# **Understanding Automobile Industry Quality System**

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Abstract: The traditional Automobile Industry supply chain is divided into car manufacturers (OEM), first-tier suppliers (Tier 1), second-tier suppliers (Tier 2), third-tier suppliers (Tier 3), and after-market suppliers (AM). OEM is the well-known as Nissan, Ford, Volkswagen, Toyota, BMW, Benz... and other automotive brand companies. The number of complete vehicle parts is as high as 20,000 to 30,000, so OEMs concentrate on purchasing from Tier 1 (system integrator). Tier 1 is responsible for system integration, such as power system, transmission system, steering system, suspension system, brake system and control system, audio-visual entertainment system, etc.; according to its needs and capabilities, it can decide to make components by itself or purchase components from Tier 2 suppliers, such as tires, touch panels, airbags, air conditioners, navigation, Internet, Internet of Things, and various parts and components. Different OEMs have different methods to define its layer of suppliers by its actual operating conditions. Compared with consumer electronics industries such as mobile phones, laptops, and televisions, the automobile industry is very closed and difficult to penetrate. However, consumer electronics are gradually saturated; the proportion of automobile electronic parts has increased; after the trend of electric vehicles/self-driving cars has been determined, changes have gradually begun.

Several changes in the automobile industry are taking place at the same time, including changes in power sources (electric), driving styles (self-driving), business models (sharing/cross-industry integration) ...etc. For the development of companies, whether they keep up with this wave of trends is the key to future development and growth, this is not a topic that the author can discuss. However, from the supplier chain: purchasing, production controlling, incoming, production and shipping to the demand chain: ordering, logistics delivery, retail, and maintain service, it can integrate the all processes to be a value chain through computation, communication, controlling, collaboration and real time response. The quality requirements of all processes of the value chain would be much more transparent. As the demand chain, product and service will be required more accurate, speedy, reliable, safety, ecological, and environmental. As the supplier chain, the product and service will be required more easily to design, manufacture, change, transport, maintain, recycle and trace. This also means that more industries and individual companies will have to pass the certifications of various systems due to the requirements of the automobile industry supply chain customers, especially the quality management system requirements. This article aims to introduce how OEMs in the automobile industry require their supply chains to comply with quality management systems.

**Keyword:** APQP, IATF, AIAG, VDA, functional safety.

## I. Introduction

In response to the revision of ISO 9000:1994, the three major US automobile companies (GM, Ford and Chrysler) based on ISO 9000:1994, integrated the quality system requirements of suppliers of GM's "NAO Targets for Excellence", Ford's "Q-101 Quality System Standard" and Chrysler's "Supplier Quality Assurance Manual", and then the first version of the quality system requirements QS 9000 was issued in August 1994. They place extremely strict requirements on suppliers, including quality, service, price and technology. In order to achieve continuous improvement, prevent defects, reduce waste and maintain stable quality, the three major US automobile companies have put forward clear quality assurance requirements for suppliers. In other words, to supply the products/components to them and be their suppliers, suppliers must meet the requirements of the QS 9000 standard. Its requirements include: Part 1: Requirements based on ISO 9000; Part 2: Specific requirements of customers and the following five core tools:

- (1) APQP: Advanced Product Quality Planning and Control Plan
- (2) FMEA: Failure Mode Effects Analysis
- (3) MSA: Measurement System Analysis
- (4) SPC: Statistical Process Control
- (5) PPAP: Production Parts Approval Process

The second edition was released in February 1995 and the third edition was released in March 1998. As QS 9000 was recognized by more and more automobile OEMs, many OEMs had put forward QS 9000 requirements to their suppliers, making QS 9000 certification flourish. Once suppliers pass QS 9000 certification, they can simultaneously obtain certificate of ISO 9001 or ISO 9002. However, only passing ISO 9000 do not guarantee that it will pass QS 9000. There are many supplementary provisions of QS 9000 which still need to be reviewed.

Since automobile suppliers have passed the QS 9000 quality system certification, their certificates cannot be recognized in all countries around the world. In order to reduce unnecessary waste of resources for automobile suppliers and facilitate the implementation of global purchasing strategies by automobile companies. The representatives of the International Automobile Task Force (IATF), ISO/TC 176, the quality management and quality assurance committee and its subcommittees, integrated QS 9000 (US), VDA6.1 (Germany), EAQF94 (France) and AVSQ95 (Italy) and other quality system requirements, formulated the ISO/TS 16949 technical specifications, and had been issued in 1999 for application.

The copyright of this standard is owned by ANFIA in Italy, CFA/FIEV in France, VDA in Germany and GM, Ford and Chrysler in the United States. ISO/TS 16949 is an international technical specification, its purpose is similar to QS 9000 and VDA 6.1.

The IATF revised ISO/TS 16949 and included the ISO 9001:2000 version in 2002. ISO/TS 16949 technical specifications are in line with the current automobile quality system requirements in the global automobile industry, and can avoid multiple certification audits. The release of ISO/TS 16949 technical specifications can be temporarily applied by the automobile industry to collect information and experience in use. In the ISO/TS 16949 technical specification, the text with a box as ISO 9001 is the copyright of ISO. The specific requirements of the automobile industry are outside the box. Since then, ISO/TS 16949 as a technical specification for automobile sector quality management systems, had become one of the most widely used international standards in the automobile industry, harmonizing the different assessment and certification systems in the global automobile supply chain.

On October 3rd, 2016 IATF 16949:2016 was published by the IATF and replaces the current ISO/TS 16949, defining the requirements of a quality management system for organizations in the automobile industry. The organizations which originally obtained certification of the ISO/TS 16949:2009 need to complete the revision before the deadline of ISO 9001:2015 (September 14, 2018) and obtain a third-party certification to continue to be a supply chain for the automobile industry.

IATF 16949:2016 is a high-level structure (HLS) quality management system standard based on ISO 9001:2015 (QMS requirements). It is also a process method based on the PDCA cycle of risk-based thinking. Its ultimate goal is to organize a set of quality management for the automobile supply chain to achieve continuous improvement, prevent defects, reduce waste and maintain stable quality. It is expected that all automobile supply chain organizations, except bulk basic raw materials (such as suppliers of iron ore, coal, and scrap steel), must obtain IATF 16949 third party certification. Figure 1 shows the status of the distribution of third-party certification issued by AIAG on the Internet as of the transition period ending January 31, 2018. There are about 68,355 certificates worldwide, the distribution of different regions: Asia Pacific 46,764 sites 68.41%, Europe 11.577 sites 16.94%, North America 6,226 sites 9.11%, Middle East 1,769 Sites 2.59%, South & Central America 1,508 Sites 2.21% and Africa 509 sites 0.74%. Top ten number of certified sites of IATF 16949 certificates before August 31, 2018, as shown in Table 1. [1]

#### AIAG\_ Global IATF Certificate Distribution Distribution of the 68,355 ISO/TS 16949 and IATF 16949 certified sites as of 31st January 2018 EUROPE 11577 sites 16.94 % of worldwide total GERMANY 3280 NORTH AMERICA **ITALY 1406** ASIA PACIFIC 6226 sites FRANCE 981 46764 sites % of worldwide total **SPAIN 943** 68.41 % of worldwide total UNITED STATES 4067 CZECH REPUBLIC 747 MEXICO 1660 UK 640 **CHINA 30555** POLAND 666 CANADA 492 REP. OF KOREA 5189 INDIA 5305 MIDDLE EAST **JAPAN 1533** THAILAND 1532 1769 sites SOUTH & CENTRAL TAIWAN/ROC 1278 2.59 % of worldwide total **AMERICA** MALAYSIA 536 1508 sites TURKEY 952 **IRAN 767** 2.21 % of worldwide total Brazil 1182 **AFRICA** 509 sites 0.74 % of worldwide total

Figure 1: The distribution of different regions

Table 1: Top ten number of certified sites of IATF 16949 certificates before August 31, 2018

Rank	Year Country	2015/12	2016	2017	2018/1	2018/6	2018/8
	Total of Certified Sites	62942	67358	68620	68355	66965	66663
1	China	25498	27998	30255	30555	30495	30712
2	India	4992	5222	5338	5305	5171	5086
3	Korea	5089	5275	5337	5189	4834	4646
4	Unite State	4345	4333	4169	4067	3886	3816
5	Germany	3473	3479	3326	3280	3128	3058
6	Mexico	1441	1542	1640	1660	1638	1626
7	Japan	1482	1512	1531	1533	1525	1520
8	Thailand	1468	1520	1552	1532	1496	1513
9	Italy	1345	1399	1367	406	391	1386
10	Taiwan	1323	1381	1402	1278	1248	1248

The members of IATF are composed of 9 European and American automobile manufacturers and 5 national supervision agencies, as shown in Figure 2. The 9 OEM members include:

- BMW Group
- FAC US LLC
- FCA Italy Spa
- Daimler AG
- Ford Motor Company
- General Motors
- PSA Group
- Renault
- Volkswagen AG

The 5 national supervision units are:

- AIAG (Automobile Industry Action Group)
- ANFIA (Associazione Nazionale Fra Industrie Automobilistiche)
- FIEV (Fédération des industries des équipments pour véhicules)
- SMMT (Society of Motor Manufacturers and Traders)
- VDA (Verband der Automobilindustrie)

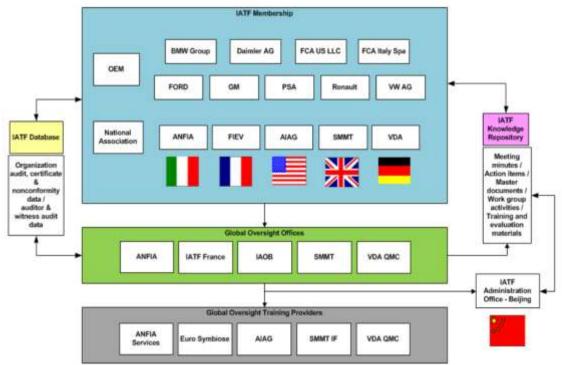


Figure 2: IATF membership architecture

Under this framework, the IATF will manage and supervise the certification body's responsibilities, and delegate the following supervision units:

- ANFIA
- IATF France
- IAOB (International Automobile Oversight Bureau)
- SMMT
- VDA QMC

As can be seen from the above, the IATF is a joint European and American organization responsible for formulating the IATF 16949 standard. VDA QMC is one of IATF-accredited certification body, and its management is located in Germany. AIAG is also one of IATF-accredited training unit, which provides enterprises with training and management and login auditor qualifications. To summarize the history of IATF 16949 standard development, please refer to Figure 3.

# Understand IATF 16949 2016

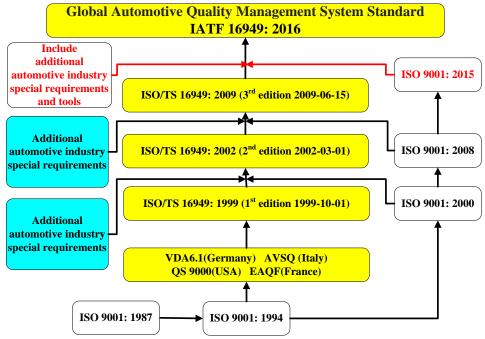


Figure 3: History of IATF 16949 standard development

# II. Supply Chain for the Automobile Industry

Automobile is an industrial product with a long history and higher complexity. Taking ordinary passenger cars as an example, a car has more than 8,000 subassemblies and near 30,000 components. Among them, automobile electronics play an important role. Automobile electronics can be divided into two categories. One is the control device integrated with mechanical components, such as power transmission (electronic ignition, automatic transmission), sensors (pressure, temperature, image), safety (collision-proof radar) and other electronic systems; another type is an electronic device that can be used independently, such as satellite navigation and audio-visual entertainment systems. The development of the ICT industry has also evolved from  $3G \rightarrow 4G \rightarrow 5G$ , especially the era of internet vehicles has come, many traditional industries have gradually transformed from the ICT industry to the supply chain of the automobile industry. This is also an inevitable trend, shown as Figure 4: ICT in the automobile industry.

In terms of the supply chain of the automobile industry, the classification of its new products is divided into the following types by shipping packaging:

- (1) CBU (Complete Build Unit): models for vehicle development and packaging export;
- (2) CKD (Complete Knock-Down): shipment of automobile parts for certain vehicles from the manufacturing plant for these vehicles to plants in different countries where they are assembled;
- (3) SKD (Semi-complete Knock-Down): this package consists of dismantling and packaging up certain parts of a vehicle for shipment to other assembly plants where the parts will then be re-assembled;
- (4) IKD (Incomplete Knock-Down): The production line in the factory is not assembled, based on the import tariff limit of the buyer's country, it is directly exported as subassemblies or components.

As the development process is divided into the following types:

- (1) NM (New Model): a newly developed model;
- (2) MC (Model Change): Most of the performance mechanism or shape of the extended model has changed;
- (3) MMC (Min. Model Change): The extension model of assembly and configuration or a small part of the modeling change.



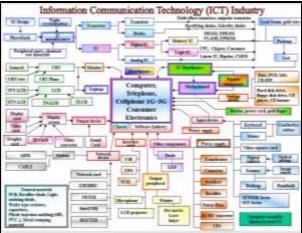


Figure 4: ICT in the automobile industry

The suppliers of each stage of the automobile supply chain system are classified according to the degree of product integration, as shown in Table 2. Please also refer to Figure 5: Schematic diagram of automobile related components and Figure 6: Schematic diagram of automobile electronics.

Table 2: Stage of Supplier Chain

Stage of Suppliers	Feature				
ОЕМ	In general, OEM is automobile original equipment manufacturers, but some of component manufacturers have design, brand, innovation and other capabilities are also included.				
Tier 1	Tier 1 suppliers are companies that supply parts or systems directly to OEMs.				
Tier 2	Tier 2 suppliers are often experts in their specific domain, but they also support a lot of non-automobile customers.				
Tier 3	Tier 3 refers to suppliers of raw, or close-to-raw, materials like metal or plastic.				
AfterMarket	They supply aftermarket repairs of original parts, but there are also aftermarket repairs of non-original parts.				



Figure 5: Schematic diagram of automobile related components [2]

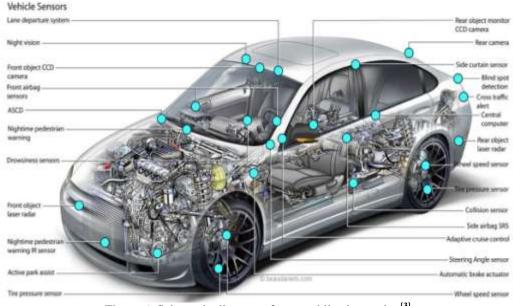


Figure 6: Schematic diagram of automobile electronics [3]

The suppliers of each stage of the automobile supply chain system also subject to extremely strict requirements on suppliers, including quality, service, price and technology. In order to achieve continuous improvement, prevent defects, reduce waste and maintain stable quality, it is still necessary to implement the Advanced Product Quality Planning (APQP), which has been popular in the automobile industry for two decades. In process of design and development of new products, all stages include OEMs, Tier 1, Tier 2, Tier 3 and Aftermarket must establish and maintain documented procedures to meet the customer's requirements. Generally, APQP is used by the automobile industry as a common reference template. APQP divides the product / process development into the planning and evaluation phase, product design development phase, process design development phase, product and process validation phase and mass production, the timeline is shown in Figure 7: Milestones of Advanced Product Quality Planning.

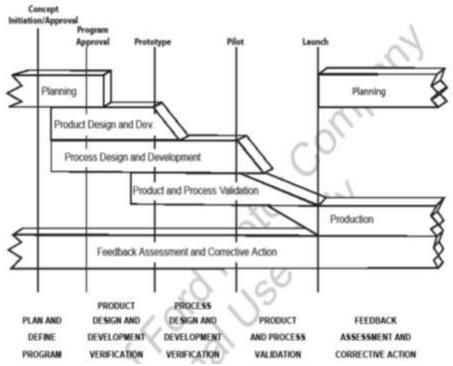


Figure 7: Milestones of Advanced Product Quality Planning

# III. Advanced Product Quality Planning

IATF 16949:2016 define the quality management system requirements of the automobile industry. In addition, there are 5 related core tools: APQP / FMEA / MSA / SPC / PPAP, and APQP is the most important core tool among them. APQP divides the product / process development into the planning and evaluation phase, product design development phase, process design development phase, product and process validation phase and mass production. The inter-relationship diagram of the quality methodologies applied at each stage of APQP, is shown in Figure 8.

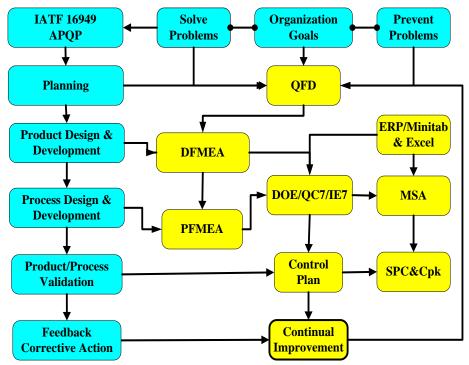


Figure 8: inter-relationship diagram of the quality methodologies of APQP

APQP mainly interprets that a product / process development should establish a complete quality planning and control plan from R&D to mass production, to define the activities at each phase to ensure the planning and evaluation phase, product design development phase, process design development phase, product and process validation phase and mass production can effectively operate. It is to implement the spirit of continuous improvement.

Product quality planning can be applied to three types of suppliers: suppliers responsible for design / production; suppliers responsible for production only; suppliers responsible for providing services (such as heat treatment, storage, transportation, etc.) Basic principles of product quality planning: product quality planning is a structured method; the main purpose is to establish planning steps and required timelines to meet customer needs. Effective product quality planning depends on the efforts of top management to achieve the promise of customer satisfaction, the benefits of quality planning are as follows:

- To direct resources to satisfy the customer.
- To promote early identification of required changes.
- To avoid late changes.
- To provide a quality product on time at the lowest cost.

The supplier first step in product quality planning is to assign a process owner for the APQP project. In addition, a cross functional team should be established to assure effective product quality planning. The team should include representatives from multiple functions such as sales, R&D, manufacturing, material control, purchasing, quality, suppliers, and customers, as appropriate. And in the Simultaneous Engineering mode, APQP team members participate in the quality planning of the product from R & D to mass production at each stage, perform various tasks, and promote the introduction of high-quality products as early as possible.

During the planning period, the team will encounter many product and process design problems. These problems should be recorded on a matrix with specified responsibilities and time schedules. In difficult cases, it is recommended to use a multi-party argumentation method. For problem analysis techniques, the appendix B of the reference manual can be used. The methods and an example of APQP related operations are listed as follows and in Table 3. [4]

- Bench marking
- Cause and Effect Diagram
- PERT / Gantt Chart
- Design of Experiment (DOE)
- Manufacturability
- Design Verification Plan and Report (DVP&R)
- Mistake-proof
- Flow Chart
- Quality Function Deployment (QFD)
- Failure Mode and Effect Analysis (FMEA)

Table 3: an example of APQP related operations

			1		· · ·	1		P related operations			
STAGE	TASKS	SALES	R&D	QUALITY	PROD.	PURCHAS E	APQP Team	DESIGN REVIEWS	DOCUMENTS		
ning	1.Sample Requirement	•					$\Diamond$	1.Project Launch	1.Capacity Analysis		
	2.Capacity Analysis	$\Diamond$	•					2.Project Review	2.Development Schedule		
	3.Design Planning		<b>*</b>					3.Special Product and	3. Preliminary Process Flow Chart		
	4.Preliminary BOM	$\Diamond$	<b>*</b>				$\Diamond$	Process Characteristics			
	5.Preliminary Process	$\Diamond$	$\Diamond$	$\Diamond$	$\sim$	$\stackrel{\sim}{\diamond}$	$\stackrel{\sim}{\diamond}$	4.Capacity Analysis Review			
<b>[2a</b> ]			$\stackrel{\vee}{lack}$	$\stackrel{\vee}{\diamond}$	_	$\times$	$\stackrel{\sim}{\circ}$	5.Feasibility Assessment	5.QFD		
I	5.QFD	$\Diamond$		$\vee$	$\Diamond$	$\vee$	$\vee$	, and the second	6.Feasibility Assessment		
	6.Development Schedule		•						7.Design Review Record		
	7.Design Review (1)						▼				
	1.Material Specifications		•					1.Material & Engineering	1.Development Schedule		
	2.Engineering Drawings							Specifications Review	2.Material Drawing & Specifications 3.Materials Control		
=	3.Materials Control		<b>♦</b>			$  \Diamond  $		2.Design Schedule Review			
le n	4.Prototype Build		•	$\Diamond$	$\Diamond$	$\Diamond$	$\Diamond$	3.New Materials Review			
	5.DFMEA			Ò	_ <u> </u>	Ť	Ò	4.Sample Test Review	4.Prototype Control Plan		
	6.Prototype Build		À	<u> </u>	$\Diamond$		<u> </u>	5.Sample Approval Review	5.Sample MO 6.Sample Test Report		
) se	7.Gages/Testing		_		<u> </u>			6.Prototype Control Plan			
Ď	Equipment Requirements		<b>♦</b>	$\Diamond$				7.DFMEA	7.Sample Approval Report		
ct	8.Sample Submission	$\Diamond$	•					8. New Equipment, Tooling,	8.DFMEA		
∥ đạ	*		•				ļ	Facilities Requirements	9.Material Approval		
Product Development	9.Design Review (2)						•	9. Gages/Testing	10.Team Feasibility		
1	10.5							Equipment Requirements	Commitment		
	10.Team Feasibility	$\Diamond$	$\Diamond$	$\Diamond$	$\Diamond$	$\Diamond$	•	10.Special Product and	Communent		
	Commitment		*	ľ	*	*		Process Characteristics			
	1.Packaging	$\wedge$		^	$\wedge$			1.Packaging	1.Development Schedule		
	Material/Specifications	$\Diamond$	•	$\Diamond$	$\Diamond$			Material/Specifications	2.Packaging Drawing		
	2.Quality System Review			•			$\Diamond$	2.Quality System Review	3.Quality System Review		
+-	3.Process Flow Chart		•	$\Diamond$	$\Diamond$		Ť	3.Process Flow Chart	4.Process Flow Chart		
Process Development	4.Plant Layout		$\Diamond$	ŏ	×			4.Plant Layout	5.Plant Layout		
	·		×		_			5.Mold/Tool Schedule	6. Mold/Tool Schedule		
	5.Mold/Tool Schedule		•					6.Product and Process	7.PFMEA		
e Ve	6.Special Product and	$\Diamond$	•	$\Diamond$	$\Diamond$			Characteristics	8.Pilot Run Control Plan		
Ă	Process Characteristics	•		·		-		7.PFMEA	9.Standard Operation		
SSS	7.PFMEA		•				$\Diamond$	8.Pilot Run Control Plan	J.Standard Operation		
30	8.Pilot Run Control Plan		•				$\Diamond$	9.Standard Operation			
Pr	9.Standard Operation		<b>♦</b>	$\Diamond$	$\Diamond$			10.MSA			
	10.MSA		$\Diamond$	<b>♦</b>	$\Diamond$			11 Capability Study			
								12.Process Development			
	11.Capability Study				•		$\Diamond$	Review			
<b> </b>						1		1.Pilot Run Verification	1 Dilot Dun Mosting		
	1.Pilot Run Meeting		•	$\Diamond$	$\Diamond$	$\Diamond$	$\Diamond$	2.Mass Production	1.Pilot Run Meeting Record		
			Ľ	Ľ	Ľ	Ľ	Ľ	Evaluation	2.Pilot Run Report		
								3.MSA Evaluation	4.Mass Production		
Ħ	2.Pilot Run		$\Diamond$	$\Diamond$	•			4.Product and Process	Evaluation		
<b>F</b>								Characteristics Evaluation	5.Control Plan		
Pilot Run	3.Design Review (2)			$\Diamond$	$\Diamond$	$\Diamond$		5.Packaging Evaluation	6.MSA Report		
Pil	5.2051gii 10 vie w (2)		•	~	~	~		6.Capability Study	7.Capability Study Report		
								Evaluation	8.Parts Submission Warrant		
	4.Design Review (3)								9.APQP Summary Report		
	Doorgii Roviow (3)						•		10.Product Development		
uo	1 M D 1					<del>  _   _   _   _   _   _   _   _   _   _</del>		1 E	Problem Solving Report		
	1.Mass Production		$\Diamond$	$\Diamond$	•	$\Diamond$		1.Equipment and tooling	1.Reduced variation 2.Improved customer		
	2.Design Review (3)		•	$\Diamond$	$\Diamond$	$\Diamond$		effectiveness evaluation	satisfaction		
	3.Design Review (4)				İ	1	_	2.Customer feedback	3 Improved delivery and		
Prod	J.Design Review (4)						•	information analysis review	service		
	4.Mass Production	_						3.Corrective action of	4.Lesson learned and		
	Meeting	$\Diamond$	$\Diamond$	$\Diamond$	$\Diamond$	$  \diamond  $	▼	related problems	application of best practices		
			<u> </u>		<u> </u>	1		4.Continuous Improvement	*		

#### **VDA 6.X Series**

VDA is the German Automobile Industry Association (Verband Der Automobilindustrie). It has published a series of standards that require relevant vehicle suppliers to implement or refer to. The following are related to quality majors:

- VDA 1: Documented Information and Retention
- VDA 2: Reliability Assurance for Suppliers, Production Process and Product Approval (PPA)
- VDA 3: Reliability Assurance of Car Manufacturers and Suppliers Reliability Management, Methods and Tools
- VDA 4.1: Quality Assurance Prior To Serial Application (Overview)
- VDA 4.2: Quality Assurance Prior To Serial Application (FMEA)
- VDA 4.3: Quality Assurance Prior To Serial Application (Project Planning)
- VDA 5.X: Measurement System Capability
- VDA 6.X: Certification Requirements
- VDA 7: Exchanging Quality Data
- VDA 8: Guide for quality assurance for trailer, body and truck cabinet manufacturers
- VDA 9: Emissions Fuel ConsumptionVDA 6.X quality management system certification is an extension of the automobile industry ISO 9001 required by German automobile manufacturers. Both IATF 16949 and VDA 6.X audit are derived from ISO 9001 quality management systems. VDA 6.X is divided into two areas, including the quality management system, products and processes, as shown in Figure 9. Among them, VDA 6.3: Process Audit is currently the most commonly used standard for IATF 16949 certification. There are 58 major Questionnaires in P2 ~ P7, as shown in Table 4.
- VDA 6.1: QM-System Audit (Serial Production)
- VDA 6.2: QM-System Audit (Services)
- VDA 6.3: Process Audit
- VDA 6.4: QM-System Audit (Production Equipment) VDA 6.5: Product Audit

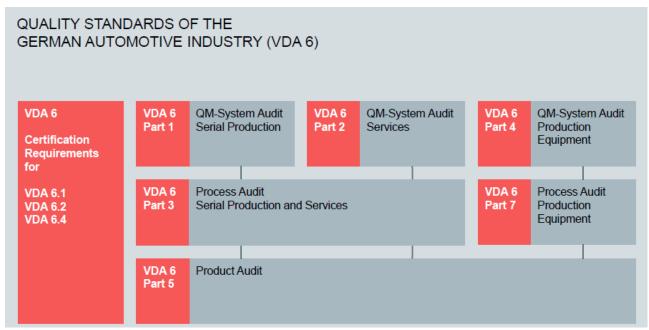


Figure 9: VDA 6.X

Table 4: 58 major Questionnaires in P2 ~ P7 of VDA 6.3						
100	Questionnaires					
P2 2.1	Project Management					
2.2	Is a project management established with a project organization?					
2.3	Are all the resources required for the project development planned and available and are changes shown?  Is there a project plan and has this been coordinated with the customer?					
2.4	Is the advanced product quality planning implemented within the project and monitored for compliance?					
3 C#	Are procurement activities of the project implemented and monitored for compliance?					
2.6	Is project management within the project insured by the management organization?					
2.7 P3	Is there an escalation process established and is effectively implemented?  Planning for the product and process development					
31	Are the specific requirements of product and process available?					
3.27	Can the manufacturing feasibility be evaluated according to product and process requirements?					
3.3	Are the activities of product and process development planned in detail?					
3.4	Are the activities for the customer care/customer satisfaction/customer service planned and field failure analysis?					
3.5 P4	Have the necessary resources been taken into account for the product and process development?  Implementation of product and process development					
4911	Are the action from the plans implemented for product and process development?					
4.2	Are the human resources available and are they qualified to insure the start of the series?					
4.3	Are the material resources available and suitable to insure the start of the series?					
4.4*	Are the required approvals and releases for the product and process development available?  Are the manufacturing and inspection specification derived from the product and process development and are they					
4.5	implemented?					
4.6	Is a performance tests carried out under the series conditions for the series release?					
4.7	Are the processes established for securing the customer care/customer satisfaction/customer service as well as the field failure analysis?					
4.8*	Is there a controlled method for the product handover from the development to the series?					
P5	Supplier Management					
5.1	Are only the approved and quality-capable suppliers used?					
5.2	Are customer requirements taken into account in the supplier chain?					
5.3	Have target agreements for supplier's performance been agreed upon and implemented?  Are the necessary releases/approvals available for the purchased products and services?					
5.5*	Is the agreed upon quality for the purchased products and services ensured?					
5.6	Are the incoming goods delivered and stored appropriately?					
5.7	Are personnel qualified for their respective tasks are responsibilities defined?					
P6 6.1	Process Analysis Production  What goes into process? (Process Input)					
6.1.1	Has process been transferred from development to series production and is a reliable start guaranteed?					
6.1.2	Are the necessary quantities/production batch sizes of incoming materials available at agreed upon time and at correct					
19(9)(6)	storage location/work-station?					
6.1.3	Are incoming materials stored appropriately and are the means of transport means/packing facilities suitable for the special characteristics of the incoming materials?					
6.1.4	Are the necessary identifications/records/releases available and allocated appropriately to the incoming materials?					
	Are changes to the product and process in the course of serial production tracked and documented?					
6.2	Are all the production processes controlled? (Process Management)  Are the requirements of the control plans complete and have they been effectively implemented?					
6.2.1	Does a repeat release for the restart of production take place?					
6.2.3*	Are special characteristics managed in the production?					
6.2.4*						
6.3	Is the flow of materials and parts secured against mixing/wrong items?					
63.1	What functions support the process? (Process Personnel) Are the employees able to fulfil their given tasks?					
6.3.2	Do the employees know their responsibilities and authority in the monitoring of the product and process quality?					
The second second second	Are the necessary personnel resources available?					
6.4	What means are used to implement process? (Material Resources)  Can the product-specific requirements from the customer be met with the manufacturing equipment?					
	Is the manufacturing equipment and tools controlled?					
6.4.3*	Can the quality requirements can be effectively monitored with the measurement and test facilitates in use?					
6.4.4	Are the work and inspection stations appropriate for the needs?					
6.5	Are tools, equipment and test equipment stored properly?  How effective is the process being carried out? Effectiveness, (Efficiency and Waste Avoidance)					
6.5.1	Are there targets set for manufacturing process?					
6.5.2	Is quality and process data collected in a way that allows analysis?					
6.5.34	In case of deviation from product and process requirements, are the causes analyzed and the corrective action checked for					
65.4	effectiveness? Are processes and products audited regularly?					
6.6	What should the process produce? (Process Result/Output)					
6.6.1	Do the quantities production batch sizes match needs and are they systematically directed to the next process?					
6.6.2	Are the products/components stored in an appropriate manner and transport facilities/packing arrangements suitable for					
6.6.3	the special characteristics of the products/components? Are the necessary records/releases retained?					
6.6.4*	Are the customer requirements met at the final product?					
P7	Customer care, customer satisfaction, service					
7.1	Are all requirements related QM system, product and process fulfilled?					
7.2	Is customer service guaranteed? Is the supply parts guaranteed?					
7.49	If there are deviations from quality requirements or complaints, are failure analysis carried out and corrective actions					
	implemented effectively?					
7.5	Are personnel qualified for their respective tasks and are responsibilities defined?					

# ISO 26262 Road Vehicles - Functional safety

The vehicle industry is an industry that never allows system failure to occur, because in the event of a failure, the vehicle manufacturer will face a huge risk of damages to the lawsuit and damage to goodwill. In order to prevent the occurrence of system failure, there must be a rigorous and reliable development process for the system development engineers follow. In the past, most of the automobile industry used FMEA to perform failure analysis and prevention. The FMEA method has a certain degree of prevention effect on hardware failure, but for prevention effect on software failure is limited. In addition to the FMEA approach, in recent years, some manufacturers have gradually applied the ISO 26262 functional safety design standard to failure analysis and prevention. The ISO 26262 standard can complement the FMEA approach for software analysis, and provides both software and hardware functional safety design. The development process is followed by development engineers, and there is a rigorous confirmation system for the results of functional safety analysis. Therefore, ISO 26262 will become the main method for the analysis of functional safety design of the vehicle industry.

The development of ISO 26262 started around 2005. The standard is mainly to harmonize IEC 61508 and focuses on the functional safety of electronic / motor systems on the vehicle. ISO 26262:2011, the first edition, the scope of application is for passengers below 3.5 tons (Passenger Cars) electronic / motor systems; ISO 26262:2018, the 2nd edition, trucks, buses, motorcycles are also covered. In the near future, the impact of ISO 26262 on the automotive industry will more than to IATF 16949.

In order to avoid the impact of the implementation of ISO 26262 on the vehicle industry, OEMs, 1-tier stage manufacturers, chip manufacturers, and equipment manufacturers around the world have started to introduce ISO 26262 in their product development process, as well as the software and hardware development tools used are also in compliance with the requirements of ISO 26262. The ISO 26262 composition architecture of ISO 26262 is as follows and Figure 10:

- (1) Vocabulary
- (2) Management of Functional Safety
- (3) Concept Phase
- (4) Product Development: System Level(5) Product Development: Hardware Level
- (6) Product Development: Software Level
- (7) Production and Operation
- (8) Supporting Processes
- (9) Automotive Safety Integrity Level-Oriented and Safety-Oriented Analyses
- (10) ISO 26262 Guideline
- (11) Guidelines on Application of ISO 26262 to Semiconductors
- (12) Adaptation of ISO 26262 for Motorcycles

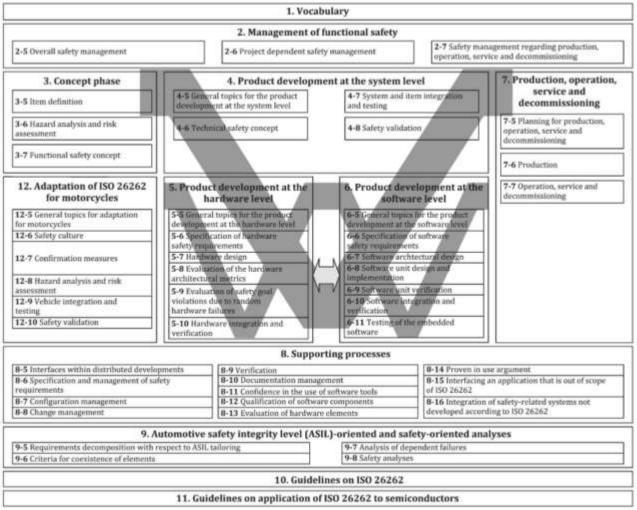


Figure 10: ISO 26262 composition architecture

#### IV. Conclusion

The author had a chance to participate in the counseling of the CTA's VDA 6.3 process audit in 2019-Q2. When author first got the VDA 6.3 Chinese-English red book, there was indeed a little bit of lacking in self-confidence, this is an area that the author has never experienced. According to the author's understanding, the content of APOP is mainly about what to do. As for how to do then it can meet the requirements of process audit VDA 6.3, it is necessary to have practical audit counseling experience. CTA has many years of experience be audited in various kinds of management systems. Looking for help from the author is to establish a theoretical foundation and long-term continuous improvement is required to make the organization invincible. The purpose of audit counseling is to pass certification. Therefore, CTA also invited consultant Mr. Cai Lugang joining the project, Mr. Cai according to the questionnaires in P2 ~ P7 of VDA 6.3, as shown in Table 4, to check the compliance status of the CTA quality management system documents one by one. The CTA quality management system documents have been changed for many years and slightly different from the current actual operation. This project is revised under the principle: "if it does not meet VDA 6.3 requirements, then amend it; if it be required by VDA 6.3 but without documents, then add it; if there are documents but never be used and/or not be required, then abolish it." Under the guidance of consultant Cai and the author's participation, and the efforts of CTA's responsible colleagues, the on-site audit was approved by URS International on May 7-9, and the formal certification took effect on June 24 2019.

In response to the release of IATF 16949:2016, CSQ/QKC has begun to conduct in-depth discussions on the quality issues related to the vehicle and rail vehicle industry since the end of 2016, examples include system requirements, process audits, risk management, reliability technologies (RAMS: Reliability, Availability, Maintainability, Safety),...etc., these topics related to preventing failures are issued. In terms of preventive quality, this is an important milestone in the development, design, and manufacturing stages of today's

vehicle-related industries. In the future, we must move towards the realm of predictive quality and proactive quality. The quality issues of the vehicle-related industries involve a wide and deep field, it is over the author's ability. There are many topics worth discussing, which is also the focus of CSQ/QKC in the near future.

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