QUALITY MANUAL
Rev. 14.5
Effective date: 3/24/2023

FOREWORD

Aearo Technologies LLC – a 3M company was incorporated in 1970 as E-A-R Division/ Cabot Corp. Today Aearo Technologies LLC provides engineered solutions focusing on solving our customer's sound, noise, vibration, harshness, and thermal problems. Service is provided to a wide variety of markets which include aviation, motor vehicles, defense, electronics, and industrial among others. To assure customer satisfaction, Aearo Technologies LLC strives to produce, and continually improve, safe, reliable products that meet or exceed customer and applicable statutory and regulatory requirements. To help ensure Aearo Technologies LLC meets these diverse needs a quality management system (QMS) compliant to the current versions of ISO 9001, AS9100, & IATF 16949 has been developed. The fundamental requirements are described in this manual.

The globalization of the industries served, and the resulting diversity of regional and national requirements and expectations complicate this objective. Aearo Technologies LLC purchases products from suppliers throughout the world. Like Aearo Technologies LLC, our suppliers have the challenge of delivering products to multiple customers and markets having varying quality requirements and expectations. To aid suppliers in meeting both Aearo Technologies' and our customer's expectations, supplier quality requirements manuals have been developed as part of Aearo Technologies' QMS.

This manual standardizes Aearo Technologies' QMS requirements to the greatest extent possible. Because of its commitment to minimizing impact on the environment, Aearo Technologies' manufacturing facilities are also registered to ISO 14001. Environmental management system requirements are addressed in a separate Environmental Management System. Where appropriate, the Environmental and Quality management systems' procedures and work instructions have been combined.

REVISION SUMMARY/RATIONALE
This manual has been revised to incorporate the latest requirements of the ISO 9001:2016, AS9100D, and IATF 16949:2016 standards, with the requirements for each standard color coded:

ISO-9001 = Black **AS-9100 = Red** **IATF-16949 = Green**

Approved by: _Edgar Patino_ Date: 2/24/2023
Divisional Mgmt. Representative

Aearo Technologies LLC Quality Manual	
Quality Management Requirements **ISO-9001 AS-9100 IATF-16949 *Shalls***	**How requirement is met:**

Revision Table

Rev.	Date:	Revision
14.5	**3/24/2023**	**Added revision table** **The following changes were made based on recent Sanctioned Interpretations** **- 6.1.2.1 Risk Analysis added item b) cyber-attack threats to information technology systems** **- 6.1.2.3 Contingency Plans added Pandemics under item c) AND added h) include in contingency plans the development and implementation of appropriate employee training and awareness.** **- 7.1.5.3.2 External laboratory clarified stated for non- accredited laboratory utilization** **- 7.2.1 Competence – supplemental added To reduce or eliminate risks to the organization, the training and awareness shall also include information about prevention relevant for the organization's working environments and employees' responsibilities, such as recognizing the symptoms of pending equipment failure and/or attempted cyber-attacks.** **- Added page numbering in footer.**

Aearo Technologies Scope Statement:

Design and Manufacture of materials, composites, and parts for noise, shock, vibration, and thermal mitigation, absorption, damping & cushioning for the Industrial, Electronic, Heavy & Durable Equipment, Aerospace, and Motor Vehicle Industries while meeting applicable Customer, Statutory, Regulatory, and Other Interested Party Requirements. Applicable customer-specific requirements are maintained in Aearo's customer-specific requirements database.

This scope applies to all functions performed by Aearo Technologies LLC Indianapolis, IN and Newark, Delaware sites. Aearo Technologies' processes and their sequence and interactions, including the type and extent of control of outsourced processes, are defined in WI-0005 Aearo Technologies QMS Processes with KPIs.

Aearo Technologies LLC does not service products.

4	**Context of the organization**		
	4.1	**Understanding the Organization and its context**	
		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.	Management Review – QP-0003 Risk & Opportunities Management Procedure – QP-0091 Quality Policy and Objectives – QP-0006 Monitor, Measure, Analysis, Evaluation, & Process Studies - QP-0014
		The organization ***shall*** monitor and review information about these external and internal issues.	Management Review - QP-0003 Monitor, Measure, Analysis, Evaluation, & Process Studies - QP-0014
		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.	
	4.2	**Understanding the needs and expectations of interested parties**	
		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:	Interested Parties & Responsibilities - WI-0871
		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.		Management Review - QP-0003 Monitor, Measure, Analysis, Evaluation, & Process Studies - QP-0014
	4.3	**Determining the scope of the quality management system**		
		The organization ***shall*** determine the boundaries and applicability of the quality management system to establish its scope.		Management Review - QP-0003
		When determining this scope, the organization ***shall*** consider:		Scope Statement
		a) the external and internal issues referred to in 4.1;		
		b) the requirements of relevant interested parties referred to in 4.2;		
		c) 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.		Scope Statement
		The scope of the organization's quality management system ***shall*** be available and be maintained as documented information.		Scope Statement
		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.		Scope Statement
		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.		
IATF		**4.3.1**	**Determining the scope of the quality management system - supplemental**	
			Supporting functions, whether on-site or remote (such as design centres, corporate headquarters, and distribution centres), ***shall*** be included in the scope of the Quality Management System (QMS).	Scope Statement

			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)	Scope Statement
			Permitted exclusions do not include manufacturing process design.	
		4.3.2	**Customer-specific requirements**	
			Customer specific requirements ***shall*** be evaluated and included in the scope of the organization's quality management system.	Scope Statement
	4.4	**Quality management system and its processes**		
		4.4.1	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.	Quality System Overview - QP-0005 Aearo Technologies QMS Processes with KPIs – WI-0005 Continual Improvement – QP-0038
AS			The organization's quality management system ***shall*** also address customer and applicable statutory and regulatory quality management system requirements.	Interested Parties & Responsibilities - WI-0871 Scope Statement Quality System Overview - QP-0005
			The organization ***shall*** determine the processes needed for the quality management system and their application throughout the organization, and ***shall***:	Aearo Technologies QMS Processes with KPIs – WI-0005
			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;	Aearo Technologies QMS Processes with KPIs – WI-0005 Management Review – QP-0003
			e) assign the responsibilities and authorities for these processes;	Aearo Technologies QMS Processes with KPIs – WI-0005 Quality System Overview - QP-0005

			f) address the risks and opportunities as determined in accordance with the requirements of 6.1;		Aearo Technologies QMS Processes with KPIs – WI-0005 Risk & Opportunities Management – QP-0091
			g) evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results.		Aearo Technologies QMS Processes with KPIs – WI-0005 Continual Improvement - QP-0038
			h) improve the processes and the quality management system.		Aearo Technologies QMS Processes with KPIs – WI-0005 Continual Improvement - QP-0038
IATF			**4.4.1.1**	The organization ***shall*** ensure conformance of all products and processes, including service parts and those that are outsourced, to all applicable customer, statutory, and regulatory requirements (see Section 8.4.2.2)	Process Control - QP-0019 Purchasing Process – QP-0072
			4.4.1.2	**Product safety**	
				The organization ***shall*** have documented processes for the management of productsafety related products and manufacturing processes, which ***shall*** Include but not be limited to the following, where applicable:	N/A
				a) identification by the organization of statutory and regulatory product-safety requirements;	
				b) customer notification of requirements in item a),	
				c) special approvals for design FMEA;	
				d) identification of product safety-related characteristics:	
				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;	
				l) training identified by the organization or customer for personnel involved in productsafety 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 of safety related requirements or documents may be required by the customer or the organization's internal processes.	
		4.4.2	To the extent necessary, the organization ***shall***:		Document and Data Control - QP-0007
			a) maintain documented information to support the operation of its processes;		
			b) retain documented information to have confidence that the processes are being carried out as planned.		
AS			The organization ***shall*** establish and maintain documented information that includes:		
			− a general description of relevant interested parties (see 4.2 a);		Interested Parties & Responsibilities - WI-0871

			− the scope of the quality management system, including boundaries and applicability (see 4.3);	Scope Statement
			− the sequence and interaction of these processes;	Aearo Technologies QMS Processes with KPIs – WI-0005
			− assignment of the responsibilities and authorities for these processes.	Aearo Technologies QMS Processes with KPIs – WI-0005
			NOTE: The above description of the quality management system can be compiled into a single source of documented information and referred to as a quality manual.	

5	**Leadership**			
	5.1	**Leadership and commitment**		
		5.1.1	**General**	

			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;	Management Review – QP-0003
			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;	Quality Policy and Objectives – QP-0006 Management Review – QP-0003
			c) ensuring the integration of the quality management system requirements into the organization's business processes;	Quality System Overview Procedure - QP-0005
			d) promoting the use of the process approach and riskbased thinking;	Aearo Technologies QMS Processes with KPIs – WI-0005 Risk & Opportunities Management – QP-0091
			e) ensuring that the resources needed for the quality management system are available;	Management Review – QP-0003

			f) communicating the importance of effective quality management and of conforming to the quality management system requirements;		Quality Policy and Objectives – QP-0006 Aearo Communication Plan - WI-0855
			g) ensuring that the quality management system achieves its intended results;		Management Review - QP-0003
			h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;		Training - General (Competence, Awareness, Motivation and Training) - QP-0021
			i) promoting improvement;		Continual Improvement – QP-0038 Training - General (Competence, Awareness, Motivation and Training) - QP-0021
			j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.		Aearo Technologies QMS Processes with KPIs – WI-0005 Management Review - QP-0003
			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.		

IATF			**5.1.1.1**	**Corporate responsibility**	
				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"),	3M Code of Conduct Handbook 3M Anti-Bribery Policy 3M Non-Retaliation Policy
			5.1.1.2	**Process effectiveness and efficiency**	
				Top management ***shall*** review the effectiveness and efficiency of the quality management system to evaluate and improve the organization's quality management system.	Internal Audit Procedure, QP-0016 Management Review – QP-0003

				The results of the process review activities ***shall*** be Included as input to the management review (see Section 9.3.2.1).	Management Review – QP-0003
			5.1.1.3	**Process owners**	
				Top management ***shall*** identify process owners who are responsible for managing the organization's processes and related outputs. Process owners ***shall*** understand their roles and be competent to perform those roles (see ISO 9001, Section 7.2).	Aearo Technologies QMS Processes with KPIs – WI-0005 Organization - QP-0013
		5.1.2	**Customer Focus**		
			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;		Advanced Product Quality Planning - QP-0001 Order Entry & Processing – QP-0037
			b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;		Advanced Product Quality Planning - QP-0001 Risk & Opportunities Management Procedure – QP-0091
			c) the focus on enhancing customer satisfaction is maintained.		Continual Improvement – QP-0038 Customer Satisfaction – QP-0015
AS			d) *product and service conformity and on-time delivery performance are measured and appropriate action is taken if planned results are not, or will not be, achieved.*		Customer Satisfaction – QP-0015 Management Review – QP-0003

	5.2	**Policy**		
		5.2.1	**Establishing the quality policy**	
			Top management ***shall*** establish, implement and maintain a quality policy that:	Quality Policy & Objectives – QP-0006
			a) is appropriate to the purpose and context of the organization and supports its strategic direction;	

			b) provides a framework for setting quality objectives;	
			c) includes a commitment to satisfy applicable requirements;	
			d) includes a commitment to continual improvement of the quality management system.	
		5.2.2	**Communicating the quality policy**	
			The quality policy ***shall***:	
			a) be available and maintained as documented information;	Quality Policy & Objectives – QP-0006
			b) be communicated, understood, and applied within the organization;	Quality Policy & Objectives – QP-0006 Training – General Procedure – QP 0021
			c) be available to relevant interested parties, as appropriate	Interested Parties & Responsibilities - WI-0871
	5.3	**Organizational roles, responsibilities and authorities**		
		Top management ***shall*** ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization.		Organization - QP-0013
		Top Management ***shall*** assign the responsibility and authority for:		Organization - QP-0013
		a) ensuring that the quality management system conforms to the requirements of this International Standard;		
		b) ensuring that the processes are delivering their intended outputs:		
		c) reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to top management;		

		d) ensuring the promotion of customer focus throughout the organization;		
		e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.		
AS		Top management ***shall*** appoint a specific member of the organization's management, identified as the management representative, who ***shall*** have the responsibility and authority for oversight of the above requirements.		Organization - QP-0013
		The management representative ***shall*** have the organizational freedom and unrestricted access to top management to resolve quality management issues.		Organization - QP-0013
		NOTE: The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.		
IATF		**5.3.1**	**Organizational roles, responsibilities and authorities - supplemental**	
			Top management ***shall*** assign personnel with the responsibility and authority to ensure that customer requirements are met. These assignments ***shall*** be documented. This includes but is not limited to the selection of special characteristics, setting quality objectives and related training, corrective and preventive actions, product design and development, capacity analysis, logistics information, customer scorecards, and customer portals.	Organization - QP-0013
		5.3.2	**Responsibility and authority for product requirements and corrective actions**	
			Top management ***shall*** ensure that:	
			a) personnel responsible for conformity to product requirements have the authority to stop shipment and stop production to correct quality problems,	Organization – QP-0013 Nonconformance Control (Indy) – QP-0020 Nonconformance Control (Newark) QP-0081
		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.	

			b) personnel with authority and responsibility for corrective action are promptly Informed of products 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;	Corrective/Preventive Action Process Environmental, Internal and Supplier Procedure – QP-0017 Customer Corrective Action Process - QP-0055 Organization – QP-0013 Customer Incident Investigation - WI-0787
			c) production operations across all shifts are staffed with personnel in charge of, or delegated responsibility for, ensuring conformity to product requirements.	Organization – QP-0013

6	**Planning**			
	6.1	**Actions to address risks and opportunities**		
		6.1.1	When planning for the quality management system, the organization ***shall*** consider the issues referred to in 4.l and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:	Management Review Procedure - QP-0003
			a) give assurance that the quality management system can achieve its intended result(s);	
			b) enhance desirable effects;	
			c) prevent, or reduce, undesired effects;	
			d) achieve improvement.	
		6.1.2	The organization ***shall*** plan:	Risks & Opportunities Management Procedure – QP-0091
			a) actions to address these risks and opportunities;	
			b) how to:	

				1) integrate and implement the actions into its quality management system processes (see 4.4);	
				2) evaluate the effectiveness of these actions.	
			Actions taken to address risks and opportunities ***shall*** be proportionate to the potential impact on the conformity of products and services.		
			NOTE 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.		
IATF			**6.1.2.1**	**Risk analysis**	
				The organization ***shall*** include In Its risk analysis, at a minimum, a) lessons learned from product recalls, product audits, field returns and repairs, complaints, scrap, and rework. b) cyber-attack threats to information technology systems.	Risk & Opportunities Management Procedure - QP-0091
				The organization ***shall*** retain documented information as evidence of the results of risk analysis.	Document and Data Control - QP-0007
			6.1.2.2	**Preventive action**	
				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.	Corrective/Preventive Action Process Environmental, Internal and Supplier Procedure – QP-0017

				The organization ***shall*** establish a process to lessen the impact of negative effects of risk including the following:	Corrective/Preventive Action Process Environmental, Internal and Supplier Procedure – QP-0017
				a) determining potential nonconformities and their causes;	
				b) evaluating the need for action to prevent occurrence of nonconformities:	
				c) determining and implementing action needed;	
				d) documented information of action taken:	
				e) reviewing the effectiveness of the preventive action taken;	
				f) utilizing lessons learned to prevent recurrence in similar processes (see ISO 9001, Section 7.1.6).	
			6.1.2.3	**Contingency plans**	
				The organization ***shall***:	Contingency - Business Continuity, Indianapolis – WI-0012 Contingency Plan, Newark – WI-0013
				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,	
				b) define contingency plans according to risk and impact to the customer;	
				c) prepare contingency plans for continuity of supply in the event of any of the following: but not limited to:key equipment failures (also see Section 8.5.6.1.1); interruption from externally provided products, processes, and services; recurring natural disasters; fire; pandemics; utility interruptions; cyber-attacks on information	

				technology systems; labour shortages; or infrastructure disruptions,	
				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;	
				e) periodically test the contingency plans for effectiveness (e.g., simulations, as appropriate) for cybersecurity: testing may include a simulation of a cyber-attack, regular monitoring for specific threats, identification of dependencies and prioritization of vulnerabilities. The testing is appropriate to the risk of associated customer disruption;	
				Note: cybersecurity testing may be managed internally by the organization or subcontracted as appropriate.	
				f) conduct contingency plan reviews *(at* a minimum annually) using a multidisciplinary team including top management, and update as required;	
				g) document the contingency plans and retain documented information describing any revision(s), including the person(s) who authorized the change(s).	
				h) include in contingency plans the development and implementation of appropriate employee training and awareness.	
				The contingency plans ***shall*** include provisions to validate that the manufactured product continues to meet customer specifications after the restart of production following an emergency in which	Contingency - Business Continuity, Indianapolis – WI-0012 Contingency Plan, Newark – WI-0013

				production was stopped and if the regular shutdown processes were not followed.	
	6.2	**Quality objectives and planning to achieve them**			
		6.2.1	The organization ***shall*** establish quality objectives at relevant functions, levels and processes needed for the quality management system.		Quality Policy & Objectives - QP-0006
			The quality objectives ***shall***:		Quality Policy & Objectives - QP-0006 Management Review – QP-0003
			a) be consistent with the quality policy;		
			b) be measurable;		
			c) take into account applicable requirements;		
			d) be relevant to conformity of products and services and to enhancement of customer satisfaction;		
			e) be monitored;		
			f) be communicated;		
			g) be updated as appropriate.		
			The organization ***shall*** maintain documented information on the quality objectives.		Quality Policy & Objectives - QP-0006
		6.2.2	When planning how to achieve its quality objectives, the organization ***shall*** determine:		Aearo Technologies QMS Processes with KPIs – WI-0005
			a) what will be done;		
			b) what resources will be required;		
			c) who will be responsible;		

			d) when it will be completed;		
			e) how the results will be evaluated.		
IATF			**6.2.2.1**	**Quality objectives and planning to achieve them - supplemental**	
				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.	Quality Policy & Objectives - QP-0006
				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 – QP-0003
	6.3	**Planning of changes**			
		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)			Management Review – QP-0003
		The organization ***shall*** consider:			
		a) the purpose of the changes and their potential consequences;			
		b) the integrity of the quality management system;			
		c) the availability of resources;			
		d) the allocation or reallocation of responsibilities and authorities.			
7	**Support**				
	7.1	**Resources**			

		7.1.1	**General**		
			The organization ***shall*** determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.		Organization - QP-0013
			The organization ***shall*** consider:		Organization - QP-0013
			a) the capabilities of, and constraints on, existing internal resources;		
			b) what needs to be obtained from external providers.		
		7.1.2	**People**		
			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.		Organization - QP-0013
		7.1.3	**Infrastructure**		
			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;		Advanced Product Quality Planning - QP-0001 Facilities and Tooling Management - WI-0014
			b) equipment, including hardware and software;		Advanced Product Quality Planning - QP-0001 Facilities and Tooling Management - WI-0014
			c) transportation resources;		Advanced Product Quality Planning - QP-0001 Purchasing Process – QP-0072
			d) information and communication technology.		Advanced Product Quality Planning - QP-0001 Facilities and Tooling Management - WI-0014
IATF			**7.1.3.1**	**Plant, facility, and equipment planning**	

				The organization ***shall*** use a multidisciplinary approach including risk identification and risk mitigation methods for developing and improving plant, facility, and equipment plans.	Advanced Product Quality Planning - QP-0001 Risk & Opportunities Management – QP-0091 Facilities and Tooling Management - WI-0014

				In designing plant layouts, the organization ***shall***:	Facilities and Tooling Management - WI-0014
				a) optimize material flow, material handling, and value-added use of floor space Including control of nonconforming product,	
				b) facilitate synchronous material flow, as applicable; and.	
				c) implement cyber protection of equipment and systems supporting manufacturing.	
				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 evaluating proposed changes to existing operations.	Advanced Product Quality Planning - QP-0001 Design & Development – QP-0046
				The organization ***shall*** maintain process effectiveness, including periodic re-evaluation relative to risk, 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).	Risk & Opportunities Management – QP-0091
				Assessments of manufacturing feasibility and evaluation of capacity planning ***shall*** be inputs to management reviews (see ISO 9001, Section 9.3).	Management Review – QP-0003
			NOTE 1:	These requirements should include the application of lean manufacturing principles.	
			NOTE 2:	These requirements should apply to on-site supplier activities, as applicable.	

		7.1.4	**Environment for the operation of processes**		
			The organization ***shall*** determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services.		Facilities and Tooling Management - WI-0014
			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.		
IATF		**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 requirement.		
			7.1.4.1	**Environment for the operation of processes - supplemental**	
				The organization ***shall*** maintain its premises in a state of order, cleanliness, and repair that is consistent with the product and manufacturing process needs.	Process Control – QP-0019
		7.1.5	**Monitoring and measuring resources**		
			7.1.5.1	**General**	
				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.	Control of Inspection, Measuring, and Test Equipment – Maintenance – WI-0039 (Indy); Control of Inspection, Measuring, and Test Equipment – WI-0015 (Indy) Test Equipment Calibration Procedure – WI-0043 (Newark)

				The organization ***shall*** ensure that the resources provided:		
				a) are suitable for the specific type of monitoring and measurement activities being undertaken;		Control of Inspection, Measuring, and Test Equipment – Maintenance – WI-0039 (Indy) Control of Inspection, Measuring, and Test Equipment – WI-0015 (Indy) Test Equipment Calibration Procedure – WI-0043 (Newark)
				b) are maintained to ensure their continuing fitness for their purpose.		Instrument Calibration – Maintenance (Indy) WI-0042 Test Equipment Calibration – (Indy) WI-0715 Test Equipment Calibration – (Newark) WI-0043
				The organization ***shall*** retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.		Instrument Calibration – Maintenance (Indy) WI-0042 Test Equipment Calibration – (Indy) WI-0715 Test Equipment Calibration – (Newark) WI-0043 Measurement System Analyses WI-0985
IATF				**7.1.5.1.1**	**Measurement systems analysis**	
					Statistical studies ***shall*** be conducted to analyse the variation present in the results of each type of inspection, measurement, and test equipment system identified m 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.	Measurement System Analyses WI-0985

					Records of customer acceptance of alternative methods ***shall*** be retained along with results from alternative measurement systems analysis (see Section 9.1 1.1)	Measurement System Analyses WI-0985
				NOTE:	Prioritization of MSA studies should focus on critical or special product or process characteristics.	

			7.1.5.2	**Measurement traceability**	
				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:	Instrument Calibration – Maintenance (Indy) WI-0042 Test Equipment Calibration – (Indy) WI-0715 Test Equipment Calibration Procedure (Newark) – WI-0043
				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;	
				b) identified in order to determine their status;	
				c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.	
AS				The organization ***shall*** establish, implement, and maintain a process for the recall of monitoring	Instrument Calibration – Maintenance (Indy) WI-0042 Test Equipment Calibration – (Indy) WI-0715
				and measuring equipment requiring calibration or verification.	
				The organization ***shall*** maintain a register of the monitoring and measuring equipment. The register ***shall*** include the equipment type, unique identification, location, and the calibration or verification method, frequency, and acceptance criteria.	Instrument Calibration – Maintenance (Indy) WI-0042 Test Equipment Calibration – (Indy) WI-0715

			NOTE:	Monitoring and measuring equipment can include, but are not limited to: test hardware, test software, automated test equipment (ATE), and plotters used to produce verification data. It also includes personally owned and customer supplied equipment used to provide evidence of product and service conformity.	
				Calibration or verification of monitoring and measuring equipment ***shall*** be carried out under suitable environmental conditions (see 7.1.4).	Control of Inspection, Measuring, and Test Equipment – Maintenance – WI-0039 (Indy); Control of Inspection, Measuring, and Test Equipment – WI-0015 (Indy)
				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.	Control of Inspection, Measuring, and Test Equipment – Maintenance – WI-0039 (Indy); Control of Inspection, Measuring, and Test Equipment – WI-0015 (Indy); Test Equipment Calibration Procedure – WI-0043 (Newark)
IATF		**NOTE:**	A number or another identifier traceable to the device calibration record meets the intent of the requirements in ISO 9001:2015.		
			7.1.5.2.1	**Calibration/verification records**	
				The organization ***shall*** have a documented process for managing calibration/verification records. Records of the calibration/verification activity *for* all gauges and measuring and test equipment (including employee-owned equipment relevant for measuring, customerowned 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.	Record Retention Procedure - QP-0004

				The organization ***shall*** ensure that calibration/ verification activities and records ***shall*** include the following details:	Control of Inspection, Measuring, & Test Equipment (Indy) – WI-0015 Control of Inspection, Measuring, and Test Equipment – Maintenance – WI-0039 (Indy) Test Equipment Calibration – WI-0043 (Newark)

				a) revisions following engineering changes that impact measurement systems;
				b) any out-of-specification readings as received for calibration/verification,
				c) an assessment of the risk of the Intended use of the product caused by the out-of-specification condition,
				d) when a piece of Inspection measurement and test equipment is found to be out of calibration or defective during its planned verification or calibration or during its use, documented information on the validity of 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;
				e) notification to the customer if suspect product or material has been shipped,
				f) statements of conformity to specification after calibration/verification.
				g) verification that the software version used for product and process control is as specified;
				h) records of the calibration and maintenance activities for all gauging (including employeeowned equipment, customer-owned equipment, or on-site supplier-owned equipment);

				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)		
			7.1.5.3	**Laboratory requirements**		
				7.1.5.3.1	**Internal laboratory**	
					An organization's internal laboratory facility ***shall*** have a 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 a minimum. requirements for:	ATC Lab Scope – WI-0770 Lab Scope – Indy – WI-0144 Lab Scope – Newark – WI-0115
					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 the 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.	
				7.1.5.3.2	**External laboratory**	ATC Lab Scope – WI-0770 Lab Scope – Indy – WI-0144 Lab Scope – Newark – WI-0115
					External/commercial/independent laboratory facilities used for inspection, lest, or calibration services by the Organization ***shall*** have a 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 its national equivalent (e.g., CNAS-CL01 in China) by an accreditation body (Signatory) of the ILAC MRA (International Laboratory Accreditation Forum Mutual Recognition Arrangement – www.ilac.org) and Include the relevant inspection, test, or calibration service in the scope of the accreditation (certificate); the certificate of calibration or test report ***shall*** include the mark of a national accreditation body; or	

					- Where a non-accredited laboratory is utilized (for example, but not limited to: specialist or integrated equipment, parameters with no international traceable standard reference, or original equipment manufacturers), the organization is responsible to ensure that there is evidence that the laboratory has been evaluated and meets the requirements of Section 7.1.8.3.1 of IATF 16949.	
					Note: integrated self-calibration of measurement equipment, including use of proprietary software, does not meet the requirements of calibration.	
		7.1.6	**Organizational knowledge**			
			The organization ***shall*** determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services.			Training – General Procedure – QP 0021
			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).	
	7.2	**Competence**		
		The organization ***shall***:		Training – General Procedure – QP 0021
		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.		
AS		**NOTE:** Consideration should be given for the periodic review of the necessary 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.		
IATF		**7.2.1**	**Competence – supplemental**	

			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. To reduce or eliminate risks to the organization, the training and awareness shall also include information about prevention relevant for the organization's working environments and employees' responsibilities, such as recognizing the symptoms of pending equipment failure and/or attempted cyber-attacks.	Training – General Procedure – QP 0021 3M Ethics & Compliance Training System
		7.2.2	**Competence – on-the-job training**	
			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 or 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.	Training – General Procedure – QP 0021
		7.2.3	**Internal auditor competency**	
			The organization ***shall*** have a documented process(es) to verify that internal auditors are competent, taking into account any requirements defined by the organization and/or customer-specific requirements. For additional guidance on auditor competencies, refer to ISO 19011. The organization ***shall*** maintain a list of qualified internal auditors.	Internal Audit Procedure - QP-0016

			Quality management system auditors, ***shall*** be able to demonstrate the following minimum competencies:	Internal Audit Procedure - QP-0016
			a) understanding of the automotive process approach for auditing, Including risk-based thinking;	
			b) understanding of applicable customer-specific requirements;	
			c) understanding of applicable ISO 9001 and IATF 16949 requirements related to the scope of the audit;	
			d) understanding of applicable core tool requirements related to the scope of the audit;	
			e) understanding how to plan, conduct, report and close out audit findings.	
			At a minimum, manufacturing process auditors ***shall*** demonstrate technical understanding of the relevant manufacturing process(es) to be audited, including process risk analysis (such as PFMEA) and control plan. At a minimum, product auditors ***shall*** demonstrate competence in understanding product requirements and use of relevant measuring and test equipment to verify product conformity.	Internal Audit Procedure - QP-0016
			If the organization's personnel provide the training to achieve competency, documented information ***shall*** be retained to demonstrate the trainer's competency with the above requirements.	Qualified Auditor Listing
			Maintenance of and improvement in internal auditor competence ***shall*** be demonstrated through:	Internal Audit Procedure - QP-0016
			f) executing a minimum number of audits per year, as defined by the organization; and	
			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).	
		7.2.4	**Second-party auditor competency**	
			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:	External (Supplier-Provider) Audit Procedure – QP-0036
			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**		
		The organization ***shall*** ensure that persons doing work under the organization's control are aware of:		Supplier Quality Requirements Manual Training – General Procedure – QP 0021
		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.		
AS		e) relevant quality management system documented information and changes thereto;		
		f) their contribution to product or service conformity;		
		g) their contribution to product safety;		
		h. the importance of ethical behavior.		
IATF		**7.3.1**	**Awareness – supplemental**	
			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 non-conforming product	Training – General Procedure – QP 0021
		7.3.2	**Employee motivation and empowerment**	
			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.	Motivation Awareness and Empowerment - WI-
	7.4	**Communication**		

		The organization ***shall*** determine the internal and external communications relevant to the quality management system, including:		Aearo Communication Plan - WI-0855
		a) on what it will communicate;		
		b) when to communicate;		
		c) with whom to communicate;		
		d) how to communicate;		
		e) who communicates.		
AS	**NOTE:**	Communication should include internal and external feedback relevant to the quality management system.		
	7.5	**Documented information**		
		7.5.1	**General**	

			The organization's quality management system ***shall*** include:	
			a) documented information required by this International Standard;	Aearo Technology Quality Manual - QAM-1
			b) documented information determined by the organization as being necessary for the effectiveness of the quality management system.	Master Document Matrix - WI-0021
			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.	
IATF			**7.5.1.1** **Quality management system documentation**	

				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).	Aearo Technology Quality Manual - QAM-1
				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.	Aearo Technology Quality Manual - QAM-1
				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;	Aearo Technology Quality Manual - QAM-1
				b) documented processes established for the quality management system, or reference to them;	Aearo Technology Quality Manual - QAM-1
				c) the organization's processes and their sequence and interactions (inputs and outputs), including type and extent of control of any outsourced processes;	Aearo Technologies QMS Processes with KPIs – WI-0005
				d) a document (for example, a table, a list, or a matrix) indicating where within the organization's quality management system their customer-specific requirements are addressed.	Customer Specific Requirements Database
				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 organization's processes and this Automotive QMS.	
		7.5.2	**Creating and updating**		

Quality Management Requirements **ISO-9001 AS-9100 IATF-16949 *Shalls***	**How requirement is met:**

			When creating and updating documented information, the organization ***shall*** ensure appropriate:		Document & Data Control – QP-0007 Format for Procedures, Work Instructions & Forms - QP-0071 Authorized Personnel – WI-0168
			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.		
AS		**NOTE:**	Approval implies authorized persons and approval methods are identified for the relevant types of documented information, as determined by the organization.		
		7.5.3	**Control of documented information**		
			7.5.3.1	Documented information required by the quality management system and by this International Standard ***shall*** be controlled to ensure	Record Retention Procedure – QP-0004
				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).	
			7.5.3.2	For the control of documented information, the organization ***shall*** address the following activities, as applicable:	Document & Data Control – QP-0007 Record Retention Procedure – QP-0004
				a) distribution, access, retrieval and use;	
				b) storage and preservation, including preservation of legibility;	
				c) control of changes (e.g. version control);	
				d) retention and disposition.	

AS				e) prevention of the unintended use of obsolete documented information by removal or by application of suitable identification or controls if kept for any purpose.		
				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.		Document & Data Control – QP-0007 Document Control Procedure for External Standards – QP-0012
				Documented information retained as evidence of conformity ***shall*** be protected from unintended alterations.		Record Retention procedure – QP-0004
				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.		
IATF				**7.5.3.2.1**	**Record retention**	
					The organization ***shall*** define, document, and implement a record retention policy. The control of records ***shall*** satisfy statutory, regulatory, organizational, and customer requirements.	Record Retention procedure – QP-0004
					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	Record Retention procedure – QP-0004
					otherwise specified by the customer or regulatory agency.	

					NOTE: Production part approval documented information may include approved product, applicable test equipment records, or approved test data.	
				7.5.3.2.2	**Engineering specifications**	
					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.	Document Control of External Standards – QP-0012
					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 a record of the date on which each change is implemented in production. Implementation ***shall*** include updated documents.	Document & Data Control – QP-0007 Document Control of External Standards – QP-
					Review should be completed within 10 working days of receipt of notification of engineering standards/ specifications changes.	Document Control of External Standards – QP-0012
					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 they affect documents of the production part approval process, such as control plan, risk analysis (such as FMEAs), etc.	

8	**Operation**			
	8.1	**Operational planning and control**		
		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:		
		a) determining the requirements for the products and services;		Advanced Product Quality Planning - QP-0001
AS	**NOTE:**	Determination of requirements for the products and services should include consideration of:		
		− personal and product safety;		
		− producibility and inspectability;		
		− reliability, availability, and maintainability;		
		− suitability of parts and materials used in the product;		
		− selection and development of embedded software; − product obsolescence;		
		− product obsolescence;		
		− prevention, detection, and removal of foreign objects;		
		− handling, packaging, and preservation;		
		− recycling or final disposal of the product at		
		b) establishing criteria for:		Advanced Product Quality Planning - QP-0001
			1) the processes;	

			2) the acceptance of products and services;	
AS		**NOTE:**	According to the nature of the product and depending on the specified requirements, statistical techniques can be used to support:	
			− design verification (e.g., reliability, maintainability, product safety);	
			− process control; • selection and verification of key characteristics; • process capability measurements; • statistical process control; • design of experiments;	
			− verification;	
			− failure mode, effects, and criticality analysis.	
		c) determining the resources needed to achieve conformity to the product and service requirements:		Advanced Product Quality Planning - QP-0001
AS		c) And to meet on-time delivery of products and services:		
		d) implementing control of the processes in accordance with the criteria;		
		e) determining, maintaining and retaining documented information to the extent necessary:		Advanced Product Quality Planning - QP-0001 Document and Data Control - QP-0007
			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.	
AS		f. determining the processes and controls needed to manage critical items, including production process controls when key characteristics have been identified;		Advanced Product Quality Planning – QP-0001
		g. engaging representatives of affected organization functions for operational planning and control;		

		h. determining the process and resources to support the use and maintenance of the products and services;	
		i. determining the products and services to be obtained from external providers; j. establishing the controls needed to prevent the delivery of nonconforming products and services to the customer.	
		j. establishing the controls needed to prevent the delivery of nonconforming products and services to the customer.	
		NOTE: One method to achieve operational planning and control can be through using integrated phased processes.	

		As appropriate to the organization, customer requirements, and products and services, the organization ***shall*** plan and manage product and service provision in a structured and controlled manner including scheduled events performed in a planned sequence to meet requirements at acceptable risk, within resource and schedule constraints.	Advanced Product Quality Planning - QP-0001 Process Control – QP-0019
		NOTE: This activity is generally referred to as project planning, project management, or program management.	
		The output of this planning ***shall*** be suitable for the organization's operations.	Advanced Product Quality Planning - QP-0001
AS		**NOTE:** As an output of this planning, documented information specifying the processes of the quality management system and the resources to be applied to a specific product, service, project, or contract can be referred to as a quality plan.	
		The organization ***shall*** control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.	Advanced Product Quality Planning - QP-0001 Process Control – QP-0019
		The organization ***shall*** ensure that outsourced processes are controlled (see *8.4)*.	Purchasing Procedure – QP-0072
AS		The organization ***shall*** establish, implement, and maintain a process to plan and control the temporary or permanent transfer of work, to ensure the continuing conformity of the work to requirements. The process ***shall*** ensure that work transfer impacts and risks are managed.	Control of Work Transfers – QP-0070

		NOTE: For the control of work transfer from the organization to an external provider, or from an external provider to another external provider, see 8.4. For the control of work transfer from one organization facility to another, or from an external provider to the organization, see 8.5.		
IATF		**8.1.1**	**Operational planning and control -- supplemental**	
			When planning for product realization, the following topics ***shall*** be Included:	Advanced Product Quality Planning – QP-0001
			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 1 c), refer to the required verification, validation, monitoring, measurement, inspection, and test activities specific to the product and the criteria for product acceptance.	Advanced Product Quality Planning – QP-0001
		8.1.2	**Confidentiality**	
			The organization ***shall*** ensure the confidentiality of customer-contracted products and projects under development, including related product information.	Design & Development – QP-0046
AS		**8.1.1**	**Operational Risk Management**	
			The organization ***shall*** plan, implement, and control a process for managing operational risks to the achievement of applicable requirements, which includes as appropriate to the organization and the products and services:	Risk & Opportunity Management – QP-0091
			a. assignment of responsibilities for operational risk management;	
			b. definition of risk assessment criteria (e.g., likelihood, consequences, risk acceptance);	
			c. identification, assessment, and communication of risks throughout operations;	

			d. identification, implementation, and management of actions to mitigate risks that exceed the defined risk acceptance criteria;	
			e. acceptance of risks remaining after implementation of mitigating actions.	
			NOTE: 1: While clause 6.1 addresses the risks and opportunities when planning for the quality management system of the organization, the scope of this clause (8.1.1) is limited to the risks associated to the operational processes needed for the provision of products and services (clause 8).	
			NOTE 2: Within the aviation, space, and defense industry, risk is generally expressed in terms of the likelihood of occurrence and the severity of the consequences.	
		8.1.2	**Configuration Management**	
			The organization ***shall*** plan, implement, and control a process for configuration management as appropriate to the organization and its products and services in order to ensure the identification and control of physical and functional attributes throughout the product lifecycle. This process ***shall***:	Control of Design and Development Changes & Configuration Management – Aerospace – QP-0025
			a. control product identity and traceability to requirements, including the implementation of identified changes;	
			b. ensure that the documented information (e.g., requirements, design, verification, validation and acceptance documentation) is consistent with the actual attributes of the products and services.	
		8.1.3	**Product Safety**	
			The organization ***shall*** plan, implement, and control the processes needed to assure product safety during the entire product life cycle, as appropriate to the organization and the product.	N/A
			NOTE: Examples of these processes include:	

			− assessment of hazards and management of associated risks (see 8.1.1);	
			− management of safety critical items;	
			− analysis and reporting of occurred events affecting safety;	
			− communication of these events and training of persons.	
		8.1.4	**Prevention of Counterfeit Parts**	
			The organization ***shall*** plan, implement, and control processes, appropriate to the organization and the product, for the prevention of counterfeit or suspect counterfeit part use and their inclusion in product(s) delivered to the customer.	Nonconformance Control - QP-0020 (Indy) Purchasing Process – QP-0072
			NOTE: Counterfeit part prevention processes should consider:	
			− training of appropriate persons in the awareness and prevention of counterfeit parts;	
			− application of a parts obsolescence monitoring program;	
			− controls for acquiring externally provided product from original or authorized manufacturers, authorized distributors, or other approved sources;	
			− requirements for assuring traceability of parts and components to their original or authorized manufacturers;	
			− verification and test methodologies to detect counterfeit parts; − monitoring of counterfeit parts reporting from external sources; − quarantine and reporting of suspect or detected counterfeit parts.	
	8.2	**Requirements for products and services**		
		8.2.1	**Customer communication**	
			Communication with customers ***shall*** include:	Communication, Internal & External – WI-0855
			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.		
IATF		**8.2.1.1**	**Customer communication - supplemental**		
			Written or verbal communication shall be in the language agreed with 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).		Communication, Internal & External – WI-0855
		8.2.2	**Determining the requirements for products and services**		
			When determining the requirements for the products and services to be offered to customers, the organization shall ensure that:		Advanced Product Quality Planning - QP-0001
			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.		
AS			c) special requirements of the products and services are determined;		
			d) operational risks (e.g., new technology, ability and capacity to provide, short delivery time frame) have been identified.		
IATF			**8.2.2.1**	**Determining the requirements for products and services -- supplemental**	Advanced Product Quality Planning – QP-0001

				These requirements ***shall*** Include recycling, environmental impact, and characteristics identified as a result of the organization's 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 of material.	
		8.2.3	**Review of the requirements for products and services**		
			8.2.3.1	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:	Advanced Product Quality Planning – QP-0001
				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.		
AS				This review ***shall*** be coordinated with applicable functions of the organization.		Advanced Product Quality Planning - QP-0001
				If upon review the organization determines that some customer requirements cannot be met or can only partially be met, the organization ***shall*** negotiate a mutually acceptable requirement with the customer.		Advanced Product Quality Planning - QP-0001
				The organization ***shall*** ensure that contract or order requirements differing from those previously defined are resolved.		Advanced Product Quality Planning - QP-0001 Order Entry & Processing – QP-0037
				The customer's requirements ***shall*** be confirmed by the organization before acceptance, when the customer does not provide a documented statement of their requirements.		Advanced Product Quality Planning - QP-0001
				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.		
IATF				**8.2.3.1.1**	**Review of the requirements for products and services -- supplemental**	
					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.	Advanced Product Quality Planning - QP-0001
				8.2.3.1.2	**Customer-designated special characteristics**	
					The organization ***shall*** conform to customer requirements for designation, approval	Advanced Product Quality Planning - QP-0001

					documentation, and control of special characteristics.	

				8.2.3.1.3	**Organization manufacturing feasibility**	
					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 of 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.	Advanced Product Quality Planning - QP-0001
					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.	Advanced Product Quality Planning - QP-0001
			8.2.3.2	The organization ***shall*** retain documented information. as applicable:		Advanced Product Quality Planning - QP-0001 Document and Data Control - QP-0007
				a) on the results or the review;		
				b) on any new requirements for the products and services.		
		8.2.4	**Changes to requirements for products and services**			

			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.		Advanced Product Quality Planning - QP-0001 Document and Data Control - QP-0007
	8.3	**Design and development of products and services**			
		8.3.1	**General**		
			The organization ***shall*** establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services.		Design & Development - QP-0046
IATF			**8.3.1.1**	**Design and development of products and services -- supplemental**	Design & Development - QP-0046
				The requirements of ISO 9001, 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.	
		8.3.2	**Design and development planning**		
			In determining the stages and controls for design and development, the organization ***shall*** consider:		Design & Development - QP-0046
			a) the nature, duration and complexity of the design and development activities;		
			b) the required process stages, including applicable design and development reviews;		
			c) the required design and development verification and validation activities;		
			d) the responsibilities and authorities involved in the design and development process;		
			e) the internal and external resource needs for the design and development of products and services;		

			f) the need to control interfaces between persons involved in the design and development process;		
			g) the need for involvement of customers and users in the design and development process;		
			h) the requirements for subsequent provision of products and services;		
			i) the level of control expected for the design and development process by customers and other relevant interested parties;		
			j) the documented information needed to demonstrate that design and development requirements have been met.		
AS			When appropriate, the organization ***shall*** divide the design and development effort into distinct activities and, for each activity, define the tasks, necessary resources, responsibilities, design content, and inputs and outputs.		Design & Development - QP-0046

			Design and development planning ***shall*** consider the ability to provide, verify, test and maintain products and services (reference output of 8.1 a).		Design & Development - QP-0046
IATF			**8.3.2.1**	**Design and development planning – supplemental**	
				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:	Design & Development - QP-0046
				a) project management (for example, APQP or VOA-RGA);	
				b) product and manufacturing process design activities (for example, OFM and OFA), 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 news, control plans, and standard work instructions).	
				NOTE: A multidisciplinary approach typically includes the organization's design, manufacturing, engineering, quality, production, purchasing, supplier, maintenance. and other appropriate functions.	
			8.3.2.2	**Product design skills**	
				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.	Design & Development - QP-0046
				NOTE: An example of product design skills is the application of digitized mathematically based data.	
			8.3.2.3	**Development of products with embedded software**	N/A
				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 organization's 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.	
				The organization ***shall*** include software development within the scope of their Internal audit programme (see Section 9.2 2.1)	

		8.3.3	**Design and development inputs**		
			The organization ***shall*** determine the requirements essential for the specific types of products and services to be designed and developed. The organization ***shall*** consider:		Design & Development - QP-0046
			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.		
AS			f. when applicable, the potential consequences of obsolescence (e.g., materials, processes, components, equipment, products).		
			Inputs ***shall*** be adequate for design and development purposes, complete and unambiguous.		Design & Development - QP-0046
			Conflicting design and development inputs ***shall*** be resolved.		Design & Development - QP-0046
			The organization ***shall*** retain documented information on design and development inputs.		Design & Development - QP-0046 Record Retention Procedure - QP-0004
AS			**NOTE:** The organization can also consider as design and development inputs other information such as benchmarking, external provider feedback, internally generated data, and in-service data.		
IATF			**8.3.3.1**	**Product design input**	
				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:	Design & Development - QP-0046

				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:	
				g) applicable statutory and regulatory requirements of the customer-identified country of destination, if provided;	
				h) embedded software requirements.	N/A
				The organization shalt have a process to deploy information gained from previous design projects, competitive product analysis (benchmarking), supplier feedback, internal input, field data, and other relevant sources for current and future projects of a similar nature.	Design & Development - QP-0046

				NOTE: One approach for considering design alternatives is the use of trade-off curves.	
			8.3.3.2	**Manufacturing process design input**	
				The organization ***shall*** identify, document, and review manufacturing process design input requirements including but not limited to the following:	Design & Development - QP-0046

				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.	
			8.3.3.3	**Special characteristics**	
				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 risk analysis performed by the organization, and ***shall*** include the following"	Design & Development - QP-0046

				a) documentation of all special characteristics in the product and/or manufacturing documents (as required), relevant risk analysis (such as Process FMEA), control plans, and standard work/operator instructions; special characteristics are identified with specific markings and are documented in the manufacturing documents which show the creation of, or the controls required, for the special characteristics;	
				b) development of control and monitoring strategies for special characteristics of products and production processes;	
				c) customer-specified approvals, when required:	
				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.	
		8.3.4	**Design and development controls**		
			The organization ***shall*** apply controls to the design and development process to ensure that:		Design & Development - QP-0046
			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.		
AS			g. progression to the next stage is authorized.		
			Participants in design and development reviews ***shall*** include representatives of functions concerned with the design and development stage(s) being reviewed.		Design & Development - QP-0046

			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.		
AS			**8.3.4.1**	When tests are necessary for verification and validation, these tests ***shall*** be planned, controlled, reviewed, and documented to ensure and prove the following:	Design & Development - QP-0046
				a. test plans or specifications identify the test item being tested and the resources being used, define test objectives and conditions, parameters to be recorded and relevant acceptance criteria;	
				b. test procedures describe the test methods to be used, how to perform the test, and how to record the results;	
				c. the correct configuration of the test item is submitted for the test;	
				d. the requirements of the test plan and the test procedures are observed;	
				e. the acceptance criteria are met.	
				Monitoring and measuring devices used for testing ***shall*** be controlled as defined in clause 7.1.5.	

				At the completion of design and development, the organization ***shall*** ensure that reports, calculations, test results, etc., are able to demonstrate that the design for the product or service meets the specification requirements for all identified operational conditions.	Design & Development - QP-0046
IATF			**8.3.4.1**	**Monitoring**	
				Measurements at specified stages during the design and development of products and processes ***shall*** be defined, analysed, and reported with summary results as an input to management review (see Section 9.3.2.1).	Design & Development - QP-0046

				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_	Design & Development - QP-0046
				NOTE: When appropriate, these measurements may include quality risks, costs, lead limes, critical paths, and other measurements.	
			8.3.4.2	**Design and development validation**	
				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.	Design & Development - QP-0046
				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 final customer's product.	Design & Development - QP-0046
			8.3.4.3	**Prototype programme**	

				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.	Design & Development - QP-0046
				All performance-testing activities ***shall*** be monitored for timely completion and conformity to requirements.	Design & Development - QP-0046
				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).	Design & Development - QP-0046
			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).	Design & Development - QP-0046
				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.	Design & Development - QP-0046
				The organization ***shall*** obtain documented product approval prior to shipment, if required by the customer. Records of such approval ***shall*** be retained.	Design & Development - QP-0046
				NOTE: Product approval should be subsequent to the verification of the manufacturing process.	
		8.3.5	**Design and development outputs**		
			The organization ***shall*** ensure that design and development outputs:		Design & Development - QP-0046

			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.		
AS			e. specify, as applicable, any critical items, including any key characteristics, and specific actions to be taken for these items;		
			f. are approved by authorized person(s) prior to release.		
			The organization ***shall*** define the data required to allow the product to be identified, manufactured, verified, used, and maintained.		Design & Development - QP-0046
			NOTE: Data can include:		
			− the drawings, part lists, and specifications necessary to define the configuration and the design features of the product;		
			− the material, process, manufacturing, assembly, handling, packaging, and preservation data needed to provide and maintain a conforming product or service;		
			− the technical data and repair schemes for operating and maintaining the product.		
			The organization ***shall*** retain documented information on design and development outputs.		Design & Development - QP-0046 Record Retention Procedure - QP-0004
IATF			**8.3.5.1**	**Design and development outputs -- supplemental**	
				The product design output ***shall*** be expressed in terms that can be verified and validated against product design input requirements. The product	Design & Development - QP-0046

				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 OFSS, 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;	
				h) service diagnostic guidelines and repair and serviceability instructions:	
				i) service part requirements;	
				j) packaging and labeling requirements for shipping.	
				NOTE: Interim design outputs should include any engineering problems being resolved through a tradeoff process.	

			8.3.5.2	**Manufacturing process design output**	

				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:	Design & Development - QP-0046
				a) specifications and drawings;	
				b) special characteristics for product and manufacturing process;	
				c) Identification of process input variables that 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;	
				h) maintenance plans and instructions;	
				i) control plan (see Annex A);	
				j) standard work and work instructions:	
				k) process approval acceptance criteria;	
				l) data for Quality, reliability, maintainability, and measurability;	

				m) results of error-proofing identification and verification, as appropriate;	
				n) methods of rapid detection, feedback, and correction of product/manufacturing process nonconformities.	
		8.3.6	**Design and development changes**		
			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.		Design & Development - QP-0046
AS			The organization ***shall*** implement a process with criteria for notifying its customer, prior to implementation, about changes that affect customer requirements.		Design & Development - QP-0046
			The organization ***shall*** retain documented information on:		Design & Development - QP-0046 Record Retention Procedure - QP-0004
			a) design and development changes;		
			b) the results of reviews;		
			c) the authorization of the changes;		
			d) the actions taken to prevent adverse impacts.		
AS			Design and development changes ***shall*** be controlled in accordance with the configuration management process requirements.		Design & Development - QP-0046 Control of Design & Development Changes & Configuration Management - Aerospace – QP-0025
IATF			**8.3.6.1**	**Design and development changes - supplemental**	

				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.	Design & Development - QP-0046
				If required by the customer, the organization ***shall*** obtain documented approval, or a documented waiver, from the customer prior to production implementation.	Design & Development - QP-0046

				For products with embedded software, the organization ***shall*** document the revision level of software and hardware as part of the change record.	Design & Development - QP-0046
	8.4	**Control of externally provided processes, products and services**			
		8.4.1	**General**		
				The organization ***shall*** ensure that externally provided processes, products and services conform to requirements.	Purchasing Process – QP-0072
AS				The organization ***shall*** be responsible for the conformity of all externally provided processes, products, and services, including from sources defined by the customer.	Purchasing Process – QP-0072
				The organization ***shall*** ensure, when required, that customer-designated or approved external providers, including process sources (e.g., special processes), are used.	Purchasing Process – QP-0072
				The organization ***shall*** identify and manage the risks associated with the external provision of processes, products, and services, as well as the selection and use of external providers.	Purchasing Process – QP-0072

			The organization ***shall*** require that external providers apply appropriate controls to their direct and sub-tier external providers, to ensure that requirements are met.	Purchasing Process – QP-0072
			The organization ***shall*** determine the controls to be applied to externally provided processes, products and services when:	Purchasing Process – QP-0072
			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 an 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 reevaluation of external providers, based on their ability to	Purchasing Process – QP-0072
			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.	
AS			**NOTE:** During external provider evaluation and selection, the organization can use quality data from objective and reliable external sources, as evaluated by the organization (e.g., information from accredited quality management system or process certification bodies, external provider approvals from government authorities or customers). Use of such data would be only one element of an organization's external provider control process and the organization remains responsible for verifying that externally provided processes, products, and services meet specified requirements.	
			8.4.1.1 The Organization ***shall***:	Purchasing Process – QP-0072

				a. define the process, responsibilities, and authority for the approval status decision, changes of the approval status, and conditions for a controlled use of external providers depending on their approval status;	
				b. maintain a register of its external providers that includes approval status (e.g., approved, conditional, disapproved) and the scope of the approval (e.g., product type, process family);	
				c. periodically review external provider performance including process, product and service conformity, and on-time delivery performance;	
				d. define the necessary actions to take when dealing with external providers that do not meet requirements;	
				e. define the requirements for controlling documented information created by and/or retained by external providers.	
IATF			**8.4.1.1**	**General – supplemental**	
				The organization ***shall*** include all products and services 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.	Purchasing Process – QP-0072

			8.4.1.2	**Supplier selection process**	
				The organization ***shall*** have a documented supplier selection process. The selection process ***shall*** include:	Purchasing Process – QP-0072
				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) multidisciplinary decision making; and	
				e) an assessment of software development capabilities, if applicable.	N/A
				Other supplier selection criteria that should be considered include the following:	Purchasing Process – QP-0072 Supplier Creation/Change Request – QF-0335
				- volume of automotive business (absolute and as a 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);	
				- design and development capabilities (including project management);	
				- manufacturing capability;	
				- change management process;	
				- business continuity planning (e.g., disaster preparedness, contingency planning);	
				- logistics process;	
				- customer service.	

			8.4.1.3	**Customer-directed sources (also known as "Directed-Buy")**	
				When specified by the customer, the organization ***shall*** purchase products, materials, or services from customer-directed sources.	Purchasing Process – QP-0072

				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.	Purchasing Process – QP-0072
		8.4.2	**Type and extent of control**		
			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.		Purchasing Process – QP-0072
			The organization ***shall***:		Purchasing Process – QP-0072
			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;	
AS				3) the results of the periodic review of external provider performance (see 8.4.1.1 c);	
			d) determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.		
AS			Verification activities of externally provided processes, products, and services ***shall*** be performed according to the		Purchasing Process – QP-0072

			risks identified by the organization. These ***shall*** include inspection or periodic testing, as applicable, when there is high risk of nonconformities including counterfeit parts.	

			NOTE 1: Customer verification activities performed at any level of the supply chain does not absolve the organization of its responsibility to provide acceptable processes, products, and services and to comply with all requirements.	
			NOTE 2: Verification activities can include:	
			− review of objective evidence of the conformity of the processes, products, and services from the external provider (e.g., accompanying documentation, certificate of conformity, test documentation, statistical documentation, process control documentation, results of production process verification and assessment of changes to the production process thereafter);	
			− inspection and audit at the external provider's premises;	
			− review of the required documentation;	
			− review of production part approval process data;	
			− inspection of products or verification of services upon receipt;	
			− review of delegations of product verification to the external provider.	
			When externally provided product is released for production use pending completion of all required verification activities, it ***shall*** be identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.	Purchasing Process – QP-0072 Raw Material Receiving – Indianapolis – QP-0057
			When the organization delegates verification activities to the external provider, the scope and requirements for delegation ***shall*** be defined and a register of delegations ***shall*** be maintained. The organization ***shall*** periodically monitor the external provider's delegated verification activities.	Aearo Raw Material Specifications; Raw Material Receiving – Indianapolis – QP-0057 Receiving Inspection Instructions

			When external provider test reports are utilized to verify externally provided products, the organization ***shall*** implement a process to evaluate the data in the test reports to confirm that the product meets requirements. When a customer or organization has identified raw material as a significant operational risk (e.g., critical items), the		Raw Material Receiving – Indianapolis – QP-0057 Supplier Creation/Change Request – QF-0335
			organization ***shall*** implement a process to validate the accuracy of test reports.		
IATF			**8.4.2.1**	**Type and extent of control - supplemental**	
				The organization ***shall*** have a documented process to identify outsourced processes and to select the types and extent of controls used to verify conformity of externally provided products, processes, and services to internal (organizational) and external customer requirements.	Purchasing Process – QP-0072
				The process shalt 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.	Purchasing Process – QP-0072
				Where characteristics or components “pass through” the organization’s quality management system without validation or controls, the organization shall ensure that the appropriate controls are in place at the point of manufacture.	Purchasing Process – QP-0072
			8.4.2.2	**Statutory and regulatory requirements**	
				The organization shalt 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.	Purchasing Process – QP-0072

				If the customer defines special controls for certain products with statutory and regulatory requirements, the organization ***shall*** ensure they are implemented and maintained as defined, including at suppliers.	Purchasing Process – QP-0072
			8.4.2.3	**Supplier quality management system development**	
				The organization ***shall*** require their suppliers of automotive products and services to develop, implement, and improve a quality management system (QMS) with the ultimate objective of becoming certified IATF 16949 QMS Standard.	Purchasing Process – QP-0072

				Unless otherwise authorized by the customer, the following sequence is applied to achieve the requirement: a QMS certified to ISO 9001 is the initial minimum acceptable level of development. Based on current performance and the potential risk to the customer, the objective is to move suppliers through the following QMS development progression:	Purchasing Process – QP-0072
				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 SubTier Suppliers (MAQMSR] or equivalent) through second-party audits;		
				d) certification to 1509001 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).		
				8.4.2.3.1	**Automotive product-related software or automotive products with embedded software**	N/A
					The organization ***shall*** require their suppliers of automotive productrelated 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 of a software development capability self-assessment.	
			8.4.2.4	**Supplier Monitoring**		

				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.	Purchasing Process – QP-0072
				At a minimum, the following supplier performance indicators ***shall*** be monitored:	Purchasing Process – QP-0072
				a) delivered product conformity to requirements;	
				b) customer disruptions at the receiving plant, including yard holds and stop ships;	
				c) delivery schedule performance;	
				If provided by the customer, the organization ***shall*** also include the following, as appropriate, In their supplier performance monitoring:	
				d) special status customer notifications related to quality or delivery issues;	
				e) dealer returns, warranty, field actions, and recalls.	

				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:	Supplier Performance Monitoring Development Procedure - QP-0036
					a) supplier risk assessment;	
					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.	Supplier Performance Monitoring Development Procedure - QP-0036
					The organization ***shall*** retain records of the second-party audit reports.	Supplier Performance Monitoring Development Procedure - QP-0036 Record Retention Procedure - QP-0004
					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.	Supplier Performance Monitoring Development Procedure - QP-0036
					NOTE: Guidance may be found in the IATF Auditor Guide and ISO 19011.	
			8.4.2.5	**Supplier Development**		
				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:	Purchasing Process – QP-0072
				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.	Purchasing Process – QP-0072
		8.4.3	**Information for external providers**		
			The organization ***shall*** ensure the adequacy of requirements prior to their communication to the external provider.		Purchasing Process – QP-0072
			The organization ***shall*** communicate to external providers its requirements for:		Purchasing Process – QP-0072
			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.
AS			g. design and development control;
			h. special requirements, critical items, or key characteristics;
			i. test, inspection, and verification (including production process verification);
			j. the use of statistical techniques for product acceptance and related instructions for acceptance by the organization;
			k. the need to:
			− implement a quality management system;
			− use customer-designated or approved external providers, including process sources (e.g., special processes);
			− notify the organization of nonconforming processes, products, or services and obtain approval for their disposition;

			− prevent the use of counterfeit parts (see 8.1.4);
			− notify the organization of changes to processes, products, or services, including changes of their external providers or location of manufacture, and obtain the organization's approval;
			− flow down to external providers applicable requirements including customer requirements;
			− provide test specimens for design approval, inspection/verification, investigation, or auditing;
			− retain documented information, including retention periods and disposition requirements;
			l. the right of access by the organization, their customer, and regulatory authorities to the applicable areas of facilities and to applicable documented information, at any level of the supply chain;
			m. ensuring that persons are aware of:
			− their contribution to product or service conformity;
			− their contribution to product safety;
			− the importance of ethical behavior.

IATF			**8.4.3.1**	**Information for external providers - supplemental**	
				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.	Purchasing Process – QP-0072
	8.5	**Production and service provision**			
		8.5.1	**Control of production and service provision**		
			The organization ***shall*** implement production and service provision under controlled conditions.		Process Control – QP-0019
			Controlled conditions ***shall*** include, as applicable:		
			a) the availability of documented information that defines:		Process Control – QP-0019
				1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed;	
				2) the results to be achieved;	
AS			**NOTE 1:** Documented information that defines characteristics of products and services can include digital product definition data, drawings, parts lists, materials, and process specifications.		
			NOTE 2: Documented information for activities to be performed and results to be achieved can include process flow charts, control plans, production documents (e.g.,		

			manufacturing plans, travelers, routers, work orders, process cards), and verification documents.	
			b) the availability and use of suitable monitoring and measuring resources;	Process Control - QP-0019
			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;	Record Retention List (Indy) WI-0006
AS			1. ensuring that documented information for monitoring and measurement activity for product acceptance includes:	
			− criteria for acceptance and rejection;	
			− where in the sequence verification operations are to be performed;	
			− measurement results to be retained (at a minimum an indication of acceptance or rejection);	
			− any specific monitoring and measurement equipment required and instructions associated with their use;	
			2. ensuring that when sampling is used as a means of product acceptance, the sampling plan is justified on the basis of recognized statistical principles and appropriate for use (i.e., matching the sampling plan to the criticality of the product and to the process capability).	
			d) the use of suitable infrastructure and environment for the operation of processes;	
AS			**NOTE:** Suitable infrastructure can include product specific tools (e.g., jigs, fixtures, molds) and software programs.	

			e) the appointment of competent persons, including any required qualification;	Process Control – QP-0019
			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;	
AS			**NOTE:** These processes can be referred to as special processes (see 8.5.1.2).	
			g) the implementation of actions to prevent human error;	Process Control – QP-0019 Continual Improvement – QP-0038

			h) the implementation of release, delivery and post-delivery activities.	Inspection & Test Status - Indy QP-0032 General Inspection and Testing - Newark QP-0028 Stock Shipment Procedure - WI-0139 Shipping Procedure - Newark WI-0790
IATF		**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.	
AS			i. the establishment of criteria for workmanship (e.g., written standards, representative samples, illustrations);	Process Control – QP-0019
			j. the accountability for all products during production (e.g., parts quantities, split orders, nonconforming product);	Process Control – QP-0019
			k. the control and monitoring of identified critical items, including key characteristics, in accordance with established processes;	Process Control – QP-0019
			l. the determination of methods to measure variable data (e.g., tooling, on-machine probing, inspection equipment);	Process Control – QP-0019
			m. the identification of in-process inspection/verification points when adequate verification of conformity cannot be performed at later stages;	Process Control – QP-0019
			n. the availability of evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized;	Record Retention List (Indy) WI-0006

			o. the provision for the prevention, detection, and removal of foreign objects;		Storage Area – WI-0180
			p. the control and monitoring of utilities and supplies (e.g., water, compressed air, electricity, chemical products) to the extent they affect conformity to product requirements (see 7.1.3);		Contingency - Business Continuity, Indianapolis – WI-0012
			q. the identification and recording of products released for subsequent production use pending completion of all required measuring and monitoring activities, to allow recall and replacement if it is later found that the product does not meet requirements.		General Inspection & Testing – QP-0002 (Indy) Inspection & Test Status Procedure – QP-0032 Temporary Deviation Documents & Processes – QP-0087
			8.5.1.1	**Control of Equipment, Tools, and Software Programs**	
				Equipment, tools, and software programs used to automate, control, monitor, or measure production processes ***shall*** be validated prior to final release for production and ***shall*** be maintained.	Facilities & Tooling Management – WI-0014
				Storage requirements ***shall*** be defined for production equipment or tooling in storage including any necessary periodic preservation or condition checks.	
IATF			**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.	Advanced Product Quality Planning - QP-0001

				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).	Advanced Product Quality Planning - QP-0001
				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:	Advanced Product Quality Planning - QP-0001 Process Control - QP-0019
				b) first-off/last-off part validation, as applicable;	
				c) methods for monitoring of control exercised over special characteristics (see Annex A) defined by both the customer and the organization,	
				d) the customer-required information, if any;	
				e) specified reaction plan (see Annex A); when nonconforming product is detected, the process becomes statistically unstable or not statistically capable.	
				The organization ***shall*** review control plans, and update as required, for any of the following.	
				f) the organization determines it has shipped nonconforming product to the customer;	Risks and Opportunities Management Procedure - QP-0091 Customer Corrective Action Process Procedure – QP-0055
				g) when any change occurs affecting product, manufacturing process, measurement, logistics, supply sources, production volume changes, or risk analysis (FMEA) (see Annex A);	Advanced Product Quality Planning - QP-0001 Process Control – QP-0019

				h) after a customer complaint and implementation of the associated corrective action, when applicable;	Customer Corrective Action Process Procedure – QP-0055
				i) at a set frequency based on a risk analysis.	Process Control - QP-0019 Risk & Opportunities Management Procedure - QP0091
				If required by the customer, the organization ***shall*** obtain customer approval after review or revision of the control plan.	Advanced Product Quality Planning - QP-0001 Process Control - QP-0019
AS			**8.5.1.2**	**Validation and Control of Special Processes**	
				For processes where the resulting output cannot be verified by subsequent monitoring or measurement, the organization ***shall*** establish arrangements for these processes including, as applicable:	N/A
				a. definition of criteria for the review and approval of the processes;	
				b. determination of conditions to maintain the approval;	
				c. approval of facilities and equipment;	
				d. qualification of persons;	
				e. use of specific methods and procedures for implementation and monitoring the processes;	
				f. requirements for documented information to be retained.	
IATF			**8.5.1.2**	**Standardized work – operator instructions and visual standards**	
				The organization ***shall*** ensure that standardized work documents are:	

				a) communicated to and understood by the employees who are responsible for performing the work;	Advanced Product Quality Planning – QP-0001 Document & Data Control – QP-0007 Training – General Procedure – QP-0021
				b) legible;	Document & Data Control – QP-0007
				c) presented in the language(s} understood by the personnel responsible to follow them,	Document & Data Control – QP-0007
				d) accessible for use at the designated work area(s).	Document & Data Control – QP-0007
				The standardized work documents ***shall*** also include rules for operator safety.	Format for Procedures, Work Instructions & Forms - QP-071
AS			**8.5.1.3**	**Production Process Verification**	
				The organization ***shall*** implement production process verification activities to ensure the production process is able to produce products that meet requirements.	Advanced Product Quality Planning – QP-0001 Process Control – QP-0019
				NOTE: These activities can include risk assessments, capacity studies, capability studies, and control plans.	
				The organization ***shall*** use a representative item from the first production run of a new part or assembly to verify that the production processes, production documentation, and tooling are able to produce parts and assemblies that meet requirements. This activity ***shall*** be repeated when changes occur that invalidate the original results (e.g., engineering changes, production process changes, tooling changes).	Advanced Product Quality Planning – QP-0001 Process Control – QP-0019
				NOTE: This activity can be referred to as First Article Inspection (FAI).	

				The organization ***shall*** retain documented information on the results of production process verification.	Record Retention Procedure - QP-0004
IATF			**8.5.1.3**	**Verification of job set-ups**	
				The organization ***shall***:	
				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;	Process Control - QP-0019
				b) maintain documented information for set-up personnel:	Process Control - QP-0019 Document & Data Control – QP-0007
				c) use statistical methods of verification, where applicable:	Process Control - QP-0019
				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;	Process Control - QP-0019
				e) retain records of process and product approval following set-up and first-off/last-off part validations.	Process Control - QP-0019 Record Retention Procedure - QP-0004
			8.5.1.4	**Verification after shutdown**	
				The Organization ***shall*** define and implement the necessary actions to ensure product compliance with requirements after a planned or unplanned production shutdown period.	Process Control - QP-0019
			8.5.1.5	**Total productive maintenance**	
				The organization ***shall*** develop, implement, and maintain a documented total productive maintenance system.	Total Productive Maintenance – QP-0058 (Newark) Total Productive Maintenance - QP-0093 (Indy)
				At a minimum, the system ***shall*** include the following:	Total Productive Maintenance – QP-0058 (Newark) Total Productive Maintenance - QP-0093 (Indy
				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;	
				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);	
				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**	
				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.	Facilities & Tooling Management – WI-0014

				The organization ***shall*** establish and implement a system for production tooling management, whether owned by the organization or the customer, including.	Facilities & Tooling Management – WI-0014
				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;	
				g) tool identification, such as serial or asset number; the status, such as production, repair or disposal; ownership; and location.	
				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.	Facilities & Tooling Management – WI-0014
				The organization ***shall*** implement a system to monitor these activities if any work is outsourced.	Facilities & Tooling Management – WI-0014 Purchasing Process – QP-0072
			8.5.1.7	**Production scheduling**	Order Entry & Processing – QP-0037 Production Schedule – Newark WI-0066
				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.	

				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.	
		8.5.2	**Identification and traceability**		
			The organization ***shall*** use suitable means to identify outputs when it is necessary to ensure the conformity of products and services.		Lot Identification & Traceability – QP-0056 (Newark) Product Identification & Traceability – QP-0043 (Indy)
AS			The organization ***shall*** maintain the identification of the configuration of the products and services in order to identify any differences between the actual configuration and the required configuration.		Control of Design & Development Changes & Configuration Management – Aerospace – QP-0025 Product Identification & Traceability – QP-0043 (Indy)
			The organization ***shall*** identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.		Inspection and Test Status Procedure - QP-0032 Nonconformance Control – QP-0020 (Indy) Nonconformance Control - QP-0081 (Newark)
			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.		Lot Identification & Traceability – QP-0056 (Newark) Product Identification & Traceability – QP-0043 (Indy)
IATF			**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.		
AS			When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), the organization ***shall*** establish controls for the media.		Inspection and Test Status Procedure - QP-0032 Quality Control Stamps Procedure – QP-0033
		NOTE:	Traceability requirements can include:		

			− the identification to be maintained throughout the product life;		
			− the ability to trace all products manufactured from the same batch of raw material, or from the same manufacturing batch, to the destination (e.g., delivery, scrap);		
			− for an assembly, the ability to trace its components to the assembly and then to the next higher assembly;		
			− for a product, a sequential record of its production (manufacture, assembly, inspection/verification) to be retrievable.		
IATF			**8.5.2.1**	**Identification and traceability -- supplemental**	
				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:	Advanced Product Quality Planning - QP-0001
				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 format (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 safety/regulatory characteristics	
		8.5.3	**Property Belonging to customers or external providers**		Customer / Provider Tooling & Returnable Packaging – WI-0016 Customer Supplied Raw Materials/Products – QP-0054 Facilities & Tooling Management – WI-0014

			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, the premises, intellectual property and personal data.		
		8.5.4	**Preservation**		
			The organization ***shall*** preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.		Preservation & Segregation – WI-0077 (Newark) Storage Area – WI-0180 (Indy)
			NOTE Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.		
AS			Preservation of outputs ***shall*** also include, when applicable in accordance with specifications and applicable statutory and regulatory requirements, provisions for:		Storage Area – WI-0180 (Indy)
			a. cleaning;		
			b. prevention, detection, and removal of foreign objects;		
			c. special handling and storage for sensitive products;		
			d. marking and labeling, including safety warnings and cautions;		
			e. shelf life control and stock rotation;		
			f. special handling and storage for hazardous materials.		
IATF			**8.5.4.1**	**Preservation -- supplemental**	
				Preservation ***shall*** Include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.	Lot Identification & Traceability – QP-0056 (Newark) Product Identification & Traceability – QP-0043 (Indy) Raw Material Receiving Procedure QP-0057 (Indy) Raw Material Receiving WI-0069 (Newark) Preservation & Segregation (Newark) – WI-0077 Storage Area (Indy) – WI-0180 Final Packaging (Indy) – WI-0182

				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.	Raw Material Receiving Procedure QP-0057 (Indy) Raw Material Receiving WI-0069 (Newark) Preservation & Segregation (Newark) – WI-0077 Storage Area (Indy) – WI-0180 Final Packaging (Indy) – WI-0182
				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.	Preservation & Segregation (Newark) – WI-0077 Storage Area (Indy) – WI-0180
				The organization ***shall*** use an inventory management system to optimize inventory turns over time and ensure stock rotation, such as "firsl·in-first-out- (FIFO).	Raw Material Receiving – QP-0057 (Indy) Raw Material Receiving – WI-0069 (Newark) Storage Area (Indy) – WI-0180
				The organization ***shall*** ensure that obsolete product is controlled in a manner similar to that of nonconforming product.	Nonconformance Control - QP-0020 (Indy) Nonconformance Control - QP-0081 (Newark)
				Organizations ***shall*** comply with preservation, packaging, shipping, and labeling requirements as provided by their customers.	Advanced Product Quality Planning - QP-0001
		8.5.5	**Post-delivery activities**		
			The organization ***shall*** meet requirements for post-delivery activities associated with the products and services.		N/A
			In determining the extent of post-delivery activities that are required, the organization ***shall*** consider:		
			a) statutory and regulatory requirements;		N/A
			b) the potential undesired consequences associated with its products and services;		N/A
			c) the nature, use and intended lifetime of its products and services;		N/A
			d) customer requirements;		N/A
			e) customer feedback.		N/A

			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.		
AS			f. collection and analysis of in-service data (e.g., performance, reliability, lessons learned);		N/A
			g. control, updating, and provision of technical documentation relating to product use, maintenance, repair, and overhaul;		N/A
			h. controls required for work undertaken external to the organization (e.g., off-site work);		N/A
			i. product/customer support (e.g., queries, training, warranties, maintenance, replacement parts, resources, obsolescence).		N/A
			When problems are detected after delivery, the organization ***shall*** take appropriate action including investigation and reporting.		Customer Incident Investigation - WI-0787
IATF			**8.5.5.1**	**Feedback of information from services**	
				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.	N/A
				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.	
			8.5.5.2	**Service agreement with customer**	
				When there is a service agreement with the customer, the organization ***shall***:	

				a) verify that the relevant service centres comply with applicable requirements;	N/A
				b) verify the effectiveness of any special purpose tools or measurement equipment;	N/A
				c) ensure that all service personnel are trained in applicable requirements.	N/A
		8.5.6	**Control of changes**		
			The organization ***shall*** review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.		Control of Design and Development Changes & Configuration Management (Aerospace) - QP-0025 Management of Change – WI-0842
AS			Persons authorized to approve production or service provision changes ***shall*** be identified.		Authorized Personnel - WI-0168
			NOTE: Production or service provision changes can include the changes affecting processes, production equipment, tools, or software programs.		
			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.		Control of Design and Development Changes & Configuration Management (Aerospace) - QP-0025 Management of Change – WI-0842 Record Retention Procedure - QP-0004
IATF			**8.5.6.1**	**Control of changes – supplemental**	
				The organization ***shall*** have a documented process to control and react to changes that impact product realization. The effects of any change, including those changes caused by the organization, the customer, or any supplier, ***shall*** be assessed.	Management of Change, WI-0842 Design & Development -QP-0046 Process Control – QP-0019
				The organization ***shall***:	Management of Change, WI-0842 Design & Development -QP-0046
				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.		
				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		Management of Change, WI-0842 Design & Development -QP-0046

				process) to validate the impact of any changes on the manufacturing process.		
				When required by the customer, the organization ***shall***:		Design & Development -QP-0046
				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**	
					The organization ***shall*** identify, document, and maintain a list of the process controls, including Inspection, measuring, test, and error-proofing devices. The list of process controls shall include the primary process controls and the approved back-up or alternate methods, if back-up or alternate methods exist.	Where applicable, alternative methods of process control are documented in Control Plans.

					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.	Process Control – QP-0019 Temporary Deviation to Documents and Processes – QP-0087
					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.	Temporary Deviation to Documents and Processes – QP-0087

					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.	Temporary Deviation to Documents and Processes – QP-0087
					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.	Temporary Deviation to Documents and Processes – QP-0087
					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).	Temporary Deviation to Documents and Processes – QP-0087
	8.6	**Release of products and services**				
		The organization ***shall*** implement planned arrangements at appropriate stages, to verify that the product and service requirements have been met.				Process Control Procedure – QP-0019 Raw Material Receiving Procedure QP-0057 (Indy) Releasing Raw Materials for Production Use WI-0054 (Newark)

		The release of products and services to the customer ***shall*** not proceed until the planned arrangements a have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.				Process Control Procedure – QP-0019
		The organization ***shall*** retain documented information on the release of products and services. The documented information ***shall*** include:				General Inspection and Testing (Indy) QP-0002 General Inspection and Testing (Newark) QP-0028
		a) evidence of conformity with the acceptance criteria;				
		b) traceability to the person(s) authorizing the release.				
AS		When required to demonstrate product qualification, the organization ***shall*** ensure that retained documented information provides evidence that the products and services meet the defined requirements.				General Inspection and Testing (Indy) QP-0002
		The organization ***shall*** ensure that all documented information required to accompany the products and services are present at delivery.				General Inspection and Testing (Indy) QP-0002 Order Entry & Processing Procedure – QP-0037
IATF		**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).	Process Control – QP-0019
			The organization ***shall*** ensure that the planned arrangements for initial release of products and services encompass product or service approval.	Process Control – QP-0019
			The organization ***shall*** ensure that product or service approval is accomplished after changes following initial release, according to ISO 9001, Section 8.5.6.	Process Control – QP-0019
		8.6.2	**Layout inspection and functional testing**	
			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.	Product Approval Process - QP-0040
			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.	
		8.6.3	**Appearance items**	N/A
			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.	

		8.6.4	**Verification and acceptance of conformity of externally provided products and services**	
			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:	Purchasing Process – QP-0072
			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.	
		8.6.5	**Statutory and regulatory conformity**	
			Prior to release of externally provided products into its production flow, the organization shalt 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.	Purchasing Process – QP-0072
		8.6.6	**Acceptance criteria**	
			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).	Advanced Product Quality Planning - QP-0001

	8.7	**Control of nonconforming outputs**	

		8.7.1	The organization ***shall*** ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.	Nonconformance Control Procedure – Indianapolis – QP-0020 Nonconformance Control Procedure – Newark – QP-0081
AS			**NOTE:** The term "nonconforming outputs" includes nonconforming product or service generated internally, received from an external provider, or identified by a customer.	
			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.	Nonconformance Control Procedure – Indianapolis – QP-0020 Nonconformance Control Procedure – Newark – QP-0081 Corrective/Preventive Action Process Environmental, Internal and Supplier Procedure – QP-0017 Customer Corrective Action Process Procedure – QP-0055
AS			The organization's nonconformity control process ***shall*** be maintained as documented information including the provisions for:	Corrective/Preventive Action Process Environmental, Internal and Supplier Procedure – QP-0017 Customer Corrective Action Process Procedure – QP-0055 Nonconformance Control Procedure – Indianapolis – QP-0020
			− defining the responsibility and authority for the review and disposition of nonconforming outputs and the process for approving persons making these decisions;	
			− taking actions necessary to contain the effect of the nonconformity on other processes, products, or services;	
			− timely reporting of nonconformities affecting delivered products and services to the customer and to relevant interested parties;	
			− defining corrective actions for nonconforming products and services detected after delivery, as appropriate to their impacts (see 10.2).	
			NOTE: Interested parties requiring notification of nonconforming products and services can include external providers, internal organizations, customers, distributors, and regulatory authorities.	
			The organization ***shall*** deal with nonconforming outputs in one or more of the following ways:	Nonconformance Control Procedure – Indianapolis – QP-0020 Nonconformance Control Procedure – Newark – QP-0081

			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.	
AS			Dispositions of use-as-is or repair for the acceptance of nonconforming products ***shall*** only be implemented:	Nonconformance Control Procedure – Indianapolis – QP-0020 Material Review Board Procedure – QP-0026
			− after approval by an authorized representative of the organization responsible for design or by persons having delegated authority from the design organization;	
			− after authorization by the customer, if the nonconformity results in a departure from the contract requirements.	
			Product dispositioned for scrap ***shall*** be conspicuously and permanently marked, or positively controlled, until physically rendered unusable.	Nonconformance Control Procedure – Indianapolis – QP-0020
			Counterfeit, or suspect counterfeit, parts ***shall*** be controlled to prevent reentry into the supply chain.	Nonconformance Control Procedure – Indianapolis – QP-0020

			Conformity to the requirements ***shall*** be verified when nonconforming outputs are corrected.		Material Review Board Procedure – QP-0026

IATF			**8.7.1.1**	**Customer authorization for concession**	
				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.	Material Review Board Procedure – QP-0026
				The organization ***shall*** obtain customer authorization prior to further processing for "use as is" and for repair (see 8.7.1.5) of nonconforming product. II sub-components are reused in the manufacturing process, that subcomponent reuse ***shall*** be clearly communicated to the customer in the concession or deviation permit.	Nonconformance Control Procedure – Newark – QP-0081
				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 property identified on each shipping container (this applies equally to purchased product). The organization ***shall*** approve any requests from suppliers before submission to the customer.	Nonconformance Control Procedure – Newark – QP-0081
			8.7.1.2	**Control of nonconforming product – customer-specified process**	
				The organization ***shall*** comply with applicable customer-specified controls for nonconforming product(s).	Material Review Board Procedure – QP-0026
			8.7.1.3	**Control of suspect product**	

				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	Nonconformance Control Procedure – Indianapolis – QP-0020 Nonconformance Control Procedure – Newark – QP-0081
			8.7.1.4	**Control of reworked product**	

				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.	Material Review Board Procedure – QP-0026
				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.	
			8.7.1.5	**Control of repaired product**	

				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.	Material Review Board Procedure – QP-0026
				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 reinspection 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.	
			8.7.1.6	**Customer notification**	
				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	Nonconformance Control Procedure – Indianapolis – QP-0020 Nonconformance Control Procedure – Newark – QP-0081
			8.7.1.7	**Nonconforming product disposition**	
				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,	Nonconformance Control Procedure – Indianapolis – QP-0020 Nonconformance Control Procedure – Newark – QP-0081

				The organization ***shall*** not divert nonconforming product to service or other use without prior customer approval.	Material Review Board Procedure – QP-0026
		8.7.2	The organization ***shall*** retain documented information that:		Nonconformance Control Procedure – Indianapolis – QP-0020 Nonconformance Control Procedure – Newark – QP-0081 Material Review Board Procedure – QP-0026 Corrective / Preventive Action Process – QP-0017 Customer Corrective Action Process – QP-0055
			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.		

9	**Performance evaluation**			
	9.1	**Monitoring, measurement, analysis and evaluation**		
		9.1.1	**General**	
			The organization ***shall*** determine:	Monitor, Measure, Analysis, Evaluation & Process Studies - QP-0014
			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 analysed and evaluated.	

			The organization ***shall*** evaluate the performance and the effectiveness of the quality management system.		Monitor, Measure, Analysis, Evaluation & Process Studies - QP-0014
			The organization ***shall*** retain appropriate documented information as evidence of the results.		Record Retention Procedure - QP-0004
IATF			**9.1.1.1**	**Monitoring and measurement of manufacturing processes**	
				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.	Process Control - QP-0019
				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:	Process Control – QP0019
				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.	Process Control – QP0019 Record Retention Procedure - QP-0004
			9.1.1.2	**Identification of statistical tools**	
				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.	Advanced Product Quality Planning - QP-0001
			9.1.1.3	**Application of statistical concepts**	
				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.	Implementation and Control of Statistical Techniques - QP-0023

		9.1.2	**Customer satisfaction**		
			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.		Customer Satisfaction – QP-0015 Monitor, Measure, Analysis, Evaluation & Process Studies - QP-0014
			NOTE Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, meetings with customers, marketshare analysis. Compliments, warranty claims and dealer reports.		
AS			Information to be monitored and used for the evaluation of customer satisfaction ***shall*** include, but is not limited to, product and service conformity, on-time delivery performance, customer complaints, and corrective action requests. The organization ***shall*** develop and implement plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results.		Customer Satisfaction – QP-0015
IATF			**9.1.2.1**	**Customer satisfaction – supplemental**	
				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.	Monitor, Measure, Analysis, Evaluation & Process Studies - QP-0014
				Performance indicators ***shall*** be based on objective evidence and include but not be limited to the following:	Customer Satisfaction – QP-0015 Monitor, Measure, Analysis, Evaluation & Process Studies - QP-0014
				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.	Management Review – QP-0003
		9.1.3	**Analysis and evaluation**		
			The organization shall analyze and evaluate appropriate data and information arising from monitoring and measurement.		Monitor, Measure, Analysis, Evaluation, & Process Studies - QP-0014
		Note:	Appropriate data can include information on product and service problems reported by external sources (e.g. government/industry alerts, advisories).		
			The results of analysis shall be used to evaluate:		Monitor, Measure, Analysis, Evaluation, & Process Studies - QP-0014
			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;		
			g. the need for improvements to the quality management system.		

			NOTE: Methods to analyze data can include statistical techniques.		
IATF			**9.1.3.1**	**Prioritization**	
				Trends in quality and operational performance **shall** be compared with progress towards objectives and lead to action to support prioritization of actions for improving customer satisfaction.	Management Review – QP-0003

	9.2	**Internal audit**			
		9.2.1	The organization ***shall*** conduct internal audits at planned intervals to provide information on whether the quality management system:		Internal Audit Procedure - QP-0016
			a) conforms to:		
				1) the organization's own requirements for its quality management system;	
AS				**NOTE:** The organization's own requirements should include customer and applicable statutory and regulatory quality management system requirements.	
				2) the requirements of this International Standard;	
			b) is effectively implemented and maintained.		
AS		**NOTE:**	When conducting internal audits, performance indicators can be evaluated to determine whether the quality management system is effectively implemented and maintained.		
		9.2.2	The organization ***shall***:		Internal Audit Procedure - QP-0016

			a) plan, establish, implement and maintain an audit program(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;		Internal Audit Procedure - QP-0016
			e) take appropriate correction and corrective actions without undue delay;		
			f) retain documented information as evidence of the implementation of the audit program and the audit results.		Internal Audit Procedure - QP-0016 Record Retention Procedure - QP-0004
			NOTE See ISO 19011 for guidance.		
IATF			**9.2.2.1**	**Internal audit programme**	

				The organization ***shall*** have a documented internal audit process. The process ***shall*** include the development and implementation of an internal audit programme that covers the entire quality management system including quality management system audits, manufacturing process audits, and product audits.	Internal Audit Procedure - QP-0016,
				The audit programme ***shall*** be prioritized based upon risk, internal and external performance trends, and criticality of the process(es).	Internal Audit Procedure - QP-0016
				Where the organization is responsible for software development, the organization ***shall*** include software development capability assessments in their internal audit programme.	N/A
				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 programme ***shall*** be reviewed as a part of management review.	Internal Audit Procedure - QP-0016
			9.2.2.2	**Quality management system audit**	

				The organization ***shall*** audit all quality management system processes over a three-year audit cycle, 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.	Internal Audit Procedure - QP-0016

				The complete audit cycle remains three years in length. The quality management system audit frequency for individual processes, audited within the three-year audit cycle, shall be based upon internal and external performance and risk. Organizations shall maintain justification for the assigned audit frequency of their processes. All processes are required to be sampled throughout the three-year audit cycle and audited to all applicable requirements in the IATF 16949 standard, including ISO 9001 base requirements, and any customer-specific requirements.	Internal Audit Procedure – QP-0016
			9.2.2.3	**Manufacturing process audit**	
				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.	Internal Audit Procedure - QP-0016,
				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.	Internal Audit Procedure - QP-0016
				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.	Internal Audit Procedure - QP-0016
			9.2.2.4	**Product audit**	
				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	Internal Audit Procedure - QP-0016,

				organization ***shall*** define the approach to be used.	
	9.3	**Management Review**			
		9.3.1	**General**		
			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.		Management Review – QP-0003
IATF			**9.3.1.1**	**Management review – supplemental**	
				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 performancerelated issues.	Management Review – QP-0003
		9.3.2	**Management review inputs**		
			The management review ***shall*** be planned and carried out taking into consideration:		Management Review – QP-0003
			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;	
				7) the performance of external providers;	
AS				8. on-time delivery performance;	
			d) the adequacy of resources;		
			e) the effectiveness of actions taken to address risks and opportunities (see .6J.);		
			f) opportunities for improvement.		
IATF			**9.3.2.1**	**Management review inputs -- supplemental**	
				Inputs to management review ***shall*** include:	Management Review – QP-0003
				a) cost of poor quality (cost of Internal and external nonconformance),	
				b) measures of process effectiveness;	
				c) measures of process efficiency for product realization processes, as applicable;	
				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 of 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	
				l) summary results of measurements at specified stages during the design and development of products and processes, as applicable.	
		9.3.3	**Management review outputs**		
			The outputs of the management review ***shall*** include decisions and actions related to:		Management Review – QP-0003
			a) opportunities for improvement;		
			b) any need for changes to the quality management system;		
			c) resource needs.		
AS			d. risks identified.		
			The organization ***shall*** retain documented information as evidence of the results of management reviews.		Management Review – QP-0003 Record Retention Procedure – QP-0004
IATF			**9.3.3.1**	**Management review outputs – supplemental**	
				Top management ***shall*** document and implement an action plan when customer performance targets are not met.	Management Review – QP-0003

10	**Improvement**		
	10.1	**General**	
		The organization ***shall*** determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction.	Continual Improvement – QP-0038
		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 reorganization.			
	10.2	**Nonconformity and corrective action**			
		10.2.1	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;	Corrective/Preventive Action Process Environmental, Internal and Supplier Procedure – QP-0017 Customer Corrective Action Process Procedure – QP-0055 Nonconformance Control Procedure (Indy) QP-0020 Nonconformance Control Procedure (Newark); - QP-0081
				2) deal with the consequences;	Corrective/Preventive Action Process Environmental, Internal and Supplier Procedure – QP-0017 Customer Corrective Action Process Procedure – QP-0055 Material Review Board Procedure QP-0026 Nonconformance Control Procedure (Indy) QP-0020 Nonconformance Control Procedure (Newark); - QP-0081

			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;	Corrective/Preventive Action Process Environmental, Internal and Supplier Procedure – QP-0017 Customer Corrective Action Process Procedure – QP-0055 Material Review Board Procedure - QP-0026
			2) determining the causes of the nonconformity; including, as applicable, those related to human factors;	Corrective/Preventive Action Process Environmental, Internal and Supplier Procedure – QP-0017 Customer Corrective Action Process Procedure – QP-0055
			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;	Corrective/Preventive Action Process Environmental, Internal and Supplier Procedure – QP-0017 Customer Corrective Action Process Procedure – QP-0055
			f) make changes to the quality management system, if necessary.	Corrective/Preventive Action Process Environmental, Internal and Supplier Procedure – QP-0017
AS			g. flow down corrective action requirements to an external provider when it is determined that the external provider is responsible for the nonconformity;	Corrective/Preventive Action Process Environmental, Internal and Supplier Procedure – QP-0017
			h. take specific actions when timely and effective corrective actions are not achieved.	Corrective/Preventive Action Process Environmental, Internal and Supplier Procedure – QP-0017 Customer Corrective Action Process Procedure – QP-0055
			Corrective actions ***shall*** be appropriate to the effects of the nonconformities encountered.	Corrective/Preventive Action Process Environmental, Internal and Supplier Procedure – QP-0017 Customer Corrective Action Process Procedure – QP-0055

AS			The organization ***shall*** maintain documented information that defines the nonconformity and corrective action management processes.	Record Retention Procedure – QP-0004
		10.2.2	The organization ***shall*** retain documented information as evidence of:	Record Retention Procedure – QP-0004
			a) the nature of the nonconformities and any subsequent actions taken;	Corrective/Preventive Action Process Environmental, Internal and Supplier Procedure – QP-0017 Customer Corrective Action Process Procedure – QP-0055 Material Review Board Report – QF-0021
			b) the results of any corrective action.	
IATF		**10.2.3**	**Problem solving**	
			The organization ***shall*** have a documented process(es) for problem solving, which prevent(s) recurrence, including.	Corrective/Preventive Action Process Environmental, Internal and Supplier Procedure – QP-0017 Customer Corrective Action Procedure – QP-0055
			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).	
			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.	Corrective/Preventive Action Process Environmental, Internal and Supplier Procedure – QP-0017 Customer Corrective Action Request – QP-0055
		10.2.4	**Error-proofing**	
			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.	Corrective/Preventive Action Process Environmental, Internal and Supplier Procedure – QP-0017 Customer Corrective Action Process Procedure – QP-0055
			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.	Corrective/Preventive Action Process Environmental, Internal and Supplier Procedure – QP-0017 Customer Corrective Action Process Procedure – QP-0055
		10.2.5	**Warranty management systems**	

			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.	N/A
		10.2.6	**Customer complaints and field failure test analysis**	
			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.	Customer Corrective Action Process Procedure – QP-0055
			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.	N/A
			The organization ***shall*** communicate the results of testing/analysis to the customer and also within the organization.	Corrective/Preventive Action Process Environmental, Internal and Supplier Procedure – QP-0017 Customer Corrective Action Process Procedure – QP-0055
	10.3	**Continual improvement**		
		The organization ***shall*** continually improve the suitability, adequacy and effectiveness of the quality management system.		Continual Improvement – QP-0038
		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.		Continual Improvement – QP-0038
AS		The organization ***shall*** monitor the implementation of improvement activities and evaluate the effectiveness of the results.		Continual Improvement – QP-0038
		NOTE: Examples of continual improvement opportunities can include lessons learned, problem resolutions, and the benchmarking of best practices.		

IATF		**10.3.1**	**Continual improvement -- supplemental**	

			The organization **shall** have a documented process for continual improvement. The organization **shall** include in this process the following:	Continual Improvement – QP-0038
			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).	Continual Improvement – QP-0038 Risk & Opportunities Management Procedure - QP-0091
			NOTE: Continual improvement is implemented once manufacturing processes are statistically capable and stable or when product characteristics are predictable and meet customer requirements.	

THE REMAINDER OF THIS DOCUMENT IS FOR INFORMATIONAL PURPOSES ONLY

Annex A
(informative)
ISO 9001:2015(E)
Clarification of new structure, terminology and concepts

A.1 Structure and terminology

The clause structure (i.e. clause sequence) and some of the terminology of this edition of this International Standard, in comparison with the previous edition (ISO 9001:2008), have been changed to improve alignment with other management systems standards.

There is no requirement in this International Standard for its structure and terminology to be applied to the documented information of an organization's quality management system.

The structure of clauses is intended to provide a coherent presentation of requirements, rather than a model for documenting an organization's policies, objectives and processes. The structure and content of documented information related to a quality management system can often be more relevant to its users if it relates to both the processes operated by the organization and information maintained for other purposes.

There is no requirement for the terms used by an organization to be replaced by the terms used in this International Standard to specify quality management system requirements. Organizations can choose to use terms which suit their operations (e.g. using "records", "documentation" or "protocols" rather than "documented information"; or "supplier", "partner" or "vendor" rather than "external provider"). Table A.1 shows the major differences in terminology between this edition of this International Standard and the previous edition.

Table A.1 — Major differences in terminology between ISO 9001:2008 and ISO 9001:2015

ISO 9001:2008	ISO 9001:2015
Products	Products and services
Exclusions	Not used (See Clause A.5 for clarification of applicability)
Management representative	Not used (Similar responsibilities and authorities are assigned but no requirement for a single management representative)
Documentation, quality manual, documented procedures, records	Documented information
Work environment	Environment for the operation of processes
Monitoring and measuring equipment	Monitoring and measuring resources
Purchased product	Externally provided products and services
Supplier	External provider

A.2 Products and services

ISO 9001:2008 used the term "product" to include all output categories. This edition of this International Standard uses "products and services". "Products and services" include all output categories (hardware, services, software and processed materials).

The specific inclusion of "services' is intended to highlight the differences between products and services in the application of some requirements. The characteristic of services is that at least part of the output is realized at the

interface with the customer. This means, for example. that conformity to requirements cannot necessarily be confirmed before service delivery.

In most cases, products and services are used together. Most outputs that organizations provide to customers, or are supplied to them by external providers, include both products and services. For example. a tangible or intangible product can *have* some associated service or a service can have some associated tangible or intangible product.

A.3 Understanding the needs and expectations of interested parties

Subclause 4.2 specifies requirements for the organization to determine the interested parties that are relevant to the quality management system and the requirements of those interested parties. However, .4.2 does not imply extension of quality management system requirements beyond the scope of this International Standard. As stated in the scope, this International Standard is applicable where an organization needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and aims to enhance customer satisfaction.

There is no requirement in this International Standard for the organization to consider interested parties where it has decided that those parties are not relevant to its quality management system. It is for the organization to decide if a particular requirement of a relevant interested party is relevant to its quality management system.

A.4 Risk-based thinking

The concept of risk-based thinking has been implicit in previous editions of this International Standard, e.g. through requirements for planning, review and improvement. This International Standard specifies requirements for the organization to understand its context (see 4.1.) and determine risks as a basis for planning (see 6.1). This represents the application of risk-based thinking to planning and implementing quality management system processes (see 4.4) and will assist in determining the extent of documented information.

One of the key purposes of a quality management system is to act as a preventive tool. Consequently, this International Standard does not have a separate clause or subclause on preventive action. The concept of preventive action is expressed through the use of risk-based thinking in formulating quality management system requirements.

The risk-based thinking applied in this International Standard has enabled some reduction in prescriptive requirements and their replacement by performance-based requirements. There is greater flexibility than in ISO 9001:2008 in the requirements for processes, documented information and organizational responsibilities.

Although 6.l specifies that the organization ***shall*** plan actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process. Organizations can decide whether or not to develop a more extensive risk management methodology than is required by this International Standard, e.g. through the application of other guidance or standards.

Not all the processes of a quality management system represent the same level of risk in terms of the organization's ability to meet its objectives, and the effects of uncertainty are not the same for all organizations. Under the requirements of.6.1 the organization is responsible for its application of risk-based thinking and the actions it takes to address risk, including whether or not to retain documented information as evidence of its determination of risks.

Within aviation, space, and defense, risk is expressed as a combination of severity and likelihood of having a potential negative impact to processes, products, services, customer, or end users.

Due to the complexity of aviation, space, and defense processes, products, and services, and the severity of the potential consequences of failures, a formal process to manage operational risks is required in clause 8.1.1. The operational risk management process is supported by specific requirements throughout clause 8, with the goal of developing an enhanced focus on:

- understanding risk impacts on operational processes;
- making decisions on operational processes and actions to manage (e.g., prevent, mitigate, control) potential undesired effects.

A.5 Applicability

This International Standard does not refer to "exclusions" in relation to the applicability of its requirements to the organization's quality management system. However, an organization can review the applicability of requirements due to the size or complexity of the organization. the management model it adopts, the range of the organization's activities and the nature of the risks and opportunities it encounters.

The requirements for applicability are addressed in 4.3 which defines conditions under which an organization can decide that a requirement cannot be applied to any of the processes within the scope of its quality management system. The organization can only decide that a requirement is not applicable if its decision will not result in failure to achieve conformity of products and services.

A.6 Documented information

As part of the alignment with other management system standards. a common clause on "documented information" has been adopted without significant change or addition (see L.S.). Where appropriate, text elsewhere in this International Standard has been aligned with its requirements. Consequently, "documented information" is used for all document requirements.

Where ISO 9001:2008 used specific terminology such as "document" or "documented procedures", "quality manual" or "quality plan", this edition of this International Standard defines requirements to "maintain documented information".

Where ISO 9001:2008 used the term "records" to denote documents needed to provide evidence of conformity with requirements, this is now expressed as a requirement to "retain documented information". The organization is responsible for determining what documented information needs to be retained, the period of time for which it is to be retained and the media to be used for its retention.

A requirement to "maintain" documented information does not exclude the possibility that the organization might also need to "retain" that same documented information for a particular purpose, e.g. to retain previous versions of it.

Where this International Standard refers to "information" rather than "documented information" (e.g. in 4.1: "The organization ***shall*** monitor and review the information about these external and internal issues"), there Is no requirement that this information is to be documented. In such situations, the organization can decide whether or not it is necessary or appropriate to maintain documented information.

A.7 Organizational knowledge

In 7.l.6, this International Standard addresses the need to determine and manage the knowledge maintained by the organization. to ensure the operation of its processes and that it can achieve conformity of products and services.

Requirements regarding organizational knowledge were introduced for the purpose of: a)
safeguarding the organization from loss of knowledge. e.g.
-through staff turnover;
-failure to capture and share information;
b) encouraging the organization to acquire knowledge, e.g.
- learning from
experience; - mentoring; -
benchmarking.

A.8 Control of externally provided processes, products and services

All forms of externally provided processes, products and services are addressed in M e.g. whether through: a)
purchasing from a supplier;
b) an arrangement with an associate company;
c) outsourcing processes to an external provider.

Outsourcing always has the essential characteristic of a service, since it will have at least one activity necessarily performed at the interface between the provider and the organization.

The controls required for external provision can vary widely depending on the nature of the processes, products and services. The organization can apply risk-based thinking to determine the type and extent of controls appropriate to particular external providers and externally provided processes, products and services.

IATF Annex A: Control Plan

A.1 Phase of the control plan

A control plan covers three distinct phases, as appropriate:

a) Prototype: a description of the dimensional measurements, material, and performance tests that will occur during building of the prototype. The organization ***shall*** have a prototype control plan, if required by the customer.

b) Pre-launch: a description of the dimensional measurements, material, and performance tests that occur after prototype and before full production. Pre-launch is defined as a production phase in the process of product realization that may be required after prototype build.

e) Production: documentation of product/process characteristics, process controls, tests, and measurement systems that occur during mass production. Control plans are established at a part number level; but in many cases, family control plans may cover a number of similar pans produced using a common process. Control plans are an output of the quality plan.

NOTE 1: It is recommended that the organization require its suppliers to meet the requirements of this Annex.

NOTE 2 For some bulk materials, the control plans do not list most of the production information This information can be found in the corresponding batch formulation/recipe details.

A.2 Elements of the control plan

A control plan includes, as a minimum, the following contents:

General data

a) control plan number;
b) issue date and revision date, if any;
c) customer information (see customer requirements);
d) organization's name/site designation;
e) part number{s);
f) part name/description;
g) engineering change level;
h) phase covered (prototype, pre-launch, production);
i) key contact;
j) part/process step number;
k) process name/operation description; I) functional group/area responsible.

Product control

a) product-related special characteristics;
b) other characteristics for control (number, product or process);
c) specification/tolerance,

Process control

a) process parameters (including process settings and tolerances);
b) process-related special characteristics;
c) machines, jigs, fixtures, tools for manufacturing (including Identifiers, as appropriate);

Methods

a) evaluation measurement technique;
b) error-proofing;
c) sample size and frequency;
d) control method;

Reaction plan

a) reaction plan (include or reference)