** **b) are maintained to ensure their continuing fitness for their purpose.** The organization shall retain appropriate **DOCUMENTED INFORMATION as evidence of fitness for purpose of the monitoring and measurement resources.**	The requirement for specific records of the results of calibration and verification being maintained has been replaced by "shall retain appropriate DOCUMENTED INFORMATION". The organization must have a process to ensure monitoring and measurement activities are capable and are implemented.	Develop a Turtle		QMS supervisor	June	June	Open
7.1.5.1.1 Measurement systems analysis										
IATF 16949	**7.1.5.1.1**	Modified	Statistical studies shall be conducted to analyze the variation present in the results of each type of **inspection**, measurement, and test equipment system **identified** in the control plan. The analytical methods and acceptance criteria used shall conform to those in reference manuals on Measurement Systems Analysis. Other analytical methods and acceptance criteria may be used if approved by the customer. **Records of customer acceptance of alternative methods shall be retained along with results from alternative measurement systems analysis (see section 9.1.1.1)** **Note: Prioritization of MSA studies should focus on critical or special product or process characteristics**	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. The IATF also clarifies that records of customer acceptance need to be retained along with results from alternative measurement system analysis.	Update procedure		**QMS supervisor**	June	June	Open
7.1.5.2 Measurement traceability										
ISO 9001	**7.1.5.2**	Carryover	When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be:	The requirement for specific records of the results of calibration and verification being maintained has been replaced by "shall retain appropriate DOCUMENTED INFORMATION". The organization must have a process to ensure monitoring and measurement activities are capable and are implemented.	7.0 procedure		Operations Manager			Closed
			a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as **DOCUMENTED INFORMATION;**		calibrated and verification		Operations Manager			Closed
			b) identified in order to determine their status;		numbers/record		Operations Manager			Closed
			c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.		procedure		Operations Manager			Closed
			The organization shall determine if the validity of previous measurement results has been adversely affected when measuring equipment **is found to be unfit for its intended purpose**, and shall take appropriate action as necessary.		procedure		Operations Manager			Closed
IATF 16949	**7.1.5.2**	New	Note: A number or another identifier traceability to the device calibration record meets the intent of the requirements in ISO 9001:2015	---			Operations Manager			Closed
IATF 16949	**7.1.5.2.1**	Modified	**The organization shall have a documented process for managing calibration / verification records.** Records of the calibration / verification activity for all gauges and measuring equipment (including employee-owned equipment **relevant for measuring**, customer-owned equipment, or **on-site supplier owned equipment**) needed to provide evidence of conformity to **internal** requirements, **legislative and regulatory requirements, and customer-defined requirements shall be retained.**	This updated section helps ensure that customer requirements are met through enhanced calibration / verification record retention requirements, including software installed or 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. Calibration / verification activities need to consider applicable internal, customer, legislative and regulatory requirements in order to establish approval criteria.	Review and update		QMS Supervisor	June	June	Open
			The organization shall ensure that calibration / verification activities and records shall include the following details:							Open
			a) revisions following engineering changes that **impact measurement systems;**							Open
			b) any out-of-specification readings as received for calibration / verification;							Open
			c) an assessment of the **risk of the intended use of the product caused by the** out-of-specification condition;							Open
			d) when a piece of inspection measurement and test is found to be out of calibration or defective during its planned verification or calibration or during its use, DOCUMENTED INFORMATION on the validity or previous measurement results obtained with this piece of inspection measurement and test equipment shall be retained, including the associated standard's last calibration date and the next due date on the calibration report;							Open
			e) notification to the customer if suspect product or material has been shipped;							Open
			f) statements of conformity to specification after calibration / verification;							Open
			g) verification that the software version used for product and process control is as specified;							Open
			h) records of the calibration and maintenance activities for all gauging (including employee-owned equipment, customer-owned equipment, or on-site supplier-owned equipment);							Open
			i) production-related software verification used for product and process control (including software installed on employee-owned equipment, customer-owned equipment, or on-site supplier-owned equipment).							Open
7.1.5.3 Laboratory requirements										
7.1.5.3.1 Internal laboratory										

IATF 16949	**7.1.5.3.1**	Modified	An organization's internal laboratory facility shall have defined scope that includes its capability to perform the required inspection, test, or calibration services. This laboratory scope shall be included in the quality management system documentation. The laboratory shall specify and implement, as minimum, requirements for: **a)** adequacy of the laboratory technical procedures; **b)** competency of the laboratory personnel; **c)** testing of the product; **d)** capability to perform these services correctly, traceable to the relevant process standard (such as ASTM, EN, etc.) **when no national or international standard(s) is available, the organization shall define and implement a methodology to verify measurement system capability;** **e) customer requirements, if any;** **f)** review of related records. Note: **Third party** accreditation to ISO/IEC 17025 **(or equivalent)** may be used to demonstrate the organization's in-house laboratory conformity to this requirement.	This section added a requirement to have the organization (client) define a methodology to verify measurement system capability if no applicable national or international standard(s) exist. This clause also clarifies that the applied methodology must meet customer requirements, if they exist.	Update to include a Quality Department Scope for Measurements		**QMS Supervisor**	June	June	open
7.1.5.3.2 External laboratory										
IATF 16949	**7.1.5.3.2**	Modified	External/commercial/independent laboratory facilities used for inspection, test, or calibration services by the organization shall have defined laboratory scope that includes the capability to perform the required inspection, test, or calibration, and either: - the laboratory shall be accredited to ISO/IEC 17025 or national equivalent **and include the relevant inspection test, or calibration service in the scope of the accreditation (certificate); the certification or test report shall include the mark of a national accreditation body; or** - there shall be evidence that the external laboratory is acceptable to the customer. Note: Such evidence may be demonstrated by customer assessment, for example, or by customer-approved second-party assessment that the laboratory meets the intent of ISO/IEC 17025 or national equivalent. **The second-party assessment may be performed by the organization assessing the laboratory using customer-approved method of assessment.** Calibration services may be performed by the equipment manufacturer when a qualified laboratory is not available for a given piece of equipment. **In such cases, the organization shall ensure that the requirements listed in section 7.1.5.3.1 have been met.** **Use of calibration services, other than by qualified (or customer accepted) laboratories, may be subject to government regulatory confirmation, if required.**	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 (Sec. 7.1.5.3.1) apply even when calibration is performed by the equipment manufacturer, and that use of calibration services may be subject to government regulatory confirmation, if required.	Update procedure		QMS Supervisor	June	June	Open
7.1.6 Organizational knowledge										
ISO 9001	**7.1.6**	New	**The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This knowledge shall be maintained and be made available to the extent necessary. When addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.** **NOTE 1: Organizational knowledge is knowledge specific to the organization; it is generally gained by experience. It is information that is used and shared to achieve the organization's objectives.** **NOTE 2: Organizational knowledge can be based on:** **a) internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services);** **b) external sources (e.g. standards; academia; conferences; gathering knowledge from customers or external providers).**	This is an entirely new requirement and focuses upon organic type of information being shared. The organization should consider how to determine and manage organizational knowledge required to achieve conformity of products and services and to meet its present and future needs. People and their experiences are the foundation of organizational knowledge. Capturing and sharing such experiences can generate synergies.	Control plans work instructions Lessons Learned					Closed
7.2 Competence										
ISO 9001	**7.2**	Modified	The organization shall: **a)** determine the necessary competence of **person(s) doing work under its control that affects the performance and effectiveness of the quality management system;** **b)** ensure that these persons are competent on the basis of appropriate education, training, or experience; **c)** where applicable, take actions to acquire the necessary competence, **and evaluate the effectiveness of the actions taken;** **d)** retain appropriate **DOCUMENTED INFORMATION** as evidence of competence. **NOTE: Applicable actions can include, for example, the provision of training to, the mentoring of, or the reassignment of currently employed persons; or the hiring or contracting of competent persons.**	The organization's personnel whose work impacts product requirements must be competent. The emphasis here is on competence. A training record will usually not be enough to demonstrate competence. The organization will want to assess the output of the employee's job.	Update procedure		QMS Supervisor	June	June	Open
					Improve evaluation of comptency		Team	June	June	Open
					Experienced or trained personnel		Team	June	June	Closed
					Improve		Team	June	June	Open
					Training Matrix, Training records					Closed
					Improve		Team	June	June	Open
0										

IATF 16949	**7.2.1**	Modified	The organization shall establish and maintain **a documented process(es)** for identifying training needs **including awareness (see section 7.3.1)** and achieving competence of all personnel performing activities affecting conformity to product **and process** requirements. Personnel performing specific assigned tasks shall be qualified, as required, with particular attention to the satisfaction of customer requirements.	This section adds a requirement of "awareness". Note that the use of the term "process" rather than "procedure" implies that these activities need to be managed (via the plan-do-check cycle), and not merely performed.	Employee Awareness is posted on company bulletin board					Closed
7.2.2 Competence - on-the-job training										
IATF 16949	**7.2.2**	Modified	The organization shall provide on-the-job training **(which shall include customer requirements training)** for personnel in any new or modified **responsibilities** affecting conformity to **quality** requirements, **internal requirements, regulatory of legislative requirements; this shall include** contract or agency personnel. **The level of detail required for on-the-job training shall be commensurate with the level of education the personnel possess and the complexity of the task(s) they are required to perform for their daily work. Persons** whose work can affect quality shall be informed about the consequences of nonconformity to **customer** requirements.	The IATF enhances the emphasis of on-the-job training and its importance in meeting customer requirements, including other interested parties. This training must also convey the consequences of nonconformity to customer requirements to all persons whose work affects quality.	Update to show employee participation in nonconformane of internal and external interested parties.	TBD	Team	June	June	Open
7.2.3 Internal auditor competency										
IATF 16949	**7.2.3**	Modified	**The organization shall have a documented process(es) to verify that internal auditors are competent, taking into account any customer-specific requirements. For additional guidance on auditor competencies, refer to ISO 190011.** The organization shall **maintain a list of** qualified internal auditors.	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, takes actions to address any deficiencies, assesses the effectiveness of actions taken, and records a list of the approved auditors. When training is provided, documented information must also be retained about trainer competency.	Procedure review and update		QMS Supervisor	April	May	Open
			Quality management system auditors, manufacturing process auditors, and product auditors shall be able to demonstrate the following minimum competencies:			Resume and Experience				
			a) understanding of the automotive process approach for auditing, including risk-based thinking;			Resume and Experience				Closed
			b) understanding of applicable customer-specific requirements;			Resume and Experience				Closed
			c) understanding of applicable ISO 9001 and IATF 16949 requirements related to the scope of the audit;			Resume and Experience				Closed
			d) understanding of applicable core tool requirements related to the scope of the audit;			Resume and Experience				Closed
			e) understanding how to plan, conduct, report, and close out audit findings.			Resume and Experience				Closed
			Additionally, manufacturing process auditors shall demonstrate technical understanding of the relevant manufacturing process(es) to be audited, including process risk analysis (such as PFMEA) an control plan. Product auditors shall demonstrate competence in understanding product requirements and use of relevant measuring and test equipment to verify product conformity.			Resume and Experience				Closed
			Where training is provided to achieve competency, DOCUMENTED INFORMATION shall be retained to demonstrate the trainer's competency with the above requirements.			Resume and Experience				Closed
			Maintenance of and improvement in internal auditor competence shall be demonstrated through:			Resume and Experience				Closed
			f) executing a minimum number of audits per year, as defined by the organization; and			Resume and Experience				Closed
			g) maintaining knowledge of relevant requirements based on internal changes (e.g. process technology, product technology) and external changes (e.g. ISO 9001, IATF 16949, core tools, and customer specific requirements).		Notifications from Sanctioned Interpretaions website	Notifications from Sanctioned Interpretaions website				Closed
7.2.4 Second-party auditor competency										
IATF 16949	**7.2.4**	New	**The organization shall demonstrate the competence of the auditors undertaking the second-party audits. Second-party auditors shall meet customer specific requirements for auditor qualification and demonstrate the minimum following core competencies, including understanding of:**	This new section outlines requirements for second-party auditors ensuring they are properly qualified to conduct these types of audits, with customer specific requirements being the main focus. The same core competencies that apply to internal auditors should, at a minimum, also apply to second-party auditors.	Review and update procedure		**QMS Supervisor**	June	June	Open
			a) the automotive process approach to auditing, including risk based thinking;							
			b) applicable customer and organization specific requirements;							
			c) applicable ISO 9001 and IATF 16949 requirements related to the scope of the audit;							
			d) applicable manufacturing process(es) to be audited, including PFMEA and control plan;							
			e) applicable core tool requirements related to the scope of the audit;							
			f) how to plan, conduct, prepare audit reports, and close out audit findings.							
7.3 Awareness										
ISO 9001	**7.3**	Modified	The organization shall ensure that persons doing work under the organization's control are aware of:	As stated.	Part of training	training matrix and employee checklist				Closed
			a) the quality policy;							
			b) relevant quality objectives;							
			c) their contribution to the effectiveness of the quality management system, **including the benefits of improved performance;**							
			d) the implications of not conforming with the quality management system requirements.							
7.3.1 Awareness - supplemental										
IATF 16949	**7.3.1**	Modified	The organization shall **maintain DOCUMENTED INFORMATION that demonstrates that all employees are aware of their impact on product quality and the importance of their activities in achieving, maintaining, and improving quality, including customer requirements and the risks involved for the customer with nonconforming product.**	Includes additional requirements to ensure that all employees are aware of their impact on the organization's (client's) product quality output, customer specific requirements, and risks involved for the customer with nonconforming product.	Need to update procedure and put a process in	TBD		June	June	Open

7.3.2 Employee motivation and empowerment									
IATF 16949	**7.3.2**	Modified	The organization shall **maintain a documented process(es)** to motivate employees to achieve quality objectives, to make continual improvements, and to create an environment that promotes innovation. The process shall include the promotion of quality and technological awareness throughout the whole organization.	This section did not substantially change, but now requires "maintaining a documented process" for employee motivation and empowerment, instead of simply "having a process".	Employee Awareness Matrix is posted on company bulletin board	Employee Matrix			Closed
7.4 Communication									
ISO 9001	**7.4**	Modified	The organization shall determine the **internal and external communications relevant to the quality management system**, including: **a) on what it will communicate;** **b) when to communicate;** **c) with whom to communicate;** **d) how to communicate;** **e) who communicates.**	The shift is from Top Management to the Organization. The steps are more specific and it mentions internal and external sources. Examples may include: work group meetings, bulletin boards, quality alerts, town hall meetings, emails, etc.		Bulletin Boards and Meeting	Team		Closed
0									
ISO 9001	**7.5.1**	Modified	The organization's quality management system shall include: **a) DOCUMENTED INFORMATION** required by this International Standard; **b) DOCUMENTED INFORMATION** determined by the organization as being necessary for the effectiveness of the quality management system. NOTE: The extent of **DOCUMENTED INFORMATION** for a quality management system can differ from one organization to another due to: - the size of organization and its type of activities, **processes, products and services;** - the complexity of processes and their interactions; - the competence of persons.	No specific requirement for a Quality Manual, but it may be used if wanted by the Organization. Major change from specific documents and records to the term of "DOCUMENTED INFORMATION". The intent is upon the organization to determine these.		Procedure Records Matrix			Closed
IATF 16949	**7.5.1.1**	Modified	**The organization's quality management system shall be documented and include a quality manual, which can be a series of documents (electronic or hard copy).** **The format and structure of the quality manual is at the discretion of the organization and will depend on the organization's size, culture, and complexity. If a series of documents is used, then a list shall be retained of the documents that comprise the quality manual for the organization.** **The quality manual shall include, at a minimum, the following** **a)** The scope of the quality management system, including details of and justification for any exclusions **b)** documented **processes** established for the quality management system, or reference to them **c) the organization's processes and their interactions (input and outputs), including type and extent of control of any outsourced processes** **d) a document (i.e. matrix) indicating where within the organization's quality management system their customer specific requirements are addressed.** **Note: A matrix of how the requirements of this Automotive QMS standard are addressed by the organization's processes may be used to assist with linkages of the organizations' processes and this Automotive QMS.**	The IATF retained the quality manual requirement that was removed in the 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.	Need to implement a Quality Manual	None exists	QMS Supervisor	May	May	Open
7.5.2 Creating and updating									
ISO 9001	**7.5.2**	Modified	When creating and updating **DOCUMENTED INFORMATION**, the organization shall ensure appropriate: **a)** identification **and description (e.g. a title, date, author, or reference number);** **b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic);** **c)** review and approval **for suitability** and adequacy.	Key focus upon the term "DOCUMENTED INFORMATION" in lieu of documents and records from the previous standard. The intent on control is still in place, but the organization is to determine the extent.		Procedure Records Matrix and within the form itself			Closed
7.5.3 Control of documented information									
ISO 9001	**7.5.3.1**	Modified	**DOCUMENTED INFORMATION** required by the quality management system and by this International Standard shall be controlled to ensure: **a)** it is available and **suitable for use, where and when it is needed;** **b)** it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).	Control establishes a predictable outcome.		Audit Process			closed
			For the control of **DOCUMENTED INFORMATION**, the organization shall address the following activities, as applicable: **a)** distribution, access, retrieval and use;	The organization needs to determine how the "DOCUMENTED INFORMATION" will be identified, stored, protected, retrieved, how long they will be kept, and disposed of.	Update				

ISO 9001	**7.5.3.2**	Modified	**b)** storage and preservation, including preservation of legibility; **c)** control of changes (e.g. version control); **d)** retention and disposition. **DOCUMENTED INFORMATION** of external origin determined by the organization to be necessary for the planning and operation of the quality management system shall be identified as appropriate, and be controlled. **DOCUMENTED INFORMATION** retained as evidence of conformity **shall be protected from unintended alterations.** **NOTE: Access can imply a decision regarding the permission to view the DOCUMENTED INFORMATION only, or the permission and authority to view and change the DOCUMENTED INFORMATION.**			**Records Matrix**		June	June	Open
7.5.3.2.1 Record retention										
IATF 16949	**7.5.3.2.1**	Modified	**The organization shall define, document, and implement a record retention policy.** The control of records shall satisfy statutory, regulatory, **organizational**, and customer requirements. **Production part approvals, tooling records (including maintenance and ownership), product and process design records, purchase orders (if applicable), or contracts and amendments shall be retained for the length of time that the product is active for production and service requirements, plus one calendar year, unless otherwise specified by the customer or regulatory agency.** **Note: Production part approval DOCUMENTED INFORMATION may include product, applicable test equipment records, or approved test data.**	This section now requires a record retention process that is defined and documented, and that includes the organization's record retention requirements. The clause specifically calls out production part approvals, tooling records, product and process design records, purchase orders, and contracts / amendments.	Review for compliance	Procedure	QMS Supervisor	June	June	Open
7.5.3.2.2 Engineering specifications										
IATF 16949	**7.5.3.2.2**	Modified	The organization shall have a **documented** process **describing** the review, distribution, and implementation of all customer engineering standards/specifications and **related revisions** based on customer schedules, **as required.** **When an engineering standard/specification change results in a product design change, refer to the requirements in ISO 9001 Section 8.3.6. when an engineering standard/specification change results in a product realization process change, refer to the requirements in section 8.5.6.1.** The organization shall **retain** record of the date on which each change is implemented in production. Implementation shall include updated documents. **Review should be completed within 10 working days of receipt of notification of engineering standards/specifications changes.** Note: A change in these standards/specifications may require an updated record of customer production part approval when these specifications are referenced on the design record or if the affect documents of the production part approval process, such as control plan, risk analysis (such as FMEAs), etc.	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.	Review for updates	**Procedure**		June	June	Open

Standard	Element	Is this a new requirement?	ISO 9001:2015 / IATF 16949:2016 Requirements	Commentary	Action / Resources Required	Objective Evidence	Responsible	Planned Start Date	Planned Completion Date	Status Open/In Progress/Closed/ Overdue
		New/Modified/ Carryover	**Bolded text indicates new to ISO 9001:2015 and IATF 16949:2016**							
8 Operation										
8.1 Operation planning and control										
ISO 9001	**8.1**	Modified	The organization shall plan, **implement and control the processes** (see 4.4) **needed** to meet the requirements for the provision of products and services, **and to implement the actions determined in Clause 6**, by:	Added the requirement to "control" the processes. It is important to define what the "product" is and to plan and define the manner in which the product is realized. The organization must determine if 8.1 a - 8.1 e is appropriate and act accordingly. If the organization outsources any processes, they must be controlled.	8 Operation Procedure	Quote Work sheet Receiving Process New Product - Control Plan Approved supplier list Inspection packet	Team			Closed
			a) determining the requirements for the products and services;							
			b) establishing criteria for:							
			1) the processes;							
			2) the acceptance of products and services;							
			c) determining the resources needed to achieve conformity to the product and service requirements;							
			d) implementing control of the processes in accordance with the criteria;							
			e) determining, maintaining and retaining **DOCUMENTED INFORMATION** to the extent necessary:							
			1) to have confidence that the processes have been carried out as planned;							
			2) to demonstrate the conformity of products and services to their requirements.							
			The output of this planning shall be suitable for the organization's operations.							
			The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.							
			The organization shall ensure that outsourced processes are controlled (see 8.4).							
8.1.1 Operation planning and control - supplement										
IATF 16949	**8.1.1**	Modified	**When planning for product realization, the following topics shall be included:**	This section features enhanced detail to ensure key processes are included and considered when planning for product realization. The section also clarifies the "resources needed to achieve conformity" encompasses all aspects of the development process, not just the manufacturing process requirements.	Need to be included	Procedure	**QMS Supervisor**	July	July	Open
			a) customer product requirements and technical specifications							
			b) logistics requirements							
			c) manufacturing feasibility							
			d) project planning (refer to ISO 9001, section 8.3.2)							
			e) acceptance criteria							
			The resources identified in ISO 9001, section 8.1c), refer to the required verification, validation, monitoring, measurement, inspection, and test activities specific to the product and the criteria for the product acceptance.							
8.1.2 Confidentiality										
IATF 16949	**8.1.2**	Modified	The organization shall ensure the confidentiality of customer-contracted products and projects under development, **including** related product information.	Features only a minor edit to clarify confidentiality "includes" related product information. There is no change in intent.	Need to update	Procedure	QMS Supervisor	July	July	Open
8.2 Requirements for product and services										
8.2.1 Customer communication										
	8.2.1	Modified	Communication with customers shall include:	Incorporated customer property along with establishing contingency actions. The organization must		Procedure				Closed
			a) providing information relating to products and services;							
			b) handling enquiries, contracts or orders, **including changes;**							
			c) obtaining customer feedback relating to products and services, including customer complaints;							

			d) handling or controlling customer property; **e) establishing specific requirements for contingency actions, when relevant**	establish a communication with the customer. Determine how the						
8.2.1.1 Customer communication - supplemental										
IATF 16949	**8.2.1.1**	Modified	**Written or verbal communication shall be in the language agreed by the customer.** The organization shall have the ability to communicate necessary information, including data in a customer-specified computer language and format (e.g. computer-aided design data, electronic data interchange)	Added requirement that the communication language (written or verbal) must be agreed with the customer.		Procedure				Closed
8.2.2 Determining the requirements for products and services										
ISO 9001	**8.2.2**	Modified	When determining the requirements for the products and services to be offered to customers, the organization shall ensure that: **a)** the requirements for the products and services are defined, including: 1) any applicable statutory and regulatory requirements; 2) those considered necessary by the organization; **b) the organization can meet the claims for the products and services it offers.**	The organization must determine and understand the customer's requirements relating to the product, delivery and post-delivery activities. This is an important activity that must be done in the early stages of the process.		Procedure				closed
8.2.2.1 Determining the requirements for products and services - supplemental										
IATF 16949	**8.2.2.1**	Modified	These requirements shall include recycling, environmental impact, and characteristics identified as a result of the organizations knowledge of the product and manufacturing processes. **Compliance to ISO 9001, section 8.2.2 item a) 1), shall include but not be limited to the following:** all applicable government, safety, and environmental regulations **related** to acquisition, storage, handling, recycling, elimination, or disposal or material.	Post delivery activities include any after-sales product service provided as part of the customer contract or purchase order.	Update procedure	Procedure	**QMS Supervisor**	July	July	Open
8.2.3 Review of requirements for products and services										
ISO 9001	**8.2.3.1**	Modified	The organization shall **ensure that it has the ability to meet the requirements for products and services to be offered to customers.** The organization shall conduct a review before committing to supply products and services to a customer, to include: **a)** requirements specified by the customer, including the requirements for delivery and post delivery activities; **b)** requirements not stated by the customer, but necessary for the specified or intended use, when known; **c)** requirements specified by the organization; **d)** statutory and regulatory requirements applicable to the products and services; **e)** contract or order requirements differing from those previously expressed. The organization shall ensure that contract or order requirements differing from those previously defined are resolved. The customer's requirements shall be confirmed by the organization before acceptance, when the customer does not provide a documented statement of their requirements. NOTE: In some situations, such as internet sales, a formal review is impractical for each order. Instead, the review can cover relevant product information, such as catalogues.	Prior to acceptance of a contract, the organization must determine the feasibility of meeting the customer's requirements. The key in this section is that the review is done BEFORE the acceptance. This section can be referred to as the contract review section.		Procedure - RFQ worksheet change order contract agreements acceptance Engineering communication on feabisility reviuew prior to capacity studies during quoting supplier assessments approved supplier list				closed
8.2.3.1.1 Review of the requirements for products and services - supplemental										
IATF 16949	**8.2.3.1.1**	Modified	**The organization shall retain documented evidence of a** customer-authorized waiver **for the requirements stated in ISO 9001, Section 8.2.3.1,** for a formal review.	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.	Review of customer requirements and implement	Customer Requirment Form for each customer	**QMS Supervisor**	April	April	Open
8.2.3.1.2 Customer-designated special characteristics										

IATF 16949	**8.2.3.1.2**	Modified	The organization shall **conform** to customer requirements for designation, **approval** documentation, and control of special characteristics.	This section changes the action from "demonstrate" conformity to "conform", and clarifies that it refers to "approval documentation",	Review of customer requirements and implement	customer requirement form - Inspection records - supplier documents	**Team**	April	April	Open
8.2.3.1.3 Organization manufacturing feasibility										
IATF 16949	**8.2.3.1.3**	Modified	The organization shall utilize a **multidisciplinary approach to conduct an analysis to determine if it is feasible that the organization's manufacturing processes are capable of consistently producing product that meets all the engineering and capacity requirements specified by the customer. The organization shall conduct this feasibility analysis for any manufacturing or product technology new to the organization and for any changed manufacturing process or product design.** **Additionally, the organization should validate through production runs, benchmarking studies, or other appropriate methods, their ability to make product to specifications at the required rate.**	Enhanced requirements for manufacturing feasibility analysis through the following changes: - multidisciplinary approach to analyze feasibility - requiring this analysis for any new manufacturing or product technology, and for any changed manufacturing process or product design. - recommending the organization validate their ability to make product specifications at the required rate and to consider customer-specific requirements.	Documentation showing the reviews and the studies	Analysis of the feasibility for manufacturing	**Team**	July	JUly	open
ISO 9001	**8.2.3.2**	Modified	The organization shall retain **DOCUMENTED INFORMATION**, as applicable: **a)** on the results of the review; **b) on any new requirements for the product and services.**	Documented information must be kept showing the results of the review and of any changes. This was previously called "records".						
ISO 9001	**8.2.4**	Modified	The organization shall ensure that relevant **DOCUMENTED INFORMATION** is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and **services** are changed.	No major impact. The people who are involved in the process must be made aware of any changes that occur.						
8.3 Design and development or products and services										
8.3.1 General										
ISO 9001	**8.3.1**	Modified	**The organization shall establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services.**	This is an expanded requirement in ISO 9001:2015. The organization must establish a "process" for design and development.	Process Design	Operations procdure				Closed
8.3.1.1 Design and development of products and services - supplemental										
IATF 16949	**8.3.1.1**	Modified	The requirements of **ISO 9001:2015, Section 8.3.1, shall apply to** product and manufacturing process design and development and **shall** focus on error prevention rather than detection. **The organization shall document the design and development process.**	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.	Add to procedure-Review process desgin(Include in design of manufacturing process)	Operations procedure and process Interrelations ship of Cross Functional Team	QMS Supervisor	July	July	Open
8.3.2 Design and development planning										
				Made the steps for design planning more distinct.	Exclusion	Exclusion included with the scope of the QMS				Closed
			a) the nature, duration and complexity of the design and development activities;	The organization must	Exclusion	Exclusion included with the scope of the QMS				Closed

ISO 9001	**8.3.2**	Modified	**b) the required process stages**, including applicable design and development reviews;	assign clear responsibility for the design and development of the product and the manufacturing processes to make that product. During the planning process, the organization must manage the interfaces between groups to ensure effective communication.	Exclusion	Exclusion included with the scope of the QMS				Closed
			c) the required design and development verification and validation activities;		Exclusion	Exclusion included with the scope of the QMS				Closed
			d) the responsibilities and authorities **involved in the design and development process;**		Exclusion	Exclusion included with the scope of the QMS				Closed
			e) the internal and external resource needs for the design and development of products and services;		Exclusion	Exclusion included with the scope of the QMS				Closed
			f) the need to control interfaces between persons involved in the design and development process;		Exclusion	Exclusion included with the scope of the QMS				Closed
			j) the documented information needed to demonstrate that design and development requirements have been met.		Exclusion	Exclusion included with the scope of the QMS				Closed
8.3.2.1 Design and development planning - supplemental										
IATF 16949	**8.3.2.1**	Modified	The organization shall **ensure that design and development planning includes all affected stakeholders within the organization and, as appropriate, its supply chain. Examples of areas for using such a multidisciplinary approach include but are not limited to the following:** **a) project management (for example, APQP or VDA-RGA);** **b) product and manufacturing process design activities (for example, DFM and DFA), such as consideration of the use of alternative designs and manufacturing processes;** **c)** development and review of **product design risk analysis (FMEAs)**, including actions to reduce potential risks; **d)** development and review of **manufacturing process risk analysis (for example, FMEAs, process flows**, control plans, **and standard work instructions;** Note: A multidisciplinary approach typically includes the organizations design, manufacturing, engineering, quality, production, **purchasing, supplier, maintenance**, and other appropriate **functions.**	The update to this section 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.	FMEA and Control Plan Audit	Audit results of PPAP audit	**QMS Supervisor**	July	July	Open
8.3.2.2 Product design skills										
IATF 16949	**8.3.2.2**	Modified	The organization shall ensure that personnel with product design responsibility are competent to achieve design requirements and are skilled in applicable product design tools and techniques. Applicable tools and techniques shall be identified by the organization.	This section adds a NOTE as an example of a product design skillset. There is no change in intent.	Exclusion	Exclusion included with the scope of the QMS				Closed
			Note: An example or product design skills is the application of digitized mathematically based data.		Exclusion	Exclusion included with the scope of the QMS				Closed
8.3.2.3 Development of products with embedded software										
IATF 16949	**8.3.2.3**	New	**The organization shall use a process for quality assurance for their products with internally developed embedded software. A software development assessment methodology shall be utilized to assess the organizations software development process. Using prioritization based on risk and potential impact to the customer, the organization shall retain DOCUMENTED INFORMATION of a software development capability self-assessment.**	This new section adds requirements for organization-responsible embedded software development and software development capability self-assessments.	Exclusion	Exclusion included with the scope of the QMS				Closed
			The organization shall include software development within the scope of their internal audit program.		Exclusion	Exclusion included with the scope of the QMS				Closed
8.3.3 Design and development inputs										
ISO 9001	**8.3.3**	Modified	The organization shall determine the requirements essential for the specific types of products and services to be designed and developed. The organization shall consider: **a)** functional and performance requirements; **b)** information derived from previous similar design and development activities; **c)** statutory and regulatory requirements; **d)** standards or codes of practice that the organization has committed to implement; **e) potential consequences of failure due to the nature of the products and services.**	Design inputs must be identified and documented. These inputs may come from customers, marketplace needs, regulatory requirements, standards, and specifications, skill requirements, documentation and data on existing products. The design inputs must be reviewed for accuracy and	Exclusion	Exclusion included with the scope of the QMS				closed

			Inputs shall be adequate for design and development purposes, complete and unambiguous. **Conflicting design and development inputs shall be resolved.** The organization shall retain **DOCUMENTED INFORMATION** on design and development inputs.	ensure they are not in conflict with each other.						
8.3.3.1 Product Design input										
IATF 16949	**8.3.3.1**	Modified	The organization shall identify, document, and review product design input requirements **as a result of contract review. Product design input requirements include, but are not limited to** the following: **a) product specifications including, but not limited to** special characteristics **(see Section 8.3.3.3);** **b) boundary and interface requirements;** **c)** identification, traceability, and packaging; **d) consideration of design alternatives;** **e) assessment of risks with the input requirements and the organization's ability to mitigate/manage the risks, including from the feasibility analysis;** **f)** targets for conformity to product requirements **including preservation**, reliability, durability, **serviceability, health, safety, environmental, development** timing, and cost;	This section expanded the minimum set of product design input requirements, emphasizing regulatory and software requirements. The consideration of design alternatives could involve practices which result in the trade-off curves mentioned in the added NOTE. Embedded software requirements may relate to predictability, analyzability / verifiability, and comprehensibility.	Exclusion	Exclusion included with the scope of the QMS				closed
8.3.3.2 Manufacturing process design input										
IATF 16949	**8.3.3.2**	Modified	The organization shall identify, document, and review manufacturing process design input requirements including **but not limited to the following:** **a)** product design output data **including special characteristics;** **b)** targets for productivity, process capability, **timing**, and cost; **c) manufacturing technology alternatives;** **d)** customer requirements, if any; **e)** experience from previous developments; **f) new materials;** **g) product handling and ergonomic requirements; and** **h) design for manufacturing and design for assembly.** The manufacturing process design **shall** include the use of error-proofing methods to a degree appropriate to the magnitude of the problem(s) and commensurate with the risks encountered.	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 section also further strengthened the requirements by transforming the former NOTE regarding error-proofing methods into a requirement.	Review and Update Procedure Audit of the objectives to assure each process has a target and output	Characteristics on related documentation from start to finish KPI List	Quality Manager	July	July	Open
8.3.3.3 Special characteristics										
IATF 16949	**8.3.3.3**	Modified	The organization shall **use a multidisciplinary approach to establish, document, and implement its process(es) to** identify special characteristics, **including those determined by the customer and the risks analysis performed by the organization, and shall include the following:** **a) documentation of all special characteristics in the** drawings (as required), **risk analysis (such as** FMEA), control plans, and **standard work**/operator instructions; **special characteristics are identified with specific markings and are cascaded through each of these documents;** **b) development of control and monitoring strategies for special characteristics of products and production processes;** **c) customer-specified approvals, when required;**	The changes in this section relate to identifying the source of special characteristics and including risk analysis to be performed by the customer or organization. This section also expands the list of sources used to identify special characteristics, along with	Review and Audit of Prints and customer requirements (included in manufacuring design)	Prints Customer requirements noted in supplier manual RFQ Worksheet PPAP Audit	QMS Supervisor	July	July	Open

			d) compliance with customer-specified definitions and symbols or the organization's equivalent symbols or notations, **as defined in a symbol conversion table. The symbol conversion table shall be submitted to the customer, if required.**	the related requirements. Special characteristics need to be marked in all applicable cascaded quality planning documents.						
8.3.4 Design and development controls										
ISO 9001	**8.3.4**	Modified	The organization shall **apply controls to the design and development process to ensure that:** **a) the results to be achieved are defined;** **b)** reviews are conducted to evaluate the ability of the results of design and development to meet requirements; **c)** verification activities are conducted to ensure that the design and development outputs meet the input requirements; **d)** validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use; **e)** any necessary actions are taken on problems determined during the reviews, or verification and validation activities; **f) DOCUMENTED INFORMATION** of these activities is retained. Note: Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in any combination, as is suitable for the products and services of the organization	Added the wording "process" to design to provide emphasis on process approach. Added verification and validation activities here. Design reviews must be performed according to planned arrangements. There reviews are essential to keeping the project on track and ensuring the product will meet customer and the organization's specifications. Design review should be	Exclusion					Closed
8.3.4.1 Monitoring										
IATF 16949	**8.3.4.1**	Modified	Measurements at specified stages **during the** design and development **of products and processes** shall be defined, analyzed, and reported with summary results as an input to management review **(see Section 9.3.2.1).** **When required by the customer, measurements of the product and process development activity shall be reported to the customer at stages specified, or agreed to, by the customer.** Note: **When appropriate**, these measurements may include quality risks, costs, lead times, critical paths, and other measurements.	These changes align the IATF 16949 standard with IATF OEM advanced quality activities, and aim to reduce the number of customer-specific requirements.	Update procedure and review of measurements	Management Review Record				Closed
8.3.4.2 Design and development validation										
IATF 16949	**8.3.4.2**	Modified	Design and development validation shall be performed in accordance with customer requirements, including **any applicable industry and governmental agency-issued regulatory standards. The timing of design and development validation shall be planned in alignment with customer-specified timing, as applicable.** **Where contractually agreed with the customer, this shall include evaluation of the interaction of the organization's product, including embedded software, within the system of the customer's product.**	This section features a strengthening of the requirements for design and development validation, and also added embedded software.	Review Validation of processes	Internal aduits-management review results	**QMS Supervisor**			Open
8.3.4.3 Prototype programme										
IATF 16949	**8.3.4.3**	Modified	When required by the customer, the organization shall have a prototype programme and control plan. The organization shall use, whenever possible, the same suppliers, tooling, and manufacturing processes as will be used in production. All performance-testing activities shall be monitored for timely completion and conformity to requirements. When services are outsourced, the organization shall **include the type and extent of control in the scope of its quality management system to ensure that** outsourced services **conform to requirements (see ISO 9001, Section 8.4).**	The changes in this section strengthen the standard by focusing the organization on the quality management system for managing outsourced products and services.	Exclusion					Closed
8.3.4.4 Product approval process										
			The organization shall **establish, implement, and maintain** a product and manufacturing approval **process conforming to requirements defined** by the customer**(s).**	These changes clarify approval requirements, with an emphasis on	PPAP Audit	PPAP Audit results				

IATF 16949	**8.3.4.4**	Modified	**The organization shall approve externally provided products and services per ISO 9001, Section 8.4.3, prior to submission of their part approval to the customer.** **The organization shall obtain documented** product approval **prior to shipment, if required by the customer. Records of such approval shall be retained.** Note: Product approval should be subsequent to the verification of the manufacturing process.	outsourced products and/or services and the record retention required. The use of the word "process" instead of procedure implies that the activities should be managed with an effective process approach.			**QMS Supervisor**	July	Jul;y	Open
8.3.5 Design and development outputs										
ISO 9001	**8.3.5**	Modified	The organization shall ensure that design and development outputs: **a)** meet the input requirements; **b)** are adequate for the subsequent processes for the provision of products and services; **c) include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;** **d)** specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision. **The organization shall retain DOCUMENTED INFORMATION on design and development outputs.**	Design outputs must be provided in a manner that facilitates verification against inputs. These outputs must meet input requirements, provide information for purchasing, production and service provision, contain or reference product criteria for safe and proper use.	Exclusion					Closed
8.3.5.1 Design and development outputs - supplemental										
IATF 16949	**8.3.5.1**	Modified	The product design output shall be expressed in terms that can be verified and validated against product design input requirements. The product design output shall include, **but is not limited to the following, as applicable:** **a)** design **risk analysis** (FMEA); **b)** reliability **study** results; **c)** product special characteristics; **d) results of** product **design** error-proofing, **such as DFSS, DFMA, and FTA;** **e)** product definition including **3D models, technical data packages, product manufacturing information, and geometric dimensioning & tolerancing (GD&T);** **f) 2D drawings, product manufacturing information, and geometric dimensioning & tolerancing (GD&T);** **g)** product design review results; **Note: Interim design outputs should include any engineering problems being resolved through a trade-off process.**	Product design output additions include a recognition of the use of 3D models, and inclusion of service parts and packaging. The application of GD&T tolerancing and positioning systems allows organizations to remove ambiguity and specify dimensions and related tolerances based on functionality relationships.	Exclusion					Closed
8.3.5.2 Manufacturing process design output										
IATF 16949	**8.3.5.2**	Modified	**The organization shall document the** manufacturing process design output **in a manner that enables verification against the manufacturing process design inputs. The organization shall verify the outputs against manufacturing process design input requirements**. The manufacturing process design output shall include, **but is not limited to the following:** **a)** specifications and drawings; **b) special characteristics for product and manufacturing process;** **c) identification of process input variables and impact characteristics;** **d) tooling and equipment for production and control, including capability studies of equipment and process(es);** **e)** manufacturing process flow charts/layout, **including linkage of product, process, and tooling;** **f) capacity analysis;** **g)** manufacturing process FMEA; **n)** methods of rapid detection, feedback, **and correction** of product/manufacturing process nonconformities.	Changes in this section strengthened verification requirements, process input variables, capacity analysis, maintenance plans and correction of process nonconformities. More specifically, it clarifies that the process approach methodology of verifying outputs against inputs applies to the manufacturing design process. The list of manufacturing design outputs has also expanded.	Exclusion					Closed

8.3.6 Design and development changes										
ISO 9001	**8.3.6**	Modified	The organization shall identify, review and control changes **made during, or subsequent to, the design and development of products and services**, to the extent necessary to ensure that there is no adverse impact on conformity to requirements. The organization shall retain **DOCUMENTED INFORMATION** on: **a)** design and development changes; **b)** the results of reviews; **c) the authorization of the changes;** **d) the actions taken to prevent adverse impacts.**	All design and development changes must be identified and recorded. DOCUMENTED INFORMATION of the results of the review of changes and any actions must be kept.	Update procedure	Engineering Change Order and proof from customer	QMS Supervisor	July	July	Open
8.3.6.1 Design and development changes - supplemental										
IATF 16949	**8.3.6.1**	Modified	**The organization shall evaluate all design changes after initial product approval, including those proposed by the organization or its suppliers, for potential impact on fit, form, function, performance, and/or durability. These changes shall be validated against customer requirements and approved internally, prior to production implementation.** **If required by the customer, the organization shall obtain documented approval, or a documented waiver, from the customer prior to production implementation.** **For products with embedded software, the organization shall document the revision level of software and hardware as part of the change record.**	This section strengthens the requirement for change validation and approval prior to implementation, and also added embedded software. For products with embedded software, the change record needs to document the revision level of the software (and	Update	Engineering Change Order and proof from customer worksheets	**QMS Supervisor**	July	July	Open
8.4 Control of external provided processes, products and services										
8.4.1 General										
ISO 9001	**8.4.1**	Modified	The organization shall ensure that **externally provided processes**, products and **services** conform to requirements. The organization shall determine the controls to be applied to externally provided processes, products and services **when:** **a) products and services from external providers are intended for incorporation into the organization's own products and services;** **b) products and services are provided directly to the customer(s) by external providers on behalf of the organization;** **c) a process, or part of a process, is provided by the external provider as a result of a decision by the organization;** The organization shall determine and apply criteria for the evaluation, selection, **monitoring of performance**, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. The organization shall retain **DOCUMENTED INFORMATION** of these activities and any necessary actions arising from the evaluations.	The organization must control how it ensures externally provided product, services and its processes conforms to specified requirements. Criteria for evaluation, selection, monitoring of performance and re-evaluation needs to be defined and providers selected accordingly.	Operations Procedure includes purchasing	Approved Supplier List Procedure	**QMS Supervisor**	July	July	Open
8.4.1.1 General - supplemental										
IATF 16949	**8.4.1.1**	New	**The organization shall include all products that affect customer requirements such as subassembly, sequencing, sorting, rework, and calibration services in the scope of their definition of externally provided products, processes, and services.**	The former NOTE about purchased products was broadened and elevated into a requirement.	Update procedure and approved supplier list	Approved Supplier List	QMS Supervisor	July	July	Open
			The organization shall have a documented supplier selection process. The selection shall include: **a) an assessment of the selected supplier's risk to product conformity and uninterrupted supply of the organization's product to their customers;** **b) relevant quality and delivery performance;** **c) an evaluation of the supplier's quality management system;** **d) multi-disciplinary decision making; and**	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	risk Assessment Scorecards	Supplier Assessment -and scorecards Procedures				

IATF 16949	8.4.1.2	New	**e) an assessment of software development capabilities, if applicable.** **Other supplier selection criteria that should be considered include the following:** **- volume of automotive business (absolute and as percentage of total business);** **- financial stability;** **- purchased product, material, or service complexity;** **- required technology (product or process);** **- adequacy of available resources (e.g. people, infrastructure);** **- manufacturing capability;** **- change management process;** **- business continuity planning (e.g. disaster preparedness, contingency planning);** **- logistics process;** **- customer service.**	QMS audits and include aspects such as: risk to product conformity and uninterrupted supply, relevant quality and delivery performance and evaluation of the suppliers' quality management system. The standard also provides a list of other criteria to be considered.			Quality	July	July	Open
8.4.1.3 Customer-directed sources (also known as "Directed-Buy")										
IATF 16949	8.4.1.3	Modified	When **specified by the customer, the organization shall purchase products, materials, or services from customer-directed sources.** **All requirements of Section 8.4 (except the requirements in IATF 16949, Section 8.4.1.2) are applicable to the organization's control of customer-directed sources unless specific agreements are otherwise defined by the contract between the organization and the customer.**	This section features a clarification of the organization's responsibilities for customer directed sources, even for customer directed-buy suppliers.	Add To Procedure	Procedures	QMS Supervisor	July	July	Open
8.4.2 Type and extent of control										
ISO 9001	8.4.2	Modified	The organization shall ensure that **externally provided processes**, products **and services** do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers. **The organization shall:** **a) ensure that externally provided processes remain within the control of its quality management system;** **b) define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;** **c) take into consideration:** **1) the potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements;** **2) the effectiveness of the controls applied by the external provider;** **d)** determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.	Consider the effect of the purchased product on the end product and apply suitable controls. The organization must define and implement activities to verify purchased product. Examples are: receiving inspection, certifications sent with the product, audits of suppliers, etc.	Operations Procedure	Procedures scorecards request for quote sent to external providers	QMS Supervisor	July	July	Open
8.4.2.1 Type and extent of control - supplemental										
IATF 16949	8.4.2.1	Modified	**The process shall include the criteria and actions to escalate or reduce the types and extent of controls and development activities based on supplier performance and assessment of product, material, or service risks.**	The changes in this section further strengthened the requirement for control of outsourced processes, including the assessment of risk.	Add To Procedure	Procedures	Quality	July	July	open
8.4.2.2 Statutory and regulatory requirements										
IATF 16949	8.4.2.2	Modified	**The organization shall document their process to ensure that purchased** products, **processes, and services** conform to the **current** applicable statutory and regulatory requirements **in the country of receipt, the country of shipment, and the customer-identified country of destination, if provided.**	The updates clarify and strengthen the applicability of statutory and regulatory requirements.	Update procedure	Procedures	Quality	July	July	Open

			If the customer defines special controls for the certain products with statutory and regulatory requirements, the organization shall ensure they are implemented and maintained as defined, including at suppliers.			CMRT-Reach-RoHs-Proposition 65-Nafta-IMDS				
8.4.2.3 Supplier quality management system development										
IATF 16949	**8.4.2.3**	Modified	The organization shall **require their suppliers of automotive products and services to develop, implement, and improve a quality management system certified to ISO 9001, unless otherwise authorized by the customer [e.g., item a) below], with the ultimate objective of becoming certified to this Automotive QMS Standard. Unless otherwise specified by the customer, the following sequence should be applied to achieve this requirement:** **a) compliance to ISO 9001 through second-party audits;** **b) certification to ISO 9001 through third-party audits; unless otherwise specified by the customer, suppliers to the organization shall demonstrate conformity to ISO 9001 by maintaining a third-party certification issued by a certification body bearing the accreditation mark of a recognized IAF MLA (International Accreditation Forum Multilateral Recognition Arrangement) member and where the accreditation body's main scope includes management system certification to ISO/IEC 17021;** **c) certification to ISO 9001 with compliance to other customer-defined QMS requirements (such as Minimum Automotive Quality Management System Requirements for Sub-Tier Suppliers [MAQMSRJ or equivalent) through second-party audits;** **d) certification to ISO 9001 with compliance to IATF 16949 through second-party audits;** **e) certification to 16949 through third-party audits (valid third-party certification of the supplier to IATF 16949 by an IATF-recognized certification body).**	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 sections outlines a progressive approach that goes from compliance to ISO 9001 via second-party audits all the way through certification to IATF through third-party audits.	Review-Discuss-Additional Procedure	TBD	**Team**	July	July	Open
8.4.2.3.1 Automotive product-related software or automotive products with embedded software										
IATF 16949	**8.4.2.3.1**	New	**The organization shall require their suppliers of automotive product-related software, or automotive products with embedded software, to implement and maintain a process for software quality assurance for their products.** **A software development assessment methodology shall be utilized to assess the supplier's software development process. Using prioritization based on risk and potential impact to the customer, the organization shall require the supplier to retain DOCUMENTED INFORMATION or a software development capability self-assessment.**	This new section added requirements for software development assessment methodology. These requirements align to those presented in section 8.3.2.3, but are now cascaded down to suppliers.	Add To Procedure	Procedures	Team	July	July	Open
8.4.2.4 Supplier monitoring										
IATF 16949	**8.4.2.4**	Modified	**The organization shall have a documented process and criteria to evaluate** supplier performance **in order to ensure conformity of externally provided products, processes, and services to internal and external customer requirements.** **At a minimum, the following supplier performance indicators shall be monitored:** **a)** delivered product conformity to requirements; **b)** customer disruptions **at the receiving plant, including yard holds and stop ships;** **c)** delivery schedule performance; **d) number of occurrences of** premium freight **If provided by the customer, the organization shall also include the following, as appropriate, in their supplier performance monitoring:** **e)** special status customer notifications related to quality or delivery issues; **f) dealer returns, warranty, field actions, and recalls.**	This section features strengthened requirements for supplier monitoring. The use of the term "documented process" suggests that the organization should continuously review inputs and introduce improvement actions regarding supplier monitoring data, as needed.	Add To Procedure	TBD	Quality	July	July	Open
8.4.2.4.1 Second-party audits										
			The organization shall include a second-party audit process in their supplier management approach. Second-party audits may be used for the following: **e) process audits.**	This new section aligns customer-specific requirements into the IATF 16949 standard.	Update	TBD				

IATF 16949	**8.4.2.4.1**	New	**b) supplier monitoring;** **c) supplier QMS development;** **d) product audits;** **e) process audits.** **Based on a risk analysis, including product safety/regulatory requirements, performance of the supplier, and QMS certification level, at a minimum, the organization shall document the criteria for determining the need, type, frequency, and scope of second-party audits.** **The organization shall retain records of the second-party audit reports.** **If the scope of the second-party audit is to assess the supplier's quality management system, then the approach shall be consistent with the automotive process approach.** **NOTE: Guidance may be found in the IATF Auditor Guide and ISO 19011.**	Second-party audits were not previously included in the ISO/TS 16949 standard. The organization's criteria for determining the need, frequency, and scope of second-party audits must be based on risk analysis.			**Team**	July	July	Open
8.4.2.5 Supplier development										
IATF 16949	**8.4.2.5**	Modified	The organization shall **determine the priority, type, extent, and timing of required supplier development actions for its active suppliers. Determination inputs shall include, but are not limited to** the following: **a) performance issues identified through supplier monitoring (see Section 8.4.2.4);** **b)** second-party audit **findings (see Section 8.4.2.4.1);** **c)** third-party **quality management system certification status;** **d) risk analysis.** **The organization shall implement actions necessary to resolve open (unsatisfactory) performance issues and pursue opportunities for continual improvement.**	This section adds an emphasis on performance-based supplier development activities. This suggests that the supplier monitoring process should be considered an input to the supplier development activities. These development activities should consider short and long term goals, applied corrective actions, and pursue opportunities for continual improvement.	Procedure	Procedures	Quality	July	July	Open
8.4.3 Information for external providers										
ISO 9001	**8.4.3**	Modified	The organization shall ensure the adequacy of requirements prior to their communication to the external provider. The organization shall **communicate to external providers its requirements for:** **a)** the processes, products and services to be provided; **b)** the approval of: 1) products and services; 2) methods, processes and equipment; **3) the release of products and services;** **c)** competence, including any required qualification of persons; **d) the external providers' interactions with the organization;** **e) control and monitoring of the external providers' performance to be applied by the organization;** **f)** verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises.	Externally provided products or services must be clearly described on purchasing documents. Some organizations refer to this as the Purchase Order. Prior to release to the external provider, purchasing documents must be reviewed for adequacy.	Procedure	Procedure Purchase Order to Supplier				Closed
8.4.3.1 Information for external providers - supplemental										

IATF 16949	**8.4.3.1**	New	**The organization shall pass down all applicable statutory and regulatory requirements and special product and process characteristics to their suppliers and require the suppliers to cascade all applicable requirements down the supply chain to the point of manufacture.**	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.	Add To Procedure	Procedure and Supplier Purchase Order	**Quality**	July	July	Open
8.5 Production and service provision										
8.5.1 Control of production and service provision										
ISO 9001	**8.5.1**	Modified	The organization shall implement production and service provision under controlled conditions.	The organization must ensure information is available that specifies product characteristics. Some organizations use a design record or a control plan. There are many other methods to be used. Work instructions can be used to define activities to be performed. These work instructions can be in any format. The organization must maintain the equipment used for production and service provision, where necessary. This may include preventative as well as predictive maintenance. The organization must identify and provide appropriate measuring and monitoring equipment, where necessary.	Procedure	Procedure	Team			Closed
			Controlled conditions shall include, as applicable:			FMEA				
			a) the availability of **DOCUMENTED INFORMATION** that defines:			Control Plans				
			1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed;			Manufacturing Control Plan				
			2) the results to be achieved;			Process Inspection Records				
			b) the availability and use of suitable monitoring and measuring **resources;**			Final Audit				
			c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;			Product Planning				
			d) the use of suitable infrastructure and environment for the operation of processes;			Quality Alerts				
			e) the appointment of competent persons, including any required qualification;			Feasibility				
			f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;							
			g) the implementation of actions to prevent human error;							
			h) the implementation of release, delivery and post-delivery activities.							
IATF 16949	**8.5.1**	Modified	**NOTE: Suitable infrastructure includes appropriate manufacturing equipment required to ensure product compliance. Monitoring and measuring resources include appropriate monitoring and measuring equipment required to ensure effective control of manufacturing processes.**	Clarification of suitable infrastructure.	Update and include in procedure	Operations Procedure	QMS Supervisor	July	July	open
8.5.1.1 Control plan										
			The organization shall develop control plans **(in accordance with** Annex A) at the system, subsystem, component and/or material level for the **relevant manufacturing site and all** product supplied, including those for processes producing bulk materials as well as parts. **Family control plans are acceptable for bulk material and similar parts using a common manufacturing process.**	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. This section also expanded the scope of activities to be included within the control	Audit and update	Procedure and PPAP documents	QMS Supervisor	July	July	open
			The organization shall have a control plan for pre-launch and production that **shows linkage and incorporates information from the design risk analysis (if provided by the customer), process flow diagram, and** manufacturing process **risk analysis outputs (such as** FMEA).							
			The **organization** shall, **if required by the customer, provide measurement and conformity data collected during execution of either the pre-launch or production control plans. The organization** shall **include in the control plan:**							
			a) controls used for the manufacturing process control, **including verification of job set-ups;**							
			b) first-off/last-off part validation, as applicable;							

IATF 16949	8.5.1.1	Modified	**c)** methods for monitoring of control exercised over special characteristics (see **Annex A**) defined by both the customer and the organization;	plan.						
			d) the customer-required information, if any;							
			The organization shall review control plans, and update **as required**, for any or the following:							
			f) the organization determines it has shipped nonconforming product to the customer,							
			g) when any change occurs affecting product, manufacturing process, measurement, logistics, supply sources, **production volume changes, or risk analysis** (FMEA) (see **Annex A**);							
			h) after a customer complaint and implementation of the associated corrective action, when applicable;							
			i) at a set frequency based on a risk analysis.							
			If required by the customer, the organization shall obtain customer approval after review **or revision** of the control plan.							
8.5.1.2 Standardized work - operator instructions and visual standards										
IATF 16949	8.5.1.2	Modified	The organization shall **ensure that standardized** work **documents are:**	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.	Update procedure	Procedure	QMS Supervisor	July	July	open
			a) communicated to and understood by the employees who are responsible for performing the work;			Training records				
			b) legible;							
			c) presented in the language(s) understood by the personnel responsible to follow them;							
			d) accessible for use at the designated work **area(s).**							
			The standardized work documents shall also include rules for operator safety.							
8.5.1.3 Verification of job set-ups										
IATF 16949	8.5.1.3	Modified	**The organization shall:**	The changes in this section elevate a NOTE to a requirement, and clarify record retention.	review and update	Procedure	QMS Supervisor	July	July	open
			a) verify job set-ups when performed, such as an initial run of a job, material changeover, or job change **that requires a new set-up;**			First Piece Set Up				
			b) maintain DOCUMENTED INFORMATION for set-up personnel;			Final Audit				
			c) use statistical methods of verification, where applicable;							
			d) perform first-off/last-off part validation, as applicable; where appropriate, first-off parts should be retained for comparison with the last-off parts; where appropriate, last off-parts should be retained for comparison with first-off parts in subsequent runs;							
			e) retain records of process and product approval following set-up and first-off/ last-off part validations.							
IATF 16949	8.5.1.4	New	**The organization shall define and implement the necessary actions to ensure product compliance with requirements after a planned or unplanned production shutdown period.**	Defines a new requirement for verification after shutdown, integrating industry lessons learned	Update Procedure	Procedure	Team	July	July	Open
8.5.1.5 Total productive maintenance										
			The organization shall **develop, implement, and maintain a documented total productive maintenance system.**	This section strengthens the requirement for equipment maintenance and overall proactive management of the Total Productive Maintenance (TPM). TPM should be fully integrated within the manufacturing processes. New and clarified	Review and update	Procedure		July	July	Open
			At a minimum, the system shall include the following:							
			a) identification of process equipment necessary to produce conforming product at the required volume;							
			b) availability of replacement parts for the equipment identified in item a);							
			c) provision of resource for machine, equipment, and facility maintenance;							
			d) packaging and preservation of equipment, tooling, and gauging;							
			e) applicable customer-specific requirements;							

IATF 16949	**8.5.1.5**	Modified	**f) documented maintenance objectives, for example: OEE (Overall Equipment Effectiveness), MTBF (Mean Time Between Failure), and MTTR (Mean Time To Repair), and Preventive Maintenance compliance metrics. Performance to the maintenance objectives shall form an input into management review (see ISO 9001, Section 9.3);**	requirements include: identification of process equipment; [provision of resources; applicable customer-specific requirements; documented maintenance objectives with action plans where objectives are not being achieved; use of preventative methods; and periodic overhaul.			**Team**			
			g) regular review of maintenance plan and objectives and a documented action plan to address corrective actions where objectives are not achieved;							
			h) use of preventive maintenance methods;							
			i) use of predictive maintenance methods, **as applicable;**							
			j) periodic overhaul.							
8.5.1.6 Management of production tooling and manufacturing, test, inspection tooling and equipment										
IATF 16949	**8.5.1.6**	Modified	The organization shall provide resources for tool and gauge design, fabrication, and verification activities **for production and service materials and for bulk materials, as applicable.**	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.	Update Procedure	Procedure and Maintenance documents	**engineering**	July	July	open
			The organization shall establish and implement a system for production tooling management, **whether owned by the organization or the customer**, including:							
			a) maintenance and repair facilities and personnel;							
			b) storage and recovery;							
			c) set-up;							
			d) tool-change programmes for perishable tools;							
			e) tool design modification documentation, including engineering change **level of the product;**							
			f) tool modification and revision to documentation;		Update Procedure	Procedure				
			g) tool identification, **such as serial or asset number, the status**, such as production, repair or disposal; **ownership; and location.**		Update current tool documentation	Tooling documentation				
			The organization shall verify that customer-owned tools, manufacturing equipment, and test/inspection equipment are permanently marked in a visible location so that the ownership and application of each item can be determined.							
			The organization shall implement a system to monitor these activities if any work is outsourced.							
8.5.1.7 Production scheduling										
IATF 16949	**8.5.1.7**	Modified	**The organization shall ensure that** production is scheduled in order to meet customer **orders/demands** such as Just-In-Time (JIT) and is supported by an information system that permits access to production information at key stages of the process and is order driven.	This section emphasized the importance of planning information and integrated IATF OEM customer lessons learned. This suggests the organization needs a robust feasibility review process regarding production scheduling.	Update procedure and scheduling process	Procedure and White board schedules	**Production Manager**	July	July	Opern
			The organization shall include relevant planning information during production scheduling, e.g., customer orders, supplier on-time delivery performance, capacity, shared loading (multi-part station), lead time, inventory level, preventive maintenance, and calibration.							
ISO 9001	**8.5.2**	Modified	The organization shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and **services.**	The organization must have a method in place to identify the product throughout production and service operations.		identification tags				Closed
			The organization shall identify the status of **outputs** with respect to monitoring and measurement requirements throughout production and service provision.			Production worksheets				
			The organization shall control the unique identification of the **outputs** when traceability is a requirement, and shall retain the **DOCUMENTED INFORMATION** necessary to enable traceability.			Shipping labels				
IATF 16949	**8.5.2**	New	NOTE: Inspection and test status is not indicated by the location of product in the production flow unless inherently obvious, such as material in an automated production transfer process. Alternatives are permitted if the status is clearly identified, documented, and achieves the designated purpose.	Clarification not previously included in ISO/TS 16949.	Review	Standard review	QMS Supervisor	July	July	Open

8.5.2.1 Identification and traceability- supplemental										
IATF 16949	**8.5.2.1**	Modified	**The purpose of traceability is to support identification of clear start and stop points for product received by the customer or in the field that may contain quality and/or safety-related nonconformities. Therefore, the organization shall implement identification and traceability processes as described below.** **The organization shall conduct an analysis of internal, customer, and regulatory traceability requirements for all automotive products, including developing and documenting traceability plans, based on the levels of risk or failure severity for employees, customers, and consumers. These plans shall define the appropriate traceability systems, processes, and methods by product, process, and manufacturing location that:** **a) enable the organization to identify nonconforming and/or suspect product;** **b) enable the organization to segregate nonconforming and/or suspect product;** **c) ensure the ability to meet the customer and/or regulatory response time requirements;** **d) ensure documented information is retained in the formal (electronic, hardcopy, archive) that enables the organization to meet the response time requirements;** **e) ensure serialized identification of individual products, if specified by the customer or regulatory standards;** **f) ensure the identification and traceability requirements are extended to externally provided products with safely/regulatory characteristics.**	Strengthens the requirements for traceability to support lessons learned related to field issues. Traceability configuration needs to consider the requirements of interested parties and risk assessments.	Update procedure Add 5 Why	Procedure NCR document 5 Why	**team**	July	July	Open
8.5.3 Property belonging to customers or external providers										
ISO 9001	**8.5.3**	Modified	The organization shall exercise care with property belonging to customers **or external providers** while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customers' or **external providers' property** provided for use or incorporation into the products and services. When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer or external provider and retain **DOCUMENTED INFORMATION on what has occurred.** **NOTE: A customer's or external provider's property can include materials, components, tools and equipment, premises**, intellectual property and personal data.	The organization must ensure conformity of the product during internal operations and delivery to the intended destination.	Procedure	Procedure Identified tools	**Team**			closed
8.5.4 Preservation										
ISO 9001	**8.5.4**	Modified	The organization shall preserve the **outputs** during production and service provision, to the extent necessary **to ensure** conformity to requirements. NOTE: Preservation can include identification, handling, **contamination control, packaging**, storage, **transmission or transportation**, and protection.	The organization shall preserve the outputs during production and service provision, to the extent necessary to ensure	Add note to procedure	Procedure labels -tage-I.D. number on tools	Engineering and QMS supervisor			Closed
8.5.4.1 Preservation - supplemental										
IATF 16949	**8.5.4.1**	Modified	**Preservation shall include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.** **Preservation shall apply to materials and components from external and/or internal providers from receipt through processing, including shipment and until delivery to/acceptance by the customer.** In order to detect deterioration, the **organization shall assess** at appropriate planned intervals the condition of product in stock, **the place/type of storage container, and the storage environment.** The organization shall use an inventory management system to optimize inventory turns over time and ensure stock rotation, such as "first-in-first-out" (FIFO). **The organization shall ensure that** obsolete product is controlled in a manner similar to that of nonconforming product. **Organizations shall comply with preservation, packaging, shipping, and labeling requirements as provided by their customers.**	Adds specificity to preservation controls and includes application to internal and/or external providers. Preservation principles need to be applied from the point of receiving materials all the way to product acceptance by the customer.	Review Procedure and Documentation	Procedure and documentation	**QMS Supervisor**	July	July	closed
8.5.5 Post-delivery activities										

ISO 9001	**8.5.5**	Modified	The organization shall meet requirements for post-delivery activities associated with the products and services. **In determining the extent of post-delivery activities that are required, the organization shall consider:** **a) statutory and regulatory requirements;** **b) the potential undesired consequences associated with its products and services;** **c) the nature, use and intended lifetime of its products and services;** **d) customer requirements;** **e) customer feedback.** **NOTE: Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.**	The organization must have methods in place for release, delivery and post-delivery activities, if applicable. This links back to Sec. 8.2.2 - determination of requirements related to the product.		Procedure and field failures Management Review	QMS Supervisor	July	July	Closed
8.5.5.1 Feedback of information from service										
IATF 16949	**8.5.5.1**	Modified	**The organization shall ensure that** a process for communication of information on service concerns to manufacturing, **material handling, logistics**, engineering, and design activities is established, **implemented**, and maintained. NOTE 1: The intent of the addition of "service concerns" to this sub-clause is to ensure that the organization is aware of **nonconforming product(s) and material(s) that may be identified at the customer location or in the field.** **NOTE 2: "Service concerns" should include the results of field failure test analysis (see Section 10.2.6) where applicable.**	Requirements for the section feature an expanded scope to include material handling and logistics. The new 2nd NOTE also clarifies "service concerns".	Update procedure	Procedure and Management review record	Quality			closed
Upd										
IATF 16949	**8.5.5.2**	Modified	When there is a service agreement with the customer, the organization shall: **a) verify that the relevant** service centers comply with applicable requirements; **b) verify the effectiveness of** any special purpose tools or measurement equipment; **c) ensure that all** service personnel **are trained in applicable requirements.**	This section clarifies that service centers need to comply with all applicable requirements when there is a service agreement with the customer.	Update procedure	Procedure Tool Records Equipment List	Team	July	July	Open
8.5.6 Control of changes										
ISO 9001	**8.5.6**	Modified	The organization shall review and control changes for production or service provision, to the extent necessary **to ensure continuing conformity with requirements.** The organization shall retain **DOCUMENTED INFORMATION** describing the results of the review of changes, **the person(s) authorizing the change**, and any necessary actions arising from the review.	New ISO clause to emphasize this topic. If the organization was using Sec. 7.3 for design and development of manufacturing, then this would be roughly equivalent, otherwise it is a new requirement.		Procedure ECO	Quality			Closed
8.5.6.1 Control of changes - supplemental										
IATF 16949	**8.5.6.1**	Modified	The organization shall have a documented process to control and react to changes that impact product realization. The effects or any change, including those changes caused **by the organization, the customer, or** any supplier, shall be assessed. **The organization shall:** **a) define** verification and validation activities to ensure compliance with customer requirements; **b)** validate changes before implementation; **c) document the evidence of related risk analysis;** **d) retain records of verification and validation.**	IATF strengthens the control of changes requirements in the standard to align with existing IATF OEM requirements. The changes clarify the "any change" includes those caused by the organization and/or customer, in addition to those by any supplier. The organization should also	Update procedure	Procedure-ECO-QMS documents	**Team**	July	July	

			Changes, including those made at suppliers, should require a production trial run for verification of changes (such as changes to part design, manufacturing location, or manufacturing process) to validate the impact of any changes on the manufacturing process.	ensure they have a strong process to communicate and manage changes.						Open
			When required by the customer, **the organization shall:**							
			e) notify the customer of any planned product realization changes after the most recent product approval;							
			f) obtain documented approval, prior to implementation of the change;							
			g) complete additional verification or identification requirements, such as production trial run and new product validation.							
8.5.6.1.1 Temporary change of process controls										
IATF 16949	**8.5.6.1.1**	New	**The organization shall identify, document, and maintain a list of the process controls, including inspection, measuring, test, and error-proofing devices, that includes the primary process control and the approved back-up or alternate methods.**	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 primary process control and the approved back-up or alternate methods. The use of alternative control methods is considered a process; therefore, the organization is expected to manage these activities appropriately. Daily reviews of operator standardized work must consider alternate process controls with the goal of returning to the standard process as soon as possible.	Update procedure and documents Include alternate methods of inspection with customer approval. Layered Audits - Daily leadership meetings (notes)Restart verification Identification for alternate process controls	Procedure - Layered audit document - customer approvals where necessary	**Team**	July	July	Open
			The organization shall document the process that manages the use of alternate control methods. The organization shall include in this process, based on risk analysis (such as FMEA), severity, and the internal approvals to be obtained prior to production implementation of the alternate control method.							
			Before shipping product that was inspected or tested using the alternate method, if required, the organization shall obtain approval from the customer(s). The organization shall maintain and periodically review a list of approved alternate process control methods that are referenced in the control plan.							
			Standard work instructions shall be available for each alternate process control method. The organization shall review the operation of alternate process controls on a daily basis, at a minimum, to verify implementation of standard work with the goal to return to the standard process as defined by the control plan as soon as possible. Example methods include but are not limited to the following:							
			a) daily quality focused audits (e.g., layered process audits, as applicable);							
			b) daily leadership meetings.							
			Restart verification is documented for a defined period based on severity and confirmation that all features of the error-proofing device or process are effectively reinstated.							
			The organization shall implement traceability of all product produced while any alternate process control devices or processes are being used (e.g., verification and retention of first piece and last piece from every shift).							
8.6 Release of products and services										
ISO 9001	**8.6**	Modified	The organization shall implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.	The organization must monitor and measure those characteristics necessary to verify requirements are met. These methods must be carried out at appropriate times during the process.		Procedure - Inspection records -	Quality			Closed
			The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.							
			The organization shall retain **DOCUMENTED INFORMATION** on the release of products and services. The **DOCUMENTED INFORMATION** shall include:							
			a) evidence of conformity with the acceptance criteria;							
			b) traceability to the person(s) authorizing the release.							
8.6.1 Release of products and services - supplemental										
			The organization shall ensure that the planned arrangements to verify that the product and service requirements have been met encompass the control plan and are documented as specified in the control plan (see Annex A) .	This further detail strengthens the standard to ensure process controls align with the control plan. The organization should conduct a regular control	Audit of APQP control plan against annex A	Audit results				
			The organization shall ensure that the planned arrangements for initial release of products and services encompass product or service approval.							

IATF 16949	**8.6.1**	New	**The organization shall ensure that product or service approval is accomplished after changes following initial release, according to ISO 9001, Section 8.5.6.**	conduct a regular control plan audit that compares the current approval status with the actual controls applied in the manufacturing process.			QMS Supervisor	July	July	open
8.6.2 Layout inspection and functional testing										
IATF 16949	**8.6.2**	Modified	A layout inspection and a functional verification to applicable customer engineering material and performance standards shall be performed for each product as specified in the control plans. Results shall be available for customer review. NOTE 1: Layout inspection is the complete measurement of all product dimensions shown on the design record(s). **NOTE 2: The frequency of layout inspection is determined by the customer.**	An added NOTE clarifies that frequency of layout inspections is determined by the customer.	Add to procedure but is being done	Procedure	**QMS Supervisor**	July	July	open
8.6.3 Appearance items										
IATF 16949	**8.6.3**	Modified	For organizations manufacturing parts designated by the customer as "appearance items," the organization shall provide **the following:** **a)** appropriate resources, including lighting, for evaluation; b) masters for colour, grain, gloss, metallic brilliance, texture, distinctness of image (DOI), and haptic technology, as appropriate; **c)** maintenance and control of appearance masters and evaluation equipment; **d)** verification that personnel making appearance evaluations are competent and qualified to do so.	This section on appearance items now 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.	Has not been a requirement to date but will include in procedure	Procedure	QMS Supervisor	July	July	open
8.6.4 Verification and acceptance of conformity of externally provided products and services										
IATF 16949	**8.6.4**	Modified	The organization shall have a process to **ensure** the quality of externally **provided processes**, products, **and services** utilizing one or more of the following methods: **a)** receipt and evaluation of statistical data **provided by the supplier to** the organization; **b)** receiving inspection and/or testing, such as sampling based on performance; **c)** second-**party** or third-party assessments or audits of supplier sites when coupled with records of acceptable delivered product **conformance** to requirements; **d)** part evaluation by a designated laboratory; **e)** another method agreed with the customer.	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.	Add second party assessments for suppliers receivinfg inspection and or testing certification	Procedures - Inspection records - Certs of Compliance	**QMS Supervisor**	July	July	open
8.6.5 Statutory and regulatory conformity										
IATF 16949	**8.6.5**	Modified	**Prior to release of externally provided products into its production flow, the organization shall confirm and be able to provide evidence that externally provided processes, products, and services conform to the latest** applicable statutory, regulatory) **and other** requirements **in the countries where they are manufactured and in the customer-identified countries of destination, if provided.**	Strengthens the standard for statutory and regulatory conformity to require evidence of compliance.	add externally provided requirements for statuatory and regulatory	procedure - IMDS, REACH - RoHS - Proposition 65 or other requirements requested by customer	TEAM	July	July	Open
8.6.6 Acceptance criteria										
IATF 16949	**8.6.6**	Modified	Acceptance criteria shall be defined by the organization and, where **appropriate or** required, approved by the customer. For attribute data sampling, the acceptance level shall be zero defects **(see Section 9.1.1, 1).**	This sections clarifies "where required" to be "where appropriate or required".	include attribute data where requested by customer	Procedure and data sampling and acceptance criteria	QMS Supervisor	July	July	Open
8.7 Control of nonconforming outputs										
			The organization shall ensure that **outputs** that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery. The organization shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. **This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services.**	The organization must identify and control nonconforming product and services. This could include eliminating the nonconformity, obtaining a waiver or deviation permit,		NCR Procedure NCR log				

ISO 9001	**8.7.1**	Modified	The organization shall deal with nonconforming **outputs in one or more of the following ways:** **a) correction;** **b) segregation, containment, return or suspension of provision of products and services;** **c) informing the customer;** **d)** obtaining authorization for acceptance under concession. Conformity to the requirements shall be verified when nonconforming outputs are corrected.	or re-working the product.		NCR Corrective Action Deviation request or other form of communciaton with customer	Quality			Closed
8.7.1.1 Customer authorization for concession										
IATF 16949	**8.7.1.1**	Modified	The organization shall obtain a customer concession or deviation permit prior to further processing whenever the product or manufacturing process is different from that which is currently approved. **The organization shall obtain customer authorization prior to further processing for "use as is" and rework dispositions of nonconforming product. If sub-components are reused in the manufacturing process, that sub-component reuse shall be clearly communicated to the customer in the concession or deviation permit.** The organization shall maintain a record of the expiration date or quantity authorized **under concession.** The organization shall also ensure compliance with the original or superseding specifications and requirements when the authorization expires. Material shipped **under concession** shall be properly identified on each shipping container **(this applies equally to purchased product)**. The organization shall approve any requests from suppliers before submission to the customer.	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.	Update procedure	Procedure Nonconformance Log Nonconformance and Corrective Action	Quality	August	August	Open
8.7.1.2 Control of nonconforming product - customer-specified process										
IATF 16949	**8.7.1.2**	Modified	**The organization shall comply with applicable customer-specified controls for nonconforming product(s).**	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.	Update procedure	Procedure - control plans - customer specific list	Quality	August	August	Open
8.7.1.3 Control of suspect product										
IATF 16949	**8.7.1.3**	Modified	**The organization shall ensure that** product with unidentified or suspect status is classified **and controlled** as nonconforming product. **The organization shall ensure that all appropriate manufacturing personnel receive training for containment of suspect and nonconforming product.**	The updates in this section augment the requirements for control of suspect product by ensuring containment training is implemented.	update and assure all employees are trained	Procedure - Training Competency - Training Matrix	Quality	August	August	Open
8.7.1.4 Control of reworked product										
IATF 16949	**8.7.1.4**	Modified	**The organization shall utilize risk analysis (such as FMEA) methodology to assess risks in the rework process prior to a decision to rework the product. If required by the customer, the organization shall obtain approval from the customer prior to commencing rework of the product.** **The organization shall have a documented process for rework confirmation in accordance with the control plan or other relevant DOCUMENTED INFORMATION to verify compliance to original specifications.** Instructions for **disassembly or** rework, including re-inspection **and traceability** requirements, shall be accessible to and utilized by the appropriate personnel. **The organization shall retain DOCUMENTED INFORMATION on the disposition of reworked product including quantity, disposition, disposition date, and applicable traceability information.**	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.	Update to include risk analysis fmea and procedure or instructions for rework	Rework procedure or instructions -	**Quality**	August	August	open
8.7.1.5 Control of repaired product										

IATF 16949	**8.7.1.5**	Modified	**The organization shall utilize risk analysis (such as FMEA) methodology to assess risks in the repair process prior to a decision to repair the product. The organization shall obtain approval from the customer before commencing repair of the product.** **The organization shall have a documented process for repair confirmation in accordance with the control plan or other relevant documented information.** **Instructions for disassembly or repair, including re-inspection and traceability requirements, shall be accessible to and utilized by the appropriate personnel.** **The organization shall obtain a documented customer authorization for concession for the product to be repaired.** **The organization shall retain DOCUMENTED INFORMATION on the disposition of repaired product including quantity, disposition, disposition date, and applicable traceability information.**	The changes in this section clarify the requirement and the need for follow-up with detailed information for reworked product. The requirements for repaired products are essentially the same as those for reworked products outlined in Sec. 8.7.1.4.	Parts are not normally a repair but will update procedure to include	Procedure	**QMS Supervisor**	August	August	open
8.7.1.6 Customer notification										
IATF 16949	**8.7.1.6**	Modified	**The organization shall immediately notify the customer(s) in the event that nonconforming product has been shipped. Initial communication shall be followed with detailed documentation of the event.**	While customer notification is mentioned twice in ISO/TS 16949:2009, it did not address customer notification in a stand alone section.	Update procedure	Procedure - email - deviation - or other form of documented information	**QMS Supervisor**	August	August	open
8.7.1.7 Nonconforming product disposition										
IATF 16949	**8.7.1.7**	Modified	**The organization shall have a documented process for disposition of nonconforming product not subject to rework or repair. For product not meeting requirements, the organization shall verify that the product to be scrapped is rendered unusable prior to disposal.** **The organization shall not divert nonconforming product to service or other use without prior customer approval.**	Updates in this section strengthen the requirement of disposition of nonconforming product by clarifying that organizations must also have a documented process for nonconforming product not subject to rework or repair.	Update procedure	Procedure	QMS Supervisor	August	August	open
8.7.2 Control of nonconforming outputs										
ISO 9001	**8.7.2**	Modified	The organization shall retain **DOCUMENTED INFORMATION** that: **a)** describes the nonconformity; **b)** describes the actions taken; **c) describes any concessions obtained;** **d) identifies the authority deciding the action in respect of the nonconformity.**	Not just product nonconformance.		Procdedure and Nonconformance tag				closed

Standard	Element	Is this a new requirement?	ISO 9001:2015 / IATF 16949:2016 Requirements	Commentary	Action / Resources Required	Objective Evidence	Responsible	Planned Start Date	Planned Completion Date	Status Open/In Progress/Closed/ Overdue
		New/Modified/ Carryover	**Bolded text indicates new to ISO 9001:2015 and IATF 16949:2016**							
9.0 Performance Evaluation										
9.1 Monitoring, measurement, analysis and evaluation										
9.1.1 General										
ISO 9001	**9.1.1**	Modified	The organization shall **determine:** **a) what needs to be monitored and measured;** **b)** the methods for monitoring, measurement, analysis and **evaluation** needed **to ensure valid results;** **c) when the monitoring and measuring shall be performed;** **d) when the results from monitoring and measurement shall be analyzed and evaluated.** The organization shall **evaluate the performance** and the effectiveness of the quality management system. **The organization shall retain appropriate DOCUMENTED INFORMATION as evidence of the results.**	The organization must determine the need for and implement monitoring, measurement, analysis, and improvement opportunities needed to ensure conformity of the product, the quality management system, and to continually improve. The organization must retain DOCUMENTED INFORMATION.		9 Procedure Management Review Meetings KPI Postings Sales evaluations	Team			Closed
9.1.1.1 Monitoring and measurement of manufacturing processes										
IATF 16949	**9.1.1.1**	Modified	The organization shall perform process studies on all new manufacturing (including assembly or sequencing) processes to verify process capability and to provide additional input for process control, **including those for special characteristics.** **NOTE: For some manufacturing processes, it may not be possible to demonstrate product compliance through process capability. For those processes, alternate methods such as batch conformance to specification may be used.** The organization shall maintain manufacturing process capability or performance results as specified by the customer's part approval process requirements. The organization shall verify that the process flow diagram, **PFMEA**, and control plan are implemented, **including adherence to the following:** **a)** measurement techniques; **b)** sampling plans; **c)** acceptance criteria; **d) records of actual measurement values and/or test results for variable data;** **e)** reaction plans **and escalation process** when acceptance criteria are not met. Significant process events, such as tool change or machine repair, shall be recorded **and retained as DOCUMENTED INFORMATION.** The organization shall initiate a reaction plan **indicated on** the control plan **and evaluated for impact on compliance to specifications** for characteristics that are either not statistically capable or are unstable. These reaction plans shall include containment of product and 100 percent inspection, as appropriate. A corrective action plan shall be **developed and implemented** by the organization indicating specific **actions**, timing, and assigned responsibilities to **ensure** that the process becomes stable and **statistically** capable. The plans shall be reviewed with and approved by the customer, when required. The organization shall maintain records of effective dates of process changes.	Updates to this section clarify the requirement for targeting process effectiveness and efficiency, which is an extension of the requirement to have effective and efficient processes instead of just having a process. The section further ensures that organizations support the manufacturing process through defined roles, responsibilities, and effective escalation processes to drive process capability and stability.	Update procedure	Procedure Customer satisfaction surveys or cards internal and external (Customer Satisfaction Index) Action results from Management Review or corrective actions Results of statistical techniques				open closed open open
9.1.1.2 Identification of statistical tools										

IATF 16949	**9.1.1.2**	Modified	**The organization shall determine the** appropriate use of statistical tools. **The organization shall verify that appropriate statistical tools are included as part of the advanced product quality planning (or equivalent) process and included in the design risk analysis (such as DFMEA) (where applicable), the process risk analysis (such as PFMEA), and** the control plan.	Requirements for the identification of statistical tools feature clarifications regarding documented deployment of the use of statistical tools from DFMEA, PFMEA, and APQP process.	Update procedure	Procedure and PPAP results	**Quality**	August	August	open
9.1.1.3 Application of statistical concepts										
IATF 16949	**9.1.1.3**	Modified	Statistical concepts, such as variation, control (stability), process capability, and **the consequences of** over-adjustment, shall be understood and **used by employees involved in the collection, analysis, and management of statistical data.**	This sections features a clarification regarding requirements for those involved in capturing and analyzing data; previously, this was driven across all employees regardless of relevance.	Employee training and comptency records	Training records - training matrix	**Quality**	August	August	open
9.1.2 Customer satisfaction										
ISO 9001	**9.1.2**	Modified	The organization shall monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled. The organization shall determine the methods for obtaining, **monitoring and reviewing** this information. NOTE: Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, **meetings with customers, market-share analysis**, compliments, warranty claims and dealer reports.	Customer perception was previously in a NOTE and now it is an explicit requirement.		Procedure - Customer Score cards - Internal customer satisfaction results (customer index)	Quality			Closed
IATF 16949	**9.1.2.1**	Modified	Customer satisfaction with the organization shall be monitored through continual evaluation of **internal and external** performance **indicators to ensure compliance to the product and process specifications and other customer requirements.** Performance indicators shall be based on objective evidence and include but not be limited to **the following:** **a)** delivered part quality performance; **b)** customer disruptions, **c)** field returns, **recalls, and warranty (where applicable);** **d)** delivery schedule performance (including incidents of premium freight); **e)** customer notifications related to quality or delivery issues, **including special status.** The organization shall monitor the performance of manufacturing processes to demonstrate compliance with customer requirements for product quality and process efficiency. **The monitoring shall include the review of customer performance data including online customer portals and customer scorecards, where provided.**	Updates to this section clarify customer satisfaction monitoring criteria and introduction of additional focus on warranty management. There is also additional focus to ensure all customer performance measures are regularly reviewed to reduce risk of failure to achieving customer satisfaction.	Update procedure - customer monitoring currently being will need audit.	Procedure On time delivery report recalls and warranty non applicable Premium freight records customer notification of delivery issues including special status customer monitoring	Team	August	August	open closed closed closed open open open
9.1.3 Analysis and evaluation										
ISO 9001	**9.1.3**	Modified	The organization shall analyze and **evaluate** appropriate data and information **arising from monitoring and measurement.** The results of analysis shall be used to evaluate: **a)** conformity of products and **services;** **b)** the degree of customer satisfaction; **c)** the **performance** and effectiveness of the quality management system; **d) if planning has been implemented effectively;** **e) the effectiveness of actions taken to address risks and opportunities;** **f) the performance of external providers;**	The organization must collect and analyze data about the effectiveness and suitability of the quality management system and evaluate where continual improvement can be made.		Procedure final audit and ppap approvals customer satisfaction index Management Review Internal Audits Risk analysis Improvement list of current and new	Team			Closed

			g) the need for improvements to the quality management system. NOTE: Methods to analyze data can include statistical techniques.							
9.1.3.1 Prioritization										
IATF 16949	**9.1.3.1**	Modified	Trends in quality and operational performance shall be compared with progress toward objectives and lead to action to support **prioritization or actions for improving customer satisfaction.**	The emphasis of the requirement changed from the "analysis of data" to the prioritization of actions based on performance and risk management.	Procedure	Risk FMEA	Team			Closed
9.2 Internal audit										
ISO 9001	**9.2.1**	Modified	9.2.1 The organization shall conduct internal audits at planned intervals **to provide information** on whether the quality management system: **a)** conforms to: 1) the organization's own requirements for its quality management system; 2) the requirements of this International Standard; **b)** is effectively implemented and maintained.	Audits must be performed at planned intervals. The organization makes this determination. Keep in mind that audits need to be done often enough to ensure conformity to the organization's requirements		Procedure Audit notes				closed
ISO 9001	**9.2.2**	Modified	The organization shall: **a)** plan, establish, implement and maintain an audit programme(s) including the frequency, methods, **responsibilities, planning requirements and reporting**, which shall take into consideration the importance of the processes concerned, **changes affecting the organization**, and the results of previous audits; **b)** define the audit criteria and scope for each audit; **c)** select auditors and conduct audits to ensure objectivity and the impartiality of the audit process; **d) ensure that the results of the audits are reported to relevant management;** **e)** take appropriate correction and corrective actions without undue delay; **f)** retain **DOCUMENTED INFORMATION** as evidence of the **implementation of the audit programme** and the audit results. NOTE: See ISO 19011 for guidance	System auditors are selected to do audits based on impartiality. They may not audit their own work area. Management must ensure actions are taken to eliminate detected nonconformities and their causes.		Audit Plan	**QMS Supervisor**			closed
IATF 16949	**9.2.2.1**	Modified	**The organization shall have a documented internal audit process. The process shall include the development and implementation of an** internal audit **program that** covers **the entire** quality management **system including quality management system audits, manufacturing process audits, and product audits.** **The audit programme shall be prioritized based upon risk, internal and external performance trends, and critically of the process(es).** **Where the organization is responsible for software development, the organization shall include software development capability assessments in their internal audit program.** The frequency of audits shall be **reviewed and, where appropriate, adjusted based on occurrence of process changes, internal and external nonconformities, and/or customer complaints. The effectiveness of the audit program shall be reviewed as a part of management review.**	This section strengthened the need to drive a risk-based approach to the development and deployment of an organizational-wide internal audit program. Internal audits must also consider software development capability assessments, when applicable.	Update and audit procedure and documentation	Procedure Risk Analysis Audit Schedule	**QMS Supervisor**	August	August	Open
9.2.2.2 Quality management system audit										

IATF 16949	**9.2.2.2**	Modified	The organization shall audit all quality management system **processes over each three-year calendar period, according to an annual programme, using the process approach** to verify compliance with this **Automotive QMS Standard. Integrated with these audits, the organization shall sample customer-specific quality management system requirements for effective implementation.**	Updates to this section strengthen the quality management system audit and the use of process approach, which further drives process improvements organization-wide.	include with audit schedule	Procedure and Audit Schedule	QMS Supervisor	August	August	Open
9.2.2.3 Manufacturing process audit										
IATF 16949	**9.2.2.3**	Modified	The organization shall audit **all** manufacturing **processes over each three-year calendar period** to determine **their** effectiveness **and efficiency using customer-specific required approaches for process audits. Where not defined by the customer, the organization shall determine the approach to be used.** **Within each individual audit plan, each manufacturing process shall be audited on all shifts where it occurs, including the appropriate sampling of the shift handover.** **The manufacturing process audit shall include an audit of the effective implementation of the process risk analysis (such as PFMEA), control plan, and associated documents.**	IATF 16949 also strengthens the formal approaches to ensure organizations achieve the benefits of effective manufacturing process audits.	audit procedure and audit schedule	Procedure and audit schedule and process audit FMEA and Control plan audits	QMS Supervisor	August	August	Open
9.2.2.4 Product audit										
IATF 16949	**9.2.2.4**	Modified	The organization shall audit products **using customer-specific required approaches** at appropriate stages of production and delivery to verify conformity to specified requirements. **Where not defined by the customer, the organization shall define the approach to be used.**	The strengthened product audit requirements now require the use of customer-specified approaches, when applicable	Process Audit	Procedure Process Audit Notes	**QMS Supervisor**	August	August	Open
9.3 Management review										
9.3.1 General										
ISO 9001	**9.3.1**	Carryover	Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness **and alignment with the strategic direction of the organization.**	No impact from the previous standard. Top management must review the system at planned intervals.		Procdure and audit plan and schedule	QMS Supervisor			closed
9.3.1.1 Management review- supplemental										
IATF 16949	**9.3.1.1**	Modified	**Management review shall be conducted at least annually. The frequency of management review(s) shall be increased based on risk to compliance with customer requirements resulting from internal or external changes impacting the quality management system and performance-related issues.**	This update strengthens management review requirements to include an assessment of risk and compliance to customer requirements.	Update procedure and Management Review record	Procedure and Management Review Record	**QMS Supervisor**	August	August	closed
9.3.2 Management review inputs										
ISO 9001	**9.3.2**	Modified	The management review shall be planned and carried out taking into consideration: **a)** the status of actions from previous management reviews; **b) changes in external and internal issues** that are relevant to the quality management system; **c)** information on the **performance** and effectiveness of the quality management system, including trends in: 1) customer satisfaction and feedback from relevant interested parties; **2) the extent to which quality objectives have been met;** 3) process performance and conformity of products and services; **4) nonconformities and corrective actions;** **5) monitoring and measurement results;** 6) audit results;	Management must use information from: audits (external and internal), customer feedback, process performance, product conformity, status of preventive and corrective action, follow-up actions from previous management reviews, planned changes, and recommendations for improvement.		Management Review procedure Management Review records Internal audit notes				closed

			7) the performance of external providers;							
			d) the adequacy of resources;							
			e) the effectiveness of actions taken to address risks and opportunities (see 6.1);							
			f) opportunities for improvement.							
9.3.2.1 Management review inputs - supplemental										
IATF 16949	**9.3.2.1**	Modified	Input to management review shall include: **a) cost of poor quality (cost of internal and external nonconformance);** **b) measures of process effectiveness;** **c) measures of process efficiency;** **d) product conformance;** **e) assessments of manufacturing feasibility made for changes to existing operations and for new facilities or new product (see Section 7.1.3.1);** **f) customer satisfaction (see ISO 9001, Section 9.1.2);** **g) review or performance against maintenance objectives;** **h) warranty performance (where applicable);** **i) review of customer scorecards (where applicable);** **j)** identification of potential field failures identified **through risk analysis (such as FMEA);** **k)** actual field failures and their impact on safety or the environment.	Updates to this section feature 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. A monitoring system should be in place, with criteria that trigger special unplanned management review activity.	Procedure update forms update	procedure cost of poor quality Management Review FMEA and Risk anlaysis	**Quality**	August	August	open
9.3.3 Management review outputs										
ISO 9001	**9.3.3**	Modified	The outputs of the management review shall include decisions & actions related to: **a)** opportunities for improvement; **b) any need for changes to the quality management system;** **c)** resource needs. The organization shall retain **DOCUMENTED INFORMATION** as evidence of the results of management reviews.	Management must take the review inputs and transform it into outputs.		Procedure Management Review records	Team			closed
9.3.3.1 Management review outputs - supplemental										
IATF 16949	**9.3.3.1**	Modified	**Top management shall document and implement an action plan when customer performance targets are not met.**	This enhanced section ensures action is taken where customer requirements are not achieved, and supports the continual analysis of process performance & risk.	Update procedure and management review action plan	management review procedure and management review actions	**Team**	August	August	closed

	Element	Is this a new requirement?	ISO 9001:2015 / IATF 16949:2016 Requirements	Commentary	Action / Resources Required	Objective Evidence	Responsible	Planned Start Date	Planned Completion Date	Status Open/In Progress/Closed/
		New/Modified/ Carryover	**Bolded text indicates new to ISO 9001:2015 and IATF 16949:2016**							
10.0 Improvement										
10.1 General										
ISO 9001	**10.1**	Modified	The organization shall **determine and select opportunities for improvement** and implement any necessary actions to meet customer requirements and enhance customer satisfaction. **These shall include:** **a) improving products and services to meet requirements as well as to address future needs and expectations;** **b) correcting, preventing or reducing undesired effects;** **c)** improving the **performance** and effectiveness of the quality management system. **NOTE: Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation and re-organization.**	The purpose of improvement is for an organization to both plan and actually implement actions in order to achieve intended results and enhance customer satisfaction.		Procedure Improvement list corrective action outcome reorganization	Team			closed
ISO 9001	**10.2.1**	Modified	When a nonconformity occurs, **including any arising from complaints**, the organization shall: **a) react to the nonconformity and, as applicable:** 1) take action to control and correct it; 2) deal with the consequences; **b) evaluate the need for action to eliminate the cause(s) of the nonconformity**, in order that it does not recur or occur elsewhere, by: 1) reviewing and analyzing the nonconformity; 2) determining the causes of the nonconformity; **3) determining if similar nonconformities exist, or could potentially occur;** **c)** implement any action needed; **d)** review the effectiveness of any corrective action taken; **e)** update risks and opportunities determined during planning, if necessary; **f)** make changes to the quality management system, if necessary. Corrective actions shall be appropriate to the effects of the nonconformities encountered.	The organization must identify and control nonconforming product and services. This could include eliminating the nonconformity, obtaining a waiver or deviation permit, or re-working the product. Re-verification must take place when nonconforming product is corrected.		Procedure Nonconformance area nonconformance and corrective action Process risks and opportunities	Team			closed
ISO 9001	**10.2.2**	Modified	The organization shall retain **DOCUMENTED INFORMATION** as evidence of: **a)** the nature of the nonconformities and any subsequent actions taken; **b)** the results of any corrective action.	DOCUMENTED INFORMATION of the nonconformity and any corrective action must be maintained.		procedure corrective action form open and closed status	Team			closed
10.2.3 Problem solving										
IATF 16949	**10.2.3**	Modified	The organization shall have a **documented** process**(es)** for problem solving **including:** **a) defined approaches for various types and scale of problems (e.g., new product development, current manufacturing issues, field failures, audit findings);** **b) containment, interim actions, and related activities necessary for control of nonconforming outputs (see ISO 9001, Section 8.7),** **c) root cause analysis, methodology used, analysis, and results;** **d) implementation of systemic corrective actions, including consideration of the impact on similar processes and products;** **e) verification of the effectiveness of implemented corrective actions;** **f) reviewing and, where necessary, updating the appropriate documented information (e.g., PFMEA, control plan).**	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; systematic corrective action and verification of effectiveness; and review/updates to documented information.	Procedure update. Add 5 whys	Procedure corrective action form Ncr log FMEA and control plan and updates	**Team**	August	August	Open

			Where the customer has specific prescribed processes, tools, or systems for problem solving, the organization shall use those processes, tools, or systems unless otherwise approved by the customer.							
10.2.4 Error-proofing										
IATF 16949	**10.2.4**	Modified	The organization shall **have a documented process to determine the use of appropriate** error-proofing **methodologies. Details of the method used shall be documented in the process risk analysis (such as PFMEA) and test frequencies shall be documented in the control plan.** **The process shall include the testing of error-proofing devices for failure or simulated failure. Records shall be maintained. Challenge parts, when used, shall be identified, controlled, verified, and calibrated where feasible. Error-proofing device failures shall have a reaction plan.**	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.	add error proofing procedure or work instruction that includes testing of the error proofing	Procedure testng of error proofing	**Team**	August	August	Open
10.2.5 Warranty management systems										
IATF 16949	**10.2.5**	New	**When the organization is required to provide warranty for their product(s), the organization shall implement a warranty management process. The organization shall include in the process a method for warranty part analysis, including NTF (no trouble found). When specified by the customer, the organization shall implement the required warranty management process.**	New requirement based on the increased importance of warranty management.	Powder Metals does not do Warranty/add to procedure	Procedure	QMS Supervisor	August	August	Open
10.2.6 Customer complaints and field failure test analysis										
IATF 16949	**10.2.6**	Modified	The organization shall **perform analysis on customer complaints and field failures, including any returned parts, and shall** initiate **problem solving and** corrective action to prevent recurrence.	This section includes a new requirement regarding embedded software and identification of preferred approaches.	Update procedure/NCR log	Procedure	Quaity	August	August	Open
			Where requested by the customer, this shall include analysis of the interaction of embedded software of the organization's product within the system of the final customer's product.			Ncr log		August	August	Open
			The organization shall **communicate the results of testing/analysis to the customer and also within the organization.**			Testing available		August	August	Open
10.3 Continual improvement										
ISO 9001	**10.3**	Modified	The organization shall continually improve the suitability, adequacy and effectiveness of the quality management system. The organization shall **consider the results of analysis and evaluation, and the outputs from management review**, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.	The quality policy, objectives, audit results, analysis of data and corrective and preventive action shall be used as a method to facilitate the improvement to the quality management system.		Procedure Management review follow up	Quality			closed
10.3.1 Continual improvement- supplemental										
IATF 16949	**10.3.1**	Modified	The organization shall have a documented process for continual improvement. **The organization shall include in this process the following:** **a) identification of the methodology used, objectives, measurement, effectiveness, and DOCUMENTED INFORMATION;** **b) a manufacturing process improvement action plan with emphasis on the reduction of process variation and waste;** **c) risk analysis (such as FMEA).** NOTE: Continual improvement is implemented once manufacturing processes are statistically capable and stable or when product characteristics are predictable and meet customer requirements.	Changes in this section clarify the minimum process requirements for continual improvement. Use of these methodologies should follow a structured approach that continuously identifies and addresses opportunities for improvement.	Update procedure	Procedure NCR LOG Manufacturing report Risk FMEA	**Quality**	August	August	Open