

Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P-001 Revision D	Date: 5-6-2020	Page 1 of 69
--	--	--------------------------	--------------



7

Douglas Autotech
ISO 9001:2015 /IATF 16949
Quality Manual
I-4.4-C-AD-P-001

WEB SITE- <http://www.douglasautotech.com>

Revision	Date	Person Responsible	Description of Change
B	12-13-2017	Quality Assurance Mgr.	Changes of notification to certification body page 6 of 68.
C	1-8-2019	Quality Assurance Mgr.	Added note (f) to Internal Auditor Comp. to address NSF CAR #2542, added ref. to DACH internal auditor training material to prove competency in the auditor.
D	5-6-2020	Quality Assurance Mgr.	Updated Org. Chart

Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 2 of 69
--	--	--------------------------	--------------

Scope, Field of Application and Process Approach

0.1 General

Douglas Autotech has adopted the ISO 9001/IATF 16949 Standard as its base quality management system. This documented manual specifies the quality management systems and procedures that we use.

The systems requirements of this manual are aimed at achieving customer satisfaction by consistently providing conforming product and meeting customer requirements through application of the system, continual improvement and the prevention of nonconformity. This Quality Manual conforms to the requirements and elements of the five Clauses contained in the base ISO 9001:2015 /IATF 16949 international standard. Douglas Autotech adheres to the policy statements defined for each Clause and sub-clause or element of the aforementioned standard.

The Quality Management System implemented by Douglas Autotech Corporation covers all contracted products for delivery to customers and indirectly associated activities.

0.1.1 The Bronson Facility receives:

Strategic Planning, and Purchasing support from Fuji Kiko, Ltd.
(62191/62192).

0.1.2 Bronson (Corporate) facility provides:

Purchasing, Sales / PD and Technical / Change Support for the
Hopkinsville Manufacturing Facility.

0.1.3 The Hopkinsville Facility receives from the Bronson Facility:

- (a) Management (Policy, Rationalization & Business Planning)
- (b) Product Design (Bronson Mfg.) & Coordinator from Fuji Kiko, Ltd.
- (c) Purchasing (Supplier Selection, Improvement and P.O. with releases at Mfg. sites.

Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 3 of 69
--	--	--------------------------	--------------

(d) Contract Review: Test Lab (Product Verification & Validation)

(e) Quality Assurance (Quality Manual, Level 2 Procedures)

0.1.4 The Hopkinsville Facility receives support from Fuji Kiko, Ltd
(62191/62192):

(a) Strategic Planning, Contract Review, Purchasing and Product/Process
Design and Development.

The scope of the Quality Management System registration is stated as follows:

Bronson:

IAF-QMS 17

NAICS-336330

NACE-DJ28.4

Design and manufacture of commercial steering components.

Evaluation of customer specifics are reviewed/applied.

Hopkinsville:

IAF-QMS-14 17

NACE-DH 25.2, DJ28

NAICS-336330

Manufacture of steering components and transmission selectors for the vehicle industry
as part of the design system of Fuji Kiko, Ltd.

Evaluation of customer specifics are reviewed/applied.

0.2 Quality Management Principles

Douglas Autotech adheres to the seven quality management principles listed in ISO
9001 2015.

0.3 Process Approach

Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P-001 Revision D	Date: 5-6-2020	Page 4 of 69
--	---	---------------------------------	--------------

Douglas Autotech adopts the process approach in developing, implementing and improving the QMS. The processes are managed using the PDCA cycle with an overall focus on risk-based management. The flow chart diagram can be seen in the Introduction section of this manual as well as the inputs and outputs listed where applicable in our documented processes.

Table of Contents

	Page #
Title Page	1
Quality Management System Scope, Field of Application & Process Approach	2-3
Table of Contents, Distribution Page	4
Introduction to Organization	5
Quality Manual Control- Change Notification & Documentation Scheme	6
Quality Policy and Objectives	7-8
Responsibility Matrix	9-10
Organizational Chart	11
Typical Inter-connection of Processes	12
Clauses	<u>Pages from-to</u>
Context of the Organization	13-16
Leadership	16-18
Planning	18-21
Support	21-31
Operations	31-58
Performance Evaluation	59-64
Improvement	64-67
Quality Manual Distribution	(P) – Paper
<i>Recipient</i>	<u>(E) – Electronic</u>



Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 5 of 69
--	--	--------------------------	--------------

Introduction to Douglas Autotech

Douglas Autotech was formed in 1902 as HA Douglas Manufacturing, and started automobile manufacturing when it made parts for Henry Ford's Model T. Since then we have grown tremendously.

We are an industry leader in two industries with two basic product lines. We support the heavy truck and automotive industries. Some of our customers include: Nissan, Ford, Mitsubishi, Subaru, General Motors, Toyota, Caterpillar and Volvo.

Truck Industry

On-Highway, Off-Highway, Specialty vehicles, RV's and Agriculture. We have more than 200 different applications to support this market.

Automotive Industry

We have more than 100 different applications supporting sedans, coupes, SUV's, and luxury vehicles. We offer steering systems (columns, I-Shafts, covers, keylocks, and other dressings) along with shifter applications, such as straight, tap-up/tap-down and gated shifters.

Current Markets

- Automotive
- Commercial Vehicles
- On/Off Highway
- Bus

Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 6 of 69
--	--	--------------------------	--------------

- Military
- Construction
- Specialty
- Agriculture

Quality Manual Control – Change Notification & Documentation Scheme

Douglas Autotech's Quality Manual is distributed on paper in a controlled fashion, with very few printed copies. The manual is reviewed periodically and approved by our President. The controlled electronic copy of the manual is stored in the network server and is accessible by limited authorized personnel and can only be modified by the Quality Manager and requires re-approval by the Quality Manager and President. Uncontrolled versions of the Quality Manual are available to customers upon request and are stamped "Uncontrolled" and are for reference only. Individuals listed in the Responsibility Matrix are primarily responsible for each policy, had input in the creation of the policies listed throughout the manual. The President of Douglas Autotech approves the entire manual.

Douglas Autotech shall ensure DAC personnel provides notification of changes to the certification body related to:

- a. Legal, status (Quality Manager)
- b. Commercial status (Quality Manager)
- c. Ownership status (Quality Manager)
- d. Organization and management (Document Control Coordinator)
- e. Contact address or location (Document Control Coordinator)
- f. Scope of operations under the certified management system. (Quality Manager)
- g. IATF OEM customer special status (Quality Manager)
- h. Transfer to new IATF-recognized certification body. (Quality Manager)

Quality Documentation Scheme- Douglas Autotech's Quality documentation is numbered under the following scheme.

Document Type Identification

Document Formatting & Numbering Scheme

Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 7 of 69
--	--	---------------------------------	--------------

Q = Policy Manual

P = Procedure

WI = Work Instruction

PM = Process Map

F = Form

a. I = QMS – Quality Management System Document

b. Clause No.: (Refer to IATF 16949)

c. Section No. if applicable: (Refer to IATF 16949)

d. Location: Bronson – B, Hopkinsville – H,
Corporate – C

e. Department Owner: QA-Quality, AD-
Administration, ME-Manufacturing Engineering,
PE-Product Engineering, PU-Purchasing,

f. Document Type: QM – Quality Manual, P –
Procedure, WI – Work Instruction, F – Form.

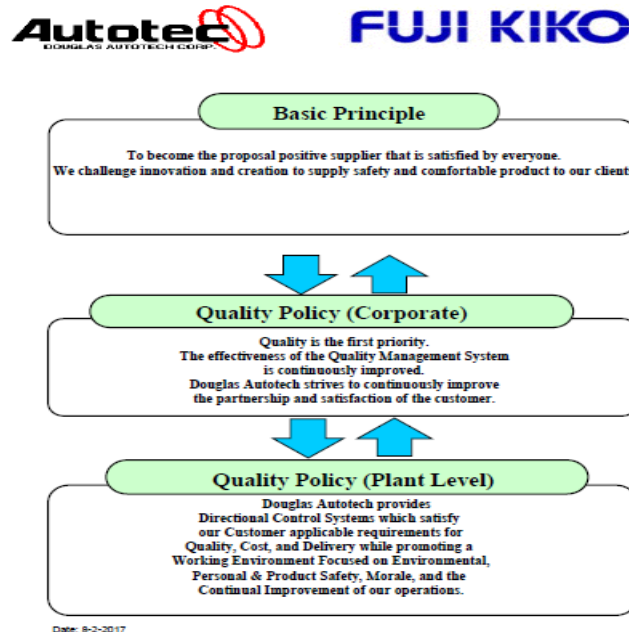
g. Sequence No.: 001, 002...etc.,

Document Control No. Example: I-7.5.2-C-AD-WI-001

I = Quality Management System Document 7.5.2 Clause/Section of IATF 16949

<p>Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement</p>	<p>Document No. I-4.4-C-AD-P-001 Revision D</p>	<p>Date: 5-6-2020</p>	<p>Page 8 of 69</p>
---	---	----------------------------------	---------------------

Quality Policy



This policy was established and endorsed by FUJI KIKO - Douglas Autotech on August 2, 2017, and will be reviewed and possibly modified as needed for continued suitability. The policy is explained and discussed at the general orientation training given to all existing and new employees. The policy is also posted in conspicuous locations throughout Douglas Autotech.

<p>Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement</p>	<p>Document No. I-4.4-C-AD-P-001 Revision D</p>	<p>Date: 5-6-2020</p>	<p>Page 9 of 69</p>
---	---	----------------------------------	---------------------

FY2017 Quality Goals/Objectives Bronson-Hopkinsville

Douglas Autotech Corporation sets Quality Goals and Objectives prior to the start of each new fiscal year.

What are the Quality Objectives?

FY2017 Quality Goals/Objectives

	Bronson	Hopkinsville
Customer DPPM	0	2
Critical Customer Defect Cases	0	0
Customer Defect Cases	0	8
Warranty % of Sales	0.12%	0.025%
Abnormal Quality Loss Cost	\$4,000	\$250,000
Internal Defect Scrap % of Sales	0.05%	.1%
Supplier DPPM	1200	3.5

Owner: Quality Department
Issue Date: 4-1-2017
Expiration Date: 3-31-2018

Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 10 of 69
--	--	---------------------------------	---------------

Responsibility Matrix (example of ISO 9001-2015 elements)

ISO 9001:2015 Sections	Pres./ Director	HR. Mgr.	Quality Mgr.	PU Mgr.	ME/PE Mgr.	PC Mgr.	Plant Mgr./Maint. Mgr.
4. Context of the organization							
4.1 Understanding the organization and its context	X						
4.2 Understanding the needs and expectations of interested parties	X						
4.3 Determining the scope of the quality management system	X						
4.4 Quality management system and its processes			X				
5. Leadership							
5.1 Leadership and commitment	X						
5.1.1 General	X						
5.1.2 Customer Focus	X						
5.2 Policy	X						
5.2.1 Establishing the quality policy	X						
5.2.2 Communicating the quality policy	X						
5.3 Organizational roles, responsibilities and authorities	X						
6. Planning							
6.1 Actions to address risks and opportunities	X						
6.2 Quality objectives and planning to achieve them	X						
6.3 Planning of changes	X						
7. Support							
7.1 Resources	X						
7.1.1 General	X						
7.1.2 People		X					
7.1.3 Infrastructure		X					
7.1.4 Environment for the operation of processes		X					
7.1.5 Monitoring and measuring resources		X					
7.1.6 Organizational knowledge	X						
7.2 Competence		X					
7.3 Awareness		X					
7.4 Communication							
7.5 Documented information			X				
7.5.1 General			X				
7.5.2 Creating and updating			X				
7.5.3 Control of documented information			X				
8. Operation							
8.1 Operational planning and control					X(ME)		X
8.2 Requirements for products and services						X	
8.2.1 Customer communications						X	
8.2.2 Determining the requirements for products and services						X	

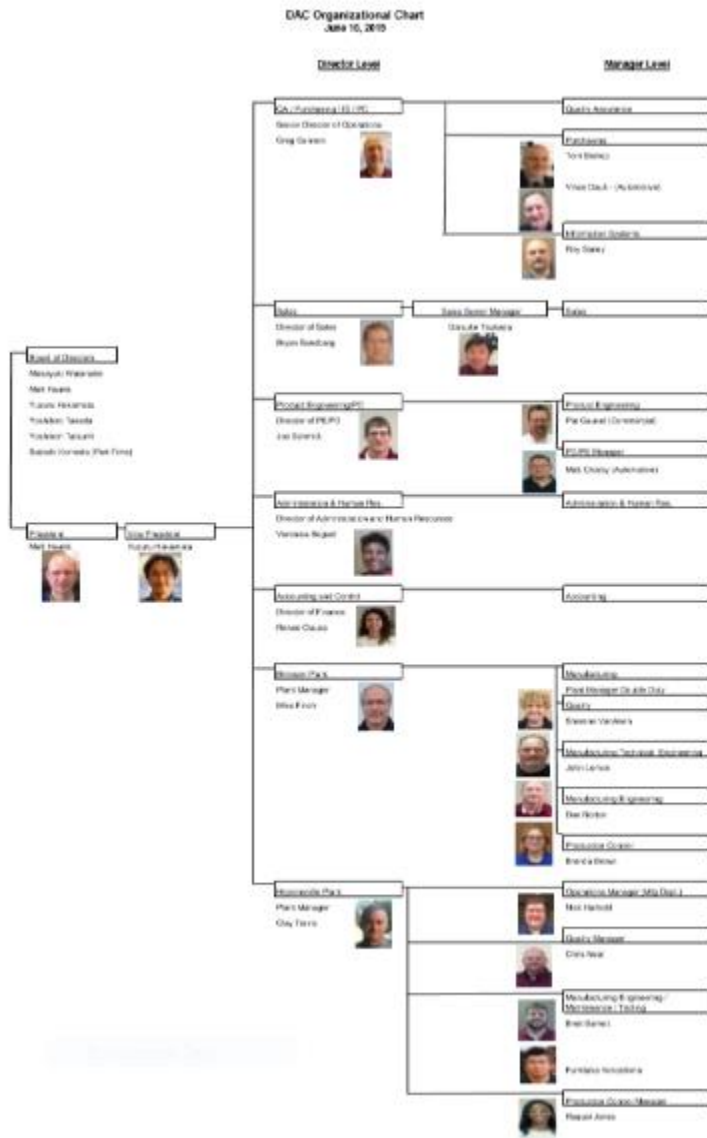
Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P-001 Revision D	Date: 5-6-2020	Page 11 of 69
--	---	---------------------------------	---------------

8.2.3 Review of the requirements for products and services							X	
8.2.4 Changes to requirements for products and services							X	
8.3 Design and development of products and services						X(PE)		
ISO 9001:2015 Sections	Pres./ Director	HR Mgr.	Quality Mgr.	PU Mgr.	ME/PE Mgr.	PC Mgr.	Plant /Maint. Mgr.	t.
8.4 Control of externally provided processes, products and services				X				
8.4.1 General				X				
8.4.2 Type and extent of control				X				
8.4.3 Information for external providers				X				
8.5 Production and service provision						X		
8.5.1 Control of production and service providers						X		
8.5.2 Identification and traceability						X		
8.5.3 Property belonging to customers or external providers						X		
8.5.4 Preservations						X		
8.5.5 Post-delivery activities						X		
8.5.6 Control of changes							X	
8.6 Release of products and services						X		
8.7 Control of nonconforming outputs			X					
9. Performance evaluation								
9.1 Monitoring, measurement, analysis and evaluation			X					
9.1.1 General			X					
9.1.2 Customer satisfaction			X					
9.1.3 Analysis and evaluation			X					
9.2 Internal Audit			X					
9.3 Management Review	X							
9.3.1 General	X							
9.3.2 Management review inputs	X							
9.3.2 Management review outputs	X							
10. Improvement								
10.1 General	X							
10.2 Nonconformity and corrective action			X					
10.3 Continual improvement	X							

Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 12 of 69
--	--	--------------------------	---------------

DAC Organization Chart

<p>Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement</p>	<p>Document No. I-4.4-C-AD-P-001 Revision D</p>	<p>Date: 5-6-2020</p>	<p>Page 13 of 69</p>
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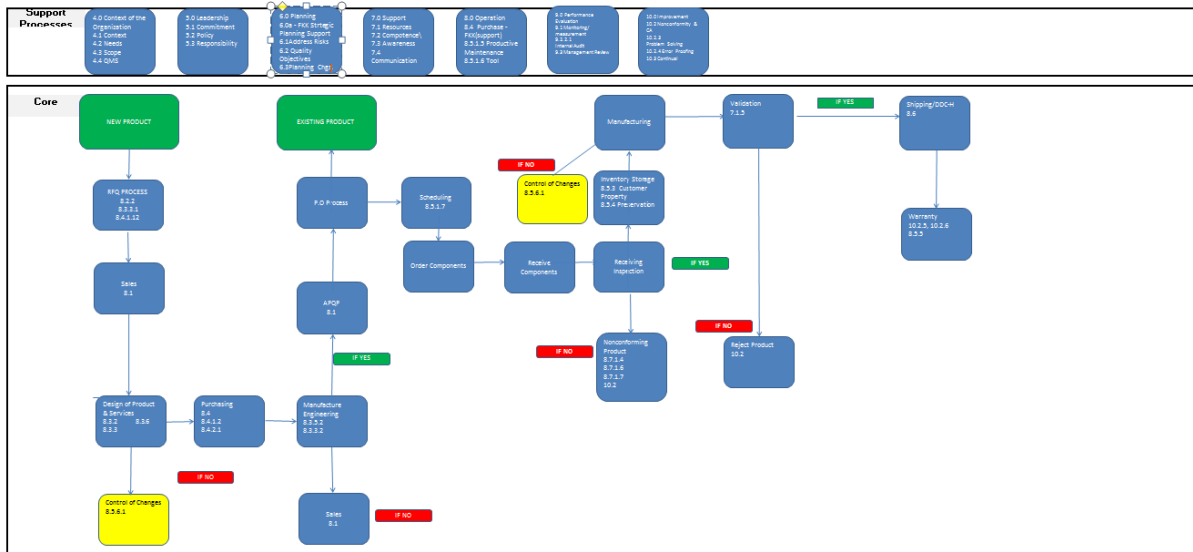


Processes Interconnection

<p>Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement</p>	<p>Document No. I-4.4-C-AD-P-001 Revision D</p>	<p>Date: 5-6-2020</p>	<p>Page 14 of 69</p>
---	---	---	----------------------



Process Interaction Map



CLAUSE 4 CONTEXT OF THE ORGANIZATION
4.1 Understanding the organization and its context

Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 15 of 69
--	--	--------------------------	---------------

We have determined our external and internal issues that are relevant to our purpose and strategic direction and that affect our ability to achieve the intended result(s) of its quality management system. A bi-annual analysis is conducted based on the following data: FKK company business plan targets, Management Review and 2nd Half Reflections activity (Fiscal Year status QMS Goals/Objectives/lessons learned). A SWOT analysis “may” be performed to further analyze these issues if deemed necessary.

We monitor and review information about these external and internal issues during our Management Review meetings.

4.2 Understanding the needs and expectations of interested parties

Due to their effect or potential effect on our ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, we determine:

- a) The interested parties that are relevant to the quality management system;
- b) The requirements of these interested parties that are relevant to the quality management system.

Douglas Autotech monitors and reviews information about these interested parties and their relevant requirements. This review is performed as part of the sales, planning and Management Review processes.

4.3 Determining the scope of the quality management system

Douglas Autotech has determined the boundaries and applicability of the quality management system to establish its scope.

When determining this scope, we considered:

- a) the external and internal issues referred to in 4.1;
- b) the requirements of relevant interested parties referred to in 4.2;
- c) our products and services.

We apply all the requirements of this International Standard as they are applicable within the determined scope of its quality management system.

The scope states the types of products and services covered (NAICS code), and provides justification for any requirement of this International Standard that we



Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 16 of 69
--	--	---------------------------------	---------------

determine is not applicable to the scope of our quality management system.(typically 8.3 Design – which Douglas Autotech Corporation does not take exception too). Conformity to this International Standard may only be claimed if the requirements determined as not being applicable do not affect our ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.

4.3.1 Determining the scope of the quality management system – supplemental

Supporting functions, whether on-site or remote (such as design centers, corporate headquarters, and distribution centers), are included in the scope of the Quality Management System (QMS).

As a full-service supplier, we adhere to all elements of the co-standards with no exclusions for design.

4.3.2 Customer-specific requirements – supplemental

Customer-specific requirements have been evaluated and are included in the scope of the organizations quality management system.

4.4 Quality management system and its processes

4.4.1 We have established, implemented, maintained and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard.

Douglas Autotech has determined the processes needed for the quality management system and their application throughout the organization, and has:

- a) determined the inputs required and the outputs expected from these processes;
- b) determined the sequence and interaction of these processes;
- c) determined 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) determined the resources needed for these processes and ensure their availability;
- e) assigned the responsibilities and authorities for these processes;
- f) addressed the risks and opportunities as determined in accordance with the requirements of 6.1;

Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 17 of 69
--	--	--------------------------	---------------

- g) evaluated these processes and implemented any changes needed to ensure that these processes achieve their intended results;
- h) improve the processes and the quality management system.

4.4.1.1 Conformance of products and processes - supplemental

The organization ensures 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).

4.4.1.2 Product safety - supplemental

Douglas Autotech utilizes a documented process for the management of product – safety related products and manufacturing processes, which includes but is not limited to the following, where applicable:

- 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 plan (see Section 9.1.1.1)
- h) Defined responsibilities, definition of escalation process, including top management, and customer notification;
- i) Training identified by the organization or customer for personnel involved in product-safety related products and associated manufacturing processes;
- j) Changes of product or process shall be approved prior to implementation, including evaluation of potential effects on product safety from process and product changes (see ISO 9001, Section 8.3.6);
- k) transfer of requirements with regard to product safety throughout the supply chain, including customer-designated sources (see Section 8.4.3.1);
- l) product traceability by manufactured lot (at a minimum) throughout the supply chain (see Section 8.5.2.1);
- m) Lessons learned for new product introduction.

Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 18 of 69
--	--	---------------------------------	---------------

4.4.2 To the extent necessary, Douglas Autotech:

- a) maintains documented information to support the operation of its processes;
- b) retains documented information to have confidence that the processes are being carried out as planned.

CLAUSE 5 LEADERSHIP

5.1 Leadership and commitment

5.1.1 General

Top management demonstrates leadership and commitment with respect to the quality management system by:

- a) taking accountability for the effectiveness of the quality management system;
- b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization;
- c) ensuring the integration of the quality management system requirements into the organization's business processes;
- d) promoting the use of the process approach and risk-based thinking;
- e) ensuring that the resources needed for the quality management system are available;
- f) communicating the importance of effective quality management and of conforming to the quality management system requirements
- g) ensuring that the quality management system achieves its intended results;
- h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;
- i) promoting improvement;
- j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

5.1.1.1 Corporate responsibility - supplemental

Douglas Autotech defines and implements corporate responsibility policies, including at a minimum an anti-bribery policy, an employee code of conduct, and an ethics escalation policy ("whistle-blowing policy")

5.1.1.2 Process effectiveness and efficiency - supplemental

Top management reviews the product realization processes and support processes to evaluate and improve their effectiveness and efficiency. The results of the process review activities are included as input to the management review (see Section 9.3.2.1.).

Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 19 of 69
--	--	---------------------------------	---------------

5.1.1.3 Process owners - supplemental

Top management identifies process owners who are responsible for managing the organizations processes and related outputs. Process owners will understand their roles and be competent to perform those roles (see ISO 9001, Section 7.2).

5.1.2 Customer focus

Top management demonstrates 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;
- b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;
- c) the focus on enhancing customer satisfaction is maintained.

5.2 Policy

5.2.1 Establishing the quality policy

Top management has established, implemented and maintains a quality policy that:

- a) is appropriate to the purpose and context of Douglas Autotech 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:

- a) is available and is maintained as documented information;
- b) is communicated, understood and applied within the organization;
- c) is available to relevant interested parties, as appropriate.

5.3 Organizational roles, responsibilities and authorities

Top management ensures that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization.

Top management assigns the responsibility and authority for:

- 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;



Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 20 of 69
--	--	---------------------------------	---------------

- 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.

5.3.1 Organizational roles, responsibilities, and authorities – supplemental

Top management assigns personnel with the responsibility and authority to ensure that customer requirements are met. These assignments are 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.

5.3.2 Responsibility and authority for product requirements and corrective actions - supplemental

Top management ensures that:


- a) Personnel responsible for conformity to product requirements have the authority to stop shipment and stop production to correct quality problems;
- 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
- c) Production operations across all shifts are staffed with personnel in charge of, or delegated responsibility for, ensuring conformity to product requirements.

CLAUSE 6 PLANNING

6.1 Actions to address risks and opportunities

6.1.1 When planning for the quality management system, we consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:

- 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.

 PAST, PRESENT, AND FUTURE INNOVATION OF STEERING TECHNOLOGY			
Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 21 of 69

6.1.2 Douglas Autotech plan:

- 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 are proportionate to the potential impact on the conformity of products and services.

6.1.2.1 Risk Analysis - supplemental

Douglas Autotech includes in its risk analysis, at a minimum, lessons learned from product recalls, product audits, field returns and repairs, complaints, scrap, and rework. Douglas Autotech retains documented information as evidence of the results of risk analysis.

6.1.2.2 Preventive action – supplemental

Douglas Autotech determines and implements action(s) to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions will be appropriate to the severity of the potential issues.

Douglas Autotech has established a process to lessen the impact of negative effects of risk including the following:

- 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 - supplemental

Douglas Autotech has:

- a) Identified and evaluated 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) Defined contingency plans according to risk and impact to the customer;
- c) Prepared contingency plans for continuity of supply in the event of the following:

Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 22 of 69
--	--	--------------------------	---------------

key equipment failures (also see Section 8.5.6.1.1); interruption from externally provided products, processes, and services; recurring natural disasters; fire; utility interruptions; labor shortages; or infrastructure disruptions;

- b) Included, 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;
- c) Periodically tests the contingency plans for effectiveness (e.g., simulations, as appropriate);
- d) Conducts contingency plan reviews (at a minimum annually) using a multidisciplinary team including top management, and updates as required;
- g) Documented the contingency plans and retain documented information describing any revision(s) including the person(s) who authorized the change(s).

The contingency plans include provisions to validate that the manufactured product continues to meet customer specifications after the re-start of production following an emergency in which production was stopped and if the regular shutdown processes were not followed.

6.2 Quality objectives and planning to achieve them

6.2.1 Douglas Autotech established quality objectives at relevant functions, levels and processes needed for the quality management system.


The quality objectives are to:

- 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.

Douglas Autotech maintains documented information on the quality objectives.

6.2.2 When planning how to achieve our quality objectives, we determine:

- a) what will be done;
- b) what resources will be required;
- c) who will be responsible;
- d) when it will be completed;

 PAST, PRESENT, AND FUTURE INNOVATION OF STEERING TECHNOLOGY			
Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 23 of 69

e) how the results will be evaluated.

6.2.2.1 Quality objectives and planning to achieve them – supplemental

Top management ensures that quality objectives to meet customer requirements are defined, established, and maintained for relevant functions, processes, and levels throughout the organization.

The results of Douglas Autotech’s review regarding interested parties and their relevant requirements are considered when Douglas Autotech establishes its annual (at a minimum) quality objectives and related performance targets (internal and external).

6.3 Planning of changes

When we determine the need for changes to the quality management system, the changes are carried out in a planned manner (see 4.4).

Douglas Autotech considers:

- 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.

CLAUSE 7 SUPPORT

7.1 Resources

7.1.1 General

Douglas Autotech determines and provides the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.

We consider:

- a) the capabilities of, and constraints on, existing internal resources;
- b) what needs to be obtained from external providers.

7.1.2 People

Douglas Autotech determines and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.

Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 24 of 69
--	--	--------------------------	---------------

7.1.3 Infrastructure

We determine, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.

NOTE Infrastructure can include:

- a) buildings and associated utilities;
- b) equipment, including hardware and software;
- c) transportation resources;
- d) information and communication technology.

7.1.3.1 Plant, facility, and equipment planning - supplemental

Douglas Autotech uses a multidisciplinary approach including risk identification and risk mitigation methods for developing and improving plant, facility, and equipment plans. In designing plant layouts, Douglas Autotech will:

- a) Optimize material flow, material handling, and value-added use of floor space including control of nonconforming product, and
- b) Facilitate synchronous material flow, as applicable.

Methods are developed and implemented to evaluate manufacturing feasibility for new product or new operations. Manufacturing feasibility assessments include capacity planning. These methods are also applicable for evaluating proposed changes to existing operations.

Douglas Autotech maintains 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).


Assessments of manufacturing feasibility and evaluation of capacity planning are inputs to management's reviews (see ISO 9001, Section 9.3).

7.1.4 Environment for the operation of processes

Douglas Autotech determines, provides and maintains the environment necessary for the operation of its processes and to achieve conformity of products and services.

7.1.4.1 Environment for the operation of processes – supplemental

Douglas Autotech maintains its premises in state of order, cleanliness, and repair that is consistent with the product and manufacturing process needs.

 PAST, PRESENT, AND FUTURE INNOVATION OF STEERING TECHNOLOGY			
Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 25 of 69

7.1.5 Monitoring and measuring resources

7.1.5.1 General

We 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.

We ensure that the resources provided:

- a) are suitable for the specific type of monitoring and measurement activities being undertaken;
- b) are maintained to ensure their continuing fitness for their purpose.

Douglas Autotech retains appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

7.1.5.1.1 Measurement systems analysis - supplemental

Statistical studies are conducted to analyze the variation present in the results of each type of inspection, measurement, and test equipment system identified in the control plan. The analytical methods and acceptance criteria used conform to those in reference manuals on measurement systems analysis. Other analytical methods and acceptance criteria may be used if approved by the customer.

Records of customer acceptance of alternative methods will be retained along with results from alternative measurement systems analysis (see Section 9.1.1.1).

7.1.5.2 Measurement traceability

When measurement traceability is a requirement, or is considered by us to be an essential part of providing confidence in the validity of measurement results, measuring equipment will be:

- 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.

Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 26 of 69
--	--	---------------------------------	---------------

We 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 take appropriate action as necessary.

7.1.5.2.1 Calibration/ Verification records - supplemental

Douglas Autotech has 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, customer –owned equipment, or on-site supplier-owned equipment) needed to provide evidence of conformity to internal requirements, legislative and regulatory requirements, and customer-defined requirements will be retained.

Douglas Autotech will ensure that calibration/ verification and records include the following details:

- 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 on the validity of previous measurements result 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 employee-owned 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



Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 27 of 69
--	--	---------------------------------	---------------

7.1.5.3.1 Internal laboratory

Douglas Autotech internal laboratory facility has a defined scope that includes its capability to perform the required inspection, test, or calibration services. This laboratory scope is included in the quality management system documentation. The laboratory will specify and implement, as a minimum, requirements for:

- a) Adequacy of the laboratory technical procedures;
- b) Competency of the laboratory personnel;
- c) Testing of the product;
- d) Capability to perform these services correctly, traceable to the relevant process standard (such as ASTM, EN, etc.); when no national or international standard(s) is available, Douglas Autotech will 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

External/commercial/independent laboratory facilities used for inspection, test, or calibration services by Douglas Autotech will 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 national equivalent 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
- There will be evidence that the external laboratory is acceptable to the customer.

NOTE: Such evidence may be demonstrated by customer assessment, for example, or by customer-approved second-party assessment that the laboratory meets the intent of ISO/IEC 17025 or national equivalent. The second-party assessment may be performed by the organization assessing the laboratory using a customer-approved method of assessment.

Calibration services may be performed by the equipment manufacturer when a qualified laboratory is not available for a given piece of equipment. In such cases, Douglas Autotech will ensure that the requirements listed in Section 7.1.5.3.1 have been met. Use of calibration services, other than by qualified (or customer accepted) laboratories, may be subject to government regulatory confirmation, if required.

 PAST, PRESENT, AND FUTURE INNOVATION OF STEERING TECHNOLOGY			
Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 28 of 69

7.1.6 Organizational knowledge

Douglas Autotech determines the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

This knowledge is maintained and is available to the extent necessary.

When addressing changing needs and trends, we consider our current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.

7.2 Competence

Douglas Autotech:


- a) determines the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;
- b) ensures that these persons are competent on the basis of appropriate education, training, or experience;
- c) where applicable, takes action to acquire the necessary competence, and evaluate the effectiveness of the actions taken;
- d) retains appropriate documented information as evidence of competence.

7.2.1 Competence – supplemental

Douglas Autotech established and maintains a document process 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 are qualified, as required, with particular attention to the satisfaction of customer requirements.

7.2.2 Competence – on-the-job training - supplemental

Douglas Autotech will provide on-the-job training (which will include customer requirements training) for personnel in any new or modified responsibilities affecting conformity to quality requirements, internal requirements, regulatory or legislative requirements; this will include contract or agency personnel. The level of detail required for on-the-job training will 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 are informed about the consequences of nonconformity to customer requirements.

 PAST, PRESENT, AND FUTURE INNOVATION OF STEERING TECHNOLOGY			
Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 29 of 69

7.2.3 Internal auditor competency - supplemental

Douglas Autotec has a documented process map to verify that internal auditors are competent, taking into account any customer-specific requirements. For additional guidance or auditor competencies, refer to ISO 19011. Douglas Autotec maintains a list of qualified internal auditors.

Quality management system auditors, manufacturing process auditors, and product auditors will all be able to demonstrate the following minimum competencies:

- 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.
- f) **Hops- Successfully complete the 2019 Internal Auditing Training which includes, but is not limited to (IATF 2019 Power Point, Internal Auditor “to do” power point.)**

Additionally, manufacturing process auditors will demonstrate technical understanding of the relevant manufacturing process(es) to be audited, including process risk analysis (such as PFMEA) and control plan. Product auditors will demonstrate competence in understanding product requirements and use if relevant measuring and test equipment to verify product conformity.

Where training is provided to achieve competency, documented information is retained to demonstrate the trainer’s competency with the above requirements.

Maintenance of and improvement in internal auditor competence is demonstrated through:

- g) Executing a minimum number of audits per year, as defined by the organization; and
- h) 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).



Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 30 of 69
--	--	---------------------------------	---------------

7.2.4 Second- party auditor competency - supplemental

Douglas Autotech will demonstrate the competence of the auditors undertaking the second-party audits. Second-party auditors will meet customer specific requirements for auditor qualification and demonstrate the minimum following core competencies, including understanding of:

- 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

We ensure that persons doing work under the organization's control are aware of:

- a) the quality policy;
- b) relevant quality objectives;
- c) their contribution to the effectiveness of the quality management system, including the benefits of improved performance;
- d) the implications of not conforming with the quality management system requirements.

7.3.1 Awareness – Supplemental

Douglas Autotech maintains 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 risk involved for the customer with conforming product.

7.3.2 Employee motivation and empowerment - supplemental

Douglas Autotech maintains a documented process to motivate employees to achieve quality objectives, to make continual improvements, and to create an environment that promotes innovation. The process will include the promotion of quality and technological awareness throughout the whole organization.

Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 31 of 69
--	--	---------------------------------	---------------

7.4 Communication

Douglas Autotech determines the internal and external communications relevant to the quality management system, including:

- a) on what it will communicate;
- b) when to communicate;
- c) with whom to communicate;
- d) how to communicate;
- e) who communicates.

7.5 Documented Information

7.5.1 General

Our quality management system includes:

- a) documented information required by this International Standard;
- b) documented information determined by us as being necessary for the effectiveness of the quality management system.

7.5.1.1 Quality management system documentation - supplemental


Douglas Autotech's quality management system is documented and includes a quality manual (I-4.4-C-AD-P-001) in addition to other referenced documents (these may be electronic and/or hard copy).

The format and structure of the quality manual is at the discretion of the organization and will depend on the organization's size, culture, and complexity. If a series of documents is used then a list will be retained of the documents that comprise the quality manual for the organization.

The quality manual includes, at a minimum, the following:

- a) The scope of the quality management system, including details of and justification for any exclusions;
- b) Documented processes established for the quality management system, or reference to them;
- c) The organization's processes and their sequence and interactions (inputs and outputs), including type and extent of control of any outsourced processes;
- d) A documented matrix indicating where within the organization's quality management system their customer-specific requirements are addressed.

NOTE: A matrix of how the requirements of this Automotive QMS standard are addressed by the organization's processes may be used to assist with linkages of the organization's processes and this Automotive QMS.

 PAST, PRESENT, AND FUTURE INNOVATION OF STEERING TECHNOLOGY			
Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P-001 Revision D	Date: 5-6-2020	Page 32 of 69

7.5.2 Creating and updating

When creating and updating documented information, we ensure appropriate:

- a) identification and description (e.g. a title, date, author, or reference number);
- b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic);
- c) review and approval for suitability and adequacy.

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:

- 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, Douglas Autotech addresses the following activities, as applicable:

- 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.

Documented information of external origin determined by Douglas Autotech to be necessary for the planning and operation of the quality management system is identified as appropriate, and is controlled.

Documented information retained as evidence of conformity is protected from unintended alterations.

7.5.3.2.1 Record retention - supplemental

Douglas Autotech has defined, established a documented process, and implemented a record retention policy. The control of records will satisfy statutory, regulatory, organizational, and customer requirements.

Productions part approvals, tooling records (including maintenance and ownership), product and process design records, purchase orders (if applicable), or contracts and amendments are retained for the length of time that the product is active for production and service requirements, plus one calendar year, unless otherwise specified by the customer or regulatory agency.



Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 33 of 69
--	--	---------------------------------	---------------

7.5.3.2.2 Engineering specifications - supplemental

Douglas Autotech has a documented process describing the review, distribution, and implementation of all customer engineering standards/ specifications and related revisions based on customer schedules, as required.

When an engineering standard/specification change results in a product design change, refer to the requirements in ISO 9001, Section 8.3.6. When an engineering standard/specification change results in a product realization process change, refer to the requirements in Section 8.5.6.1. Douglas Autotech will retain a record of the date on which each change is implemented in production. Implementation will include updated documents.

Review should be completed within 10 working days of receipt of notification of engineering standards/Specifications changes.

CLAUSE 8 OPERATION


8.1 Operational planning and control

Douglas Autotech plans, implements and controls 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;
- b) establishing criteria for:
 - 1) the processes;
 - 2) the acceptance of products and services;
- c) determining the resources needed to achieve conformity to the product and service requirements;
- d) implementing control of the processes in accordance with the criteria;
- e) determining, maintaining and retaining documented information to the extent necessary:
 - 1) to have confidence that the processes have been carried out as planned;
 - 2) to demonstrate the conformity of products and services to their requirements.

The output of this planning is suitable for our operations.

Douglas Autotech controls planned changes and reviews the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

 PAST, PRESENT, AND FUTURE INNOVATION OF STEERING TECHNOLOGY			
Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 34 of 69

We ensure that outsourced processes are controlled (see 8.4).

8.1.1 Operational planning and control – supplemental

When planning for product realization, the following topics are included:

- 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.

8.1.2 Confidentiality - supplemental

Douglas Autotec will ensure the confidentiality of customer-contracted products and projects under development, including related product information.

8.2 Requirements for products and services

8.2.1 Customer communication

Communication with customers includes:

- 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.

8.2.1.1 Customer communication – supplemental

Written or verbal communication is in the language agreed with the customer. Douglas Autotec will 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).

8.2.2 Determining the requirements for products and services

When determining the requirements for the products and services to be offered to customers, we ensure that:

- a) the requirements for the products and services are defined, including:

Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 35 of 69
--	--	--------------------------	---------------

- 1) any applicable statutory and regulatory requirements;
 - 2) those considered necessary by the organization;
- b) We can meet the claims for the products and services it offers.

8.2.2.1 Determining the requirements for products and services – supplemental

These requirements 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), will include but not be limited to the following: all applicable government, safety, and environmental regulations related to acquisition, shortage, handling, recycling, elimination, or disposal of material.

8.2.3 Review of the requirements for products and services

8.2.3.1 Douglas Autotech ensures that it has the ability to meet the requirements for products and services to be offered to customers. We conduct a review before committing to supply products and services to a customer, to include:

- a) requirements specified by the customer, including the requirements for delivery and post-delivery activities;
- b) requirements not stated by the customer, but necessary for the specified or intended use, when known;
- c) requirements specified by the organization;
- d) statutory and regulatory requirements applicable to the products and services;
- e) contract or order requirements differing from those previously expressed.

Douglas Autotech ensures that contract or order requirements differing from those previously defined are resolved.

We confirm the customer's requirements before acceptance, when the customer does not provide a documented statement of their requirements.

8.2.3.1.1 Review of the requirements for products and services – supplemental

Douglas Autotech will retain documented evidence of a customer- authorized waiver for the requirements stated in ISO 9001, Section 8.2.3.1, for formal review.

8.2.3.1.2 Customer-designated special characteristics - supplemental

Douglas Autotech will conform to customer requirements for designation, approval documentation, and control of special characteristics.

Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 36 of 69
--	--	--------------------------	---------------

8.2.3.1.3 Organization manufacturing feasibility - supplemental

Douglas Autotech will utilize a multidisciplinary approach to conduct an analysis to determine if it is feasible that the organization's manufacturing processes are capable of consistently producing product that meets all the engineering and capacity requirements specified by the customer. Douglas Autotech will conduct this feasibility analysis for any manufacturing or product technology new to the organization and for any changed manufacturing process or product design.

Additionally, the organization may validate through production runs, benchmarking studies, or other appropriate methods, their ability to make product to specifications at the required rate.

8.2.3.2 Douglas Autotech retains documented information, as applicable:

- a) on the results of the review;
- b) on any new requirements for the products and services.

8.2.4 Changes to requirements for products and services

We 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.

8.3 Design and development of products and services

8.3.1 General

Douglas Autotech establishes, implements and maintains a design and development process that is appropriate to ensure the subsequent provision of products and services.

8.3.1.1 Design and Development of products and services – supplemental

The requirements in ISO 9001, Section 8.3.1, do apply to product and manufacturing process design and development and will focus on error prevention rather than detection.

Douglas Autotech will document the design and development process.

8.3.2 Design and development planning

In determining the stages and controls for design and development, we consider:

- a) the nature, duration and complexity of the design and development activities;
- b) the required process stages, including applicable design and development reviews;



Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 37 of 69
--	--	---------------------------------	---------------

- 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.

8.3.2.1 Design and development planning – supplemental

Douglas Autotech ensures that design and development planning includes all affected stakeholders within the organization and, as appropriate, its supply chain. Examples of areas for using such a multidisciplinary approach include but are not limited to the following:

- a) Project management (for example, APQP or VDA-RGA);
- b) Product and manufacturing process design activities (for example, DFM and DFA), such as consideration of the use of alternative designs and manufacturing processes;
- c) Development and review of product design risk analysis (FMEAs), including actions to reduce potential risks;
- d) Development and review of manufacturing process risk analysis (for example, FMEAs, process flows, control plans, and standard work instructions).

NOTE: A multidisciplinary approach typically includes the organization's design, manufacturing engineering, quality, production, purchasing, supplier, maintenance, and other appropriate functions.

8.3.2.2 Product design skills - supplemental

Douglas Autotech will 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 are identified by the organization.

Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 38 of 69
--	--	--------------------------	---------------

8.3.2.3 Development of products with embedded software - supplemental

Douglas Autotech will use a process for quality assurance for their products with internally developed embedded software, if applicable. A software development assessment methodology will be utilized to assess the organization's software development process. Using prioritization based on risk and potential impact to the customer, Douglas Autotech will retain documented information of a software development capability self-assessment.

Douglas Autotech will include software development within the scope of their internal audit program (see Section 9.2.2.1) where applicable.

8.3.3 Design and development inputs

Douglas Autotech determines the requirements essential for the specific types of products and services to be designed and developed. We consider:

- a) functional and performance requirements;
- b) information derived from previous similar design and development activities;
- c) statutory and regulatory requirements;
- d) standards or codes of practice that we have committed to implement;
- e) potential consequences of failure due to the nature of the products and services.

Inputs shall be adequate for design and development purposes, complete and unambiguous.

Conflicting design and development inputs shall be resolved.

Douglas Autotech retains documented information on design and development inputs.

8.3.3.1 Product design input - supplemental

Douglas Autotech will identify, document, and review product design input requirements as a result of contract review. Product design input requirements include but are not limited to the following:

- a) Product specifications including but not limited to special characteristics (see Section 8.3.3.3);
- b) Boundary and interface requirements;
- c) Identification, traceability, and packaging;
- d) Consideration of design alternatives;

Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 39 of 69
--	--	--------------------------	---------------

- 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.

Douglas Autotec has 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.

8.3.3.2 Manufacturing process design input - supplemental

Douglas Autotec identifies, documents, and reviews manufacturing process design input requirements including but not limited to the following:

- a) Product design output data including special characteristics;
- b) Targets for productivity, process capability, timing, and cost;
- c) Manufacturing technology alternatives;
- d) Customer requirements, if any;
- e) Experience from previous developments;
- f) New materials;
- g) Product handling and ergonomic requirements; and
- h) Design for manufacturing and design for assembly

The manufacturing process design will 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 - supplemental

Douglas Autotec uses 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 will include the following:

- a) Documentation of all special characteristics in the drawings (as required), risk analysis (such as FMEA), control plans, and standard work/operator instructions; special characteristics are identified with specific markings and are cascaded through each of these documents;

Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 40 of 69
--	--	---------------------------------	---------------

- 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 will be submitted to the customer, if required.

8.3.4 Design and development controls

Douglas Autotech applies controls to the design and development process to ensure that:

- a) the results to be achieved are defined;
- b) reviews are conducted to evaluate the ability of the results of design and development to meet requirements;
- c) verification activities are conducted to ensure that the design and development outputs meet the input requirements;
- d) validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use;
- e) any necessary actions are taken on problems determined during the reviews, or verification and validation activities;
- f) documented information of these activities is retained.

8.3.4.1 Monitoring - supplemental

Measurements at specified stages during the design and development of products and processes will be defined, analyzed, and reported with summary results as an input to management review (see Section 9.3.2.1). When required by the customer, measurements of product and process development activity will be reported to the customer at stages specified, or agreed to, by the customer.

8.3.4.2 Design and development validation - supplemental

Design and development validation will be performed in accordance with customer requirements, including any applicable industry and governmental agency-issued regulatory standards. The timing of design and development validation will be planned in alignment with customer-specified timing, as applicable.

Where contractually agreed with the customer, this will include evaluation of the interaction of the organization's product, including embedded software, within the system of the final customer's product.



Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 41 of 69
--	--	---------------------------------	---------------

8.3.4.3 Prototype program - supplemental

When required by the customer, Douglas Autotech will have a prototype program and control plan. Douglas Autotech will use, whenever possible, the same suppliers, tooling, and manufacturing processes as will be used in production. All performance-testing activities will be monitored for timely completion and conformity to requirements. When services are outsourced, Douglas Autotech will 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).

8.3.4.4 Product approval process - supplemental

Douglas Autotech will establish, implement, and maintain a product and manufacturing approval process conforming to requirements defined by the customer(s). Douglas Autotech will approve externally provided products and services per ISO 9001, Section 8.4.3, prior to submission of their part approval to the customer. Douglas Autotech will obtain documented product approval prior to shipment, if required by the customer. Records of such approval shall be retained.

8.3.5 Design and development outputs

Douglas Autotech ensures that design and development outputs:

- a) meet the input requirements;
- b) are adequate for the subsequent processes for the provision of products and services;
- c) include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;
- d) specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.

We retain documented information on design and development outputs.

8.3.5.1 Design and development outputs – supplemental

The product design output will be expressed in terms that can be verified and validated against product design input requirements. The product design output will include but is not limited to the following, as applicable:

- a) Design risk analysis(FMEA);
- b) Reliability study results;
- c) Product special characteristics;

Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 42 of 69
--	--	---------------------------------	---------------

- d) Results of product design error- proofing, such as DFSS, DFMA, and FTA;
- e) Product definition including 3D models, technical data packages, product manufacturing information, and geometric dimensioning & tolerancing (GD&T);
- f) 2D drawings, product manufacturing information, and geometric dimensioning & tolerancing (GD&T);
- g) Product design review results;
- h) Service diagnostic guidelines and repair and serviceability instructions;
- i) Service part requirements
- j) Packaging and labeling requirements for shipping

8.3.5.2 Manufacturing process design output - supplemental

Douglas Autotech will document the manufacturing process design output in a manner that enables verification against the manufacturing process design inputs. Douglas Autotech will verify the outputs against manufacturing process design input requirements. The manufacturing process design output will include, but is not limited to, the following:

- a) Specifications and drawings;
- b) Special characteristics for product and manufacturing process;
- c) Identification of process input variables 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.

Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 43 of 69
--	--	---------------------------------	---------------

8.3.6 Design and development changes

Douglas Autotech identifies, reviews and controls 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.

We retain documented information on:

- a) design and development changes;
- b) the results of reviews;
- c) the authorization of the changes;
- d) the actions taken to prevent adverse impacts.

8.3.6.1 Design and development changes- supplemental

Douglas Autotech will 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 will be validated against customer requirements and approved internally, prior to production implementation. If required by the customer, Douglas Autotech will obtain documented approval, or a documented waiver, from the customer prior to production implementation. For products with embedded software, Douglas Autotech will document the revision level of software and hardware as a part of the change record.

8.4 Control of externally provided processes, products and services


8.4.1 General

Douglas Autotech ensures that externally provided processes, products and services conform to requirements.

Douglas Autotech determines the controls to be applied to externally provided processes, products and services when:

- a) products and services from external providers are intended for incorporation into our own products and services;
- b) products and services are provided directly to the customer(s) by external providers on behalf of us;
- c) a process, or part of a process, is provided by an external provider as a result of a decision by us.

We determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide

 PAST, PRESENT, AND FUTURE INNOVATION OF STEERING TECHNOLOGY			
Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 44 of 69

processes or products and services in accordance with requirements. Douglas Autotech retains documented information of these activities and any necessary actions arising from the evaluations.

8.4.1.1 General – supplemental

Douglas Autotech will include all products and services that affect customer requirements such as sub-assembly, sequencing, sorting, rework, and calibration services in the scope of their definition of extremely provided products, processes, and services.

8.4.1.2 Supplier selection process - supplemental

Douglas Autotech will have a documented supplier selection process. The selection process will include:


- a) An assessment of the selected supplier’s risk to product conformity and uninterrupted supply of the organization’s product to their customers;
- b) Relevant quality and delivery performance;
- c) An evaluation if the supplier’s quality management system;
- d) Multidisciplinary decision making; and
- e) An assessment of software development capabilities, if applicable.

Other supplier selection criteria that should be considered includes the following:

- 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 capabilities;
- 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”) - supplemental

When specified by the customer, Douglas Autotech will purchase products, materials, or service from customer-directed sources.

 PAST, PRESENT, AND FUTURE INNOVATION OF STEERING TECHNOLOGY			
Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 45 of 69

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.

8.4.2 Type and extent of control

Douglas Autotech ensures that externally provided processes, products and services do not adversely affect our ability to consistently deliver conforming products and services to its customers.

Douglas Autotech:

- a) ensures that externally provided processes remain within the control of its quality management system;
- b) defines both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;
- c) takes into consideration:
 - 1) the potential impact of the externally provided processes, products and services on the organization’s ability to consistently meet customer and applicable statutory and regulatory requirements;
 - 2) the effectiveness of the controls applied by the external provider;
- d) determines the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

8.4.2.1 Type and extent of control – supplemental

Douglas Autotech has 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.

The process will 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.

8.4.2.2 Statutory and regulatory requirements - supplemental

Douglas Autotech has documented 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.

Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 46 of 69
--	--	--------------------------	---------------

If the customer defines special controls for certain products with statutory and regulatory requirements, Douglas Autotech will ensure they are implemented and maintained as defined, including at suppliers.

8.4.2.3 Supplier quality management system development - supplemental


Douglas Autotech requires their suppliers of automotive products and services to develop, implement, and improve a quality management system certified to ISO 9001, unless otherwise authorized by the customer [e.g., item a) below], with the ultimate objective of becoming certified to the Automotive QMS Standard, IATF 16949. Unless otherwise specified by the customer, the following sequence should be applied to achieve this requirement:

- a) Compliance to ISO 9001 through second- party audits;
- b) Compliance to ISO 9001 through third – party audits; unless otherwise specified by the customer, suppliers to Douglas Autotech will demonstrate conformity to ISO 9001 by maintaining a third- party certification issued by a certification body bearing the accreditation mark of a recognized IAF MLA (international Accreditation Forum Multilateral Recognition Arrangement) member and where the accreditation body’s main scope includes management system certification to ISO/IEC 17021;
- c) Certification to ISO 9001 with compliance to other customer – defined QMS requirements (such as Minimum Automotive Quality Management System Requirements for Sub – Tier Suppliers [MAQMSR] or equivalent) through second party audits;
- d) Certification to ISO90001 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 -supplemental

Douglas Autotech requires the suppliers of automotive product – related software, or automotive products with embedded software, to implement and maintain a process for software quality assurance for their products.

A software development assessment methodology will be utilized to assess the supplier’s software development process. Using prioritization based on risk and

 PAST, PRESENT, AND FUTURE INNOVATION OF STEERING TECHNOLOGY			
Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 47 of 69

potential impact to the customer, Douglas Autotech will require the supplier to retain documented information of a software development capability self- assessment.

8.4.2.4 Supplier monitoring – supplemental

Douglas Autotech has a documented process and criteria to evaluate supplier performance in order to ensure conformity of externally provided products, processes, and services to internal and external customer requirements.

At a minimum, the following supplier performance indicators will be monitored:

- a) Delivered product conformity to requirements;
- b) Customer disruptions at the following plant, including at yard holds and stop ships;
- c) Delivery schedule performance;
- d) Number of occurrences of premium freight.

If provided by the customer, Douglas Autotech will also include the following, as appropriate, in their supplier performance monitoring:

- e) Special status customer notifications related to quality or delivery issues;
- f) Dealer returns, warranty, field actions, and recalls.

8.4.2.4.1 Second – party audits – supplemental

Douglas Autotech will include a second- party audit process in their supplier management approach. Second –party audit may be used for the following:

- a) supplier risk management;
- 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, Douglas Autotech will document the criteria for determining the need, type, frequency, and scope of second – party audits. Douglas Autotech retains records of the second –party audit reports.

If the scope of the second –party audit is to assess the supplier’s quality management system, then the approach shall be consistent with the automotive process approach.

Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 48 of 69
--	--	---------------------------------	---------------

8.4.2.5 Supplier development - supplemental

Douglas Autotech will determine the priority, type, extent, and timing of required supplier development actions for its active suppliers. Determination inputs will include but are not limited to the following:

- a) performance issues identified through supplier monitoring (see Section 8.4.2.4);
- b) second- party audit findings (see Section 8.4.2.4.1);
- c) third-party quality management system certification status;
- d) Risk analysis.

Douglas Autotech will implement actions necessary to resolve open (unsatisfactory) performance issues and pursue opportunities for continual improvement.

8.4.3 Information for external providers


Douglas Autotech ensures the adequacy of requirements prior to their communication to the external provider.

We communicate to external providers its requirements for:

- a) the processes, products and services to be provided;
- b) the approval of:
 - 1) products and services;
 - 2) methods, processes and equipment;
 - 3) the release of products and services;
- c) competence, including any required qualification of persons;
- d) the external providers' interactions with the organization;
- e) control and monitoring of the external providers' performance to be applied by the organization;
- f) verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises.

8.4.3.1 Information for external providers – supplemental

Douglas Autotech will 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.

 PAST, PRESENT, AND FUTURE INNOVATION OF STEERING TECHNOLOGY			
Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 49 of 69

8.5 Production and service provision

8.5.1 Control of production and service provision

Douglas Autotech implements production and service provision under controlled conditions.

Controlled conditions include, as applicable:

- a) the availability of documented information that defines:
 - 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;
- b) the availability and use of suitable monitoring and measuring resources;
- 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;
- d) the use of suitable infrastructure and environment for the operation of processes;
- e) the appointment of competent persons, including any required qualification;
- f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;
- g) the implementation of actions to prevent human error;
- h) the implementation of release, delivery and post-delivery activities.

8.5.1.1 Control Plan - supplemental

Douglas Autotech develops 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.

Douglas Autotech will 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).

Douglas Autotech will, if required by the customer, provide measurement and conformity data collected during execution of either the pre-launch or production control plans. Douglas Autotech will include in the control plan:

- a) Control used for the manufacturing process control, including verification of job set-ups;

Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 50 of 69
--	--	--------------------------	---------------

- 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.

Douglas Autotech will review control plans, and update as required, for any of the following:

- f) The organization determines it has shipped nonconforming product to the customer;
- g) When any change occurs affecting product, manufacturing process, measurement, logistics, supply sources, production volume changes, or risk analysis (FMEA) (see Annex A);
- h) After a customer complaint and implementation of the associated corrective action, when applicable;
- i) At a set frequency based on a risk analysis.

If required by the customer, Douglas Autotech will obtain customer approval after review or revision of the control plan.

8.5.1.2 Standardized work – operator instructions and visual standards - supplemental

Douglas Autotech ensures the standardized work documents are:

- a) Communicated to and understood by the employees who are responsible for performing the work;
- b) Legible;
- c) Presented in the language(s) understood by the personnel responsible to follow them;
- d) Accessible for use at the designated work area(s).

The standardized work documents will also include rules for operator safety.

8.5.1.3 Verification of job set-ups - supplemental

Douglas Autotech will:

- 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;
- b) Maintain documented information for set-up personnel;
- c) Use statistical methods of verification, where applicable;

Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 51 of 69
--	--	--------------------------	---------------

- d) Perform first-off/last-off part validation, as applicable; where appropriate, first-off parts should be retained for comparison with the last-off parts; where appropriate, last-off-parts should be retained for comparison with first-off parts in subsequent runs;
- e) Retain records of process and product approval following set-up and first-off/last-off part validations.
- f)

8.5.1.4 Verification after shutdown - supplemental

Douglas Autotech will define and implement the necessary actions to ensure product compliance with requirements after a planned or unplanned production shutdown period.

8.5.1.5 Total productive maintenance - supplemental

Douglas Autotech will develop, implement, and maintain a documented total productive maintenance system.

At a minimum, the system will include the following:

- a) Identification of process equipment necessary to produce conforming product at the required volume;
- b) Availability of replacement parts for the equipment identified in item a);
- c) Provision of resource for machine, equipment, and facility maintenance;
- d) Packaging and preservation of equipment, tooling, and gauging;
- e) Applicable customer-specific requirements;
- 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 will 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 and 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 - supplemental



Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 52 of 69
--	--	---------------------------------	---------------

Douglas Autotech provides resources for tool and gauge design, fabrication, and verification activities for production and service materials and for bulk materials, as applicable.

Douglas Autotech has established and implemented a system for production tooling management, whether owned by the organization or the customer, including:

- a) Maintenance and repair facilities and personnel ;
- b) Storage and recovery;
- c) Set-up;
- d) Tool-change programs 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; location.

Douglas Autotech will 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.

Douglas Autotech will implement a system to monitor these activities if any work is outsourced.


8.5.1.7 Production scheduling - supplemental

Douglas Autotech ensures 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.

Douglas Autotech will 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

Douglas Autotech uses suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

 PAST, PRESENT, AND FUTURE INNOVATION OF STEERING TECHNOLOGY			
Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P-001 Revision D	Date: 5-6-2020	Page 53 of 69

We identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

Douglas Autotech controls the unique identification of the outputs when traceability is a requirement, and retains the documented information necessary to enable traceability.

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, Douglas Autotech will implement identification and traceability processes as described below.


Douglas Autotech will 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 will define the appropriate traceability systems, processes, and methods by product, process, and manufacturing location that:

- a) Enable the organization to identify nonconforming and/or suspect product;
- b) Enable the organization to segregate nonconforming and/ or suspect product;
- c) Ensure the ability to meet the customer and/or regulatory response time requirements;
- d) Ensure documented information is retained in the 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

Douglas Autotech exercises care with property belonging to customers or external providers while it is under our control or being used by us.

We identify, verify, protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services.

 PAST, PRESENT, AND FUTURE INNOVATION OF STEERING TECHNOLOGY			
Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 54 of 69

When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, we report this to the customer or external provider and retain documented information on what has occurred.

8.5.4 Preservation

Douglas Autotech preserves the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

8.5.4.1 Preservation – supplemental

Preservation will include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.

Preservation will apply to materials and components from external and/or internal providers from receipt through processing, including shipment and until delivery to/acceptance by the customer.

In order to detect deterioration, Douglas Autotech will assess at appropriate planned intervals the condition of product in stock, the place/type of storage container, and the storage environment.

Douglas Autotech uses an inventory management system to optimize inventory turns over time and ensure stock rotation, such as “first-in-first-out” (FIFO). Douglas Autotech will ensure that obsolete product is controlled in a manner similar to that of nonconforming product.


Douglas Autotech complies with preservation, packaging, shipping, and labeling requirements as provided by their customers.

8.5.5 Post-delivery activities

We meet requirements for post-delivery activities associated with the products and services.

In determining the extent of post-delivery activities that are required, we consider:

- a) statutory and regulatory requirements;
- b) the potential undesired consequences associated with its products and services;
- c) the nature, use and intended lifetime of its products and services;
- d) customer requirements;
- e) customer feedback.

 PAST, PRESENT, AND FUTURE INNOVATION OF STEERING TECHNOLOGY			
Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P-001 Revision D	Date: 5-6-2020	Page 55 of 69

8.5.5.1 Feedback of information from service

Douglas Autotech ensures that a process for communication of information on service concerns to manufacturing, material handling, logistics, engineering, and design activities is established, implemented, and maintained.

NOTE 1: The intent of the addition of “service concerns” to this sub- clause is to ensure that the organization is aware of nonconforming product(s) and material(s) that may be identified at the customer location or in the field.

NOTE 2: “Service concerns” should include the results of field failure test analysis (see Section 10.2.6) where applicable.

8.5.5.2 Service agreement with customer

When there is a service agreement with the customer, Douglas Autotech will:

- a) Verify that the relevant service centers comply with applicable requirements;
- b) Verify the effectiveness of any special purpose tools or measurements equipment;
- c) Ensure that all service personnel are trained in applicable requirements.

8.5.6 Control of changes

Douglas Autotech reviews and controls changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.


We 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.

8.5.6.1 Control of changes- supplemental

Douglas Autotech has 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.

Douglas Autotech will:

- 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.

 PAST, PRESENT, AND FUTURE INNOVATION OF STEERING TECHNOLOGY			
Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 56 of 69

Changes, including those made at suppliers, should require a production trial run for verification of changes (such as changes to part design, manufacturing location, or manufacturing process) to validate the impact of any changes on the manufacturing process.

When required by the customer, Douglas Autotech will:

- a) Notify the customer of any planned product realization changes after the most recent product approval;
- b) Obtain documented approval, prior to implementation of the change;
- c) 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 - supplemental

Douglas Autotech will identify, document, and maintain a list of the process controls, including inspection, measuring, test, and error-proofing devices, that includes the primary process control and the approved or alternate methods.


Douglas Autotech will document the process that manages the use of alternate control methods. Douglas Autotech will include in this process, based on risk analysis (such as FMEA), severity, and the internal approvals to be obtained prior to production implantation of the alternate control method.

Before shipping product that was inspected or tested using the alternate method, if required, Douglas Autotech will obtain approval from the customer(s). Douglas Autotech will maintain and periodically review a list of approved alternate process control methods that are referenced in the control plan.

Standard work instructions are available for each alternate process control method. Douglas Autotech will review the operation of alternate process controls on a daily basis, at a minimum, to verify implementation of standard work with the goal to return to the standard process as defined by the control plan as soon as possible. Example methods include but are not limited to the following:

- a) Daily quality focused audits (e.g., layered process audits, as applicable);
- b) Daily leadership meetings.

Restart verifications is documented for a defined period based on severity and confirmation that all features of the error-proofing devices or processes are being used (e.g., verification and retention of first piece and last piece from every shift).

 PAST, PRESENT, AND FUTURE INNOVATION OF STEERING TECHNOLOGY			
Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 57 of 69

8.6 Release of products and services

Douglas Autotech implements planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.

The release of products and services to the customer will not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

We retain documented information on the release of products and services. The documented information shall include:

- a) evidence of conformity with the acceptance criteria;
- b) traceability to the person(s) authorizing the release.

8.6.1 Release of products and services – supplemental

Douglas Autotech will ensure that the planned arrangements for initial release of products and services requirements have been met encompass the control plan and are documented as specified in the control plan (see Annex A). Douglas Autotech will ensure that the planned arrangements for initial release of products and services encompass product or service approval.

Douglas Autotech will ensure that product or service approval is accomplished after changes following initial release, according to ISO 9001, Section 8.5.6.

8.6.2 Layout inspection and functional testing - supplemental

A layout inspection and a functional verification to applicable customer engineering material and performance standards will be performed for each product as specified in the control plans. Results are available for customer review.

NOTE 1: Layout inspection is the complete measurement of all product dimensions shown on the design record(s).

NOTE 2: The frequency of layout inspection is determined by the customer.

8.6.3 Appearance items - supplemental

When manufacturing parts designated by the customer as “appearance items” Douglas Autotech will provide the following:

- a) Appropriate resources, including lighting, for evaluation;

Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 58 of 69
--	--	--------------------------	---------------

- b) Masters for color, 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 - supplemental

Douglas Autotech will have a process to ensure the quality of externally provided processes, products, and services utilizing one or more of the following methods:

- a) Receipt and evaluation of statistical data provided by the supplier to the organization;
- b) Receiving inspection and/or testing, such as sampling based on performance;
- c) Second-party or third-party assessments or audits of supplier sites when coupled with records of acceptable delivered product conformance to requirements;
- d) Part evaluation by a designated laboratory;
- e) Another method agreed with the customer.

8.6.5 Statutory and regulatory conformity - supplemental

Prior to release of externally provided products into its production flow, Douglas Autotech will 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.


8.6.6 Acceptance criteria - supplemental

Acceptance criteria are 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).

8.7 Control of nonconforming outputs

8.7.1 Douglas Autotech ensures that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

We take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This also applies to nonconforming products

 PAST, PRESENT, AND FUTURE INNOVATION OF STEERING TECHNOLOGY			
Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 59 of 69

and services detected after delivery of products, during or after the provision of services.

We deal with nonconforming outputs in one or more of the following ways:

- a) correction;
- b) segregation, containment, return or suspension of provision of products and services;
- c) informing the customer;
- d) obtaining authorization for acceptance under concession.

Conformity to the requirements is verified when nonconforming outputs are corrected.

8.7.1.1 Customer authorization for concession - supplemental

Douglas Autotech will obtain a customer concession of deviation permit prior to further processing whenever the product or manufacturing process is different from which is currently approved.

Douglas Autotech will obtain customer authorization prior to further processing for “use as is” and rework dispositions of nonconforming product. If sub-components are reused in the manufacturing process, that sub-component reuse shall be clearly communicated to the customer in the concession or deviation permit.


Douglas Autotech will maintain a record of the expiration date or quantity authorized under concession. Douglas Autotech will also ensure compliance with the original or superseding specifications and requirements when the authorization expires. Material shipped under concession shall be properly identified on each shipping container (this applies equally to purchased product). Douglas Autotech will approve any requests from suppliers before submission to the customer.

8.7.1.2 Control of nonconforming product- customer-specified process - supplemental

Douglas Autotech will comply with applicable customer-specified controls for nonconforming product(s).

8.7.1.3 Control of suspect product - supplemental

Douglas Autotech ensures that product with unidentified or suspect status is classified and controlled as nonconforming product. Douglas Autotech will ensure that all

 PAST, PRESENT, AND FUTURE INNOVATION OF STEERING TECHNOLOGY			
Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 60 of 69

appropriate manufacturing personnel receive training for containment of suspect and nonconforming product.

8.7.1.4 Control of reworked product - supplemental

Douglas Autotech will 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, Douglas Autotech will obtain approval from the customer prior to commencing rework of the product.

Douglas Autotech will 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. Douglas Autotech will retain documented information on the disposition of reworked product including quantity, disposition date, and applicable traceability information.

8.7.1.5 Control of repaired product - supplemental

Douglas Autotech does not repair product.

8.7.1.6 Customer notification - supplemental


Douglas Autotech will 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.7))

8.7.1.7 Nonconforming product disposition - supplemental

Douglas Autotech has a documented process for disposition of nonconforming product not subject to rework. For product not meeting requirements, Douglas Autotech will verify that the product to be scrapped is rendered unusable prior to disposal. Douglas Autotech will not divert nonconforming product to service or other use without prior customer approval.

8.7.2 Douglas Autotech retains documented information that:

- a) describes the nonconformity;
- b) describes the actions taken;
- c) describes any concessions obtained;

 PAST, PRESENT, AND FUTURE INNOVATION OF STEERING TECHNOLOGY			
Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 61 of 69

d) identifies the authority deciding the action in respect of the nonconformity.

CLAUSE 9 PERFORMANCE EVALUATION

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

Douglas Autotech determines:

- 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 is performed;
- d) when the results from monitoring and measurement are analyzed and evaluated.

Douglas Autotech evaluates the performance and the effectiveness of the quality management system.

We retain appropriate documented information as evidence of the results.

9.1.1.1 Monitoring and measurement of manufacturing processes - supplemental

Douglas Autotech performs process studies on all new manufacturing (including assembly or sequencing) processes to verify processes to verify process capability and to provide additional input for process control, including those for special characteristics.

NOTE: For some manufacturing processes, it may not be possible to demonstrate product compliance through process capability. For those processes, alternate methods such as batch conformance to specification may be used.

Douglas Autotech maintains manufacturing process capability or performance results as specified by the customer's part approval process requirements. Douglas Autotech will verify that the process flow diagram, PFMEA, and control plan are implemented, including adherence to the following:

- a) Measurement techniques;
- b) Sampling plans;
- c) Acceptance criteria;
- d) Records of actual measurement values and/or test results for variable data;
- e) Reaction plans and escalation process when acceptance criteria are not met.

Significant process events, such as tool change or machine repair, will be recorded and retained as documented information.

Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 62 of 69
--	--	---------------------------------	---------------

Douglas Autotec will 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 will include containment of product and 100 percent inspection, as appropriate. A corrective action plan will 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 will be reviewed with and approved by the customer, when required. Douglas Autotec will maintain records of effective dates of process changes.

9.1.1.2 Identification of statistical tools - supplemental

Douglas Autotec will determine the appropriate use of statistical tools. Douglas Autotec will 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.

9.1.1.3 Application of statistical concepts - supplemental

Statistical concepts, such as variation, control (stability), process capability, and the consequences of over-adjustment, will be understood and used by employees involved in the collection, analysis, and management of statistical data.

9.1.2 Customer satisfaction

We monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled. We determine the methods for obtaining, monitoring and reviewing this information.

9.1.2.1 Customer satisfaction – supplemental

Customer satisfaction with Douglas Autotec will be monitored through continual evaluation of internal and external performance indicators to ensure compliance to the product and process specifications and other customer requirements. Performance indicators shall be based on objective evidence and include but not be limited to the following:

- a) Delivered part quality performance;
- b) Customers disruptions;
- c) Field returns, recalls, and warranty (where applicable);
- d) Delivery schedule performance (including incidents of premium freight);

Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 63 of 69
--	--	--------------------------	---------------

- e) Customer notifications related to quality or delivery issues, including special status.

Douglas Autotec will monitor the performance of manufacturing processes to demonstrate compliance with customer requirements for product quality and process efficiency. The monitoring will include the review of customer performance data including online customer portals and customer scorecards, where provided.

9.1.3 Analysis and evaluation

Douglas Autotec analyzes and evaluates appropriate data and information arising from monitoring and measurement.

The results of analysis are used to evaluate:

- a) conformity of products and services;
- b) the degree of customer satisfaction;
- c) the performance and effectiveness of the quality management system;
- d) if planning has been implemented effectively;
- e) the effectiveness of actions taken to address risks and opportunities;
- f) the performance of external providers;
- g) the need for improvements to the quality management system.

9.1.3.1 Prioritization - supplemental

Trends in quality and operational performance will be compared with progress toward objectives and lead to action to support prioritization of actions for improving customer satisfaction.

9.2 Internal audit

9.2.1 Douglas Autotec conducts internal audits at planned intervals to provide information on whether the quality management system:

- a) conforms to:
 - 1) our own requirements for its quality management system;
 - 2) the requirements of this International Standard;
- b) is effectively implemented and maintained.

9.2.2 We:

- a) plan, establish, implement and maintain an audit program(s) including the frequency, methods, responsibilities, planning requirements and reporting, which take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;

Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 64 of 69
--	--	--------------------------	---------------

- b) define the audit criteria and scope for each audit;
- c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
- d) ensure that the results of the audits are reported to relevant management;
- e) take appropriate correction and corrective actions without undue delay;
- f) retain documented information as evidence of the implementation of the audit program and the audit results.
- g) Internal auditors must go through the rules of manufacturing training to understand each process at DAC (Hopkinsville)
- h) Secondary auditors must have completed the rules of manufacturing training along with the internal auditor training provided by the lead auditor

9.2.2.1 Internal audit program - supplemental

Douglas Autotech has a documented internal audit process. The process includes the development and implementation of an internal audit program that covers the entire quality management system including quality management system audits, manufacturing process audits, and products audits.

9.2.2.2 Quality management system audit - supplemental

Douglas Autotech will audit all quality management system processes over each three-year calendar period, according to an annual program, using the process approach to verify compliance with this Automotive QMS Standard, IATF 16949. Integrated with these audits, Douglas Autotech will sample customer-specific quality management system requirements for effective implementation.

9.2.2.3 Manufacturing process audit - supplemental

Douglas Autotech will 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, Douglas Autotech will determine the approach to be used.

Within each individual audit plan, each manufacturing process shall be audited on all shifts where it occurs, including the appropriate sampling of the shift handover.

The manufacturing process audits shall include an audit of the effective implementation of the process risk analysis (such as PFMEA), control plan, and associated documents.

Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 65 of 69
--	--	--------------------------	---------------

9.2.2.4 Product audit – supplemental

Douglas Autotech will 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, Douglas Autotech will define the approach to be used.

9.3 Management review

9.3.1 General

Top management reviews Douglas Autotech's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with our strategic direction.

9.3.1.1 Management review – supplemental

Management review will be conducted at least annually. The frequency of management review(s) will be increased based on risk to compliance with customer requirements resulting from internal or external changes impacting the quality management system and performance – related issues.

9.3.2 Management review inputs

The management review is planned and carried out taking into consideration:

- a) the status of actions from previous management reviews;
- b) changes in external and internal issues that are relevant to the quality management system;
- c) information on the performance and effectiveness of the quality management system, including trends in:
 - 1) customer satisfaction and feedback from relevant interested parties;
 - 2) the extent to which quality objectives have been met;
 - 3) process performance and conformity of products and services;
 - 4) nonconformities and corrective actions;
 - 5) monitoring and measurement results;
 - 6) audit results;
 - 7) the performance of external providers;
- d) the adequacy of resources;
- e) the effectiveness of actions taken to address risks and opportunities (see 6.1);
- f) opportunities for improvement.

Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 66 of 69
--	--	---------------------------------	---------------

9.3.2.1 Management review inputs – supplemental

Input to management review will include:

- a) Cost of poor quality (cost of internal and external nonconformance);
- b) Measure of process effectiveness;
- c) Measures of process efficiency;
- d) Product conformance;
- e) Assessments of manufacturing feasibility made for changes to existing operations and for new facilities or new product (see Section 7.1.3.1);
- f) Customer satisfaction (see ISO 9001, Section 9.1.2);
- g) Review 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);

Actual field failures and their impact on safety

9.3.3 Management review outputs

The outputs of the management review include decisions and actions related to:

- a) opportunities for improvement;
- b) any need for changes to the quality management system;
- c) resource needs.

Douglas Autotech retains documented information as evidence of the results of management reviews.

9.3.3.1 Management review outputs- supplemental

Top management will document and implement an action plan when customer performance targets are not met.

CLAUSE 10 IMPROVEMENT

10.1 General

Douglas Autotech determines and selects opportunities for improvement and implements any necessary actions to meet customer requirements and enhance customer satisfaction.

These include:

- a) improving products and services to meet requirements as well as to address future needs and expectations;



Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 67 of 69
--	--	---------------------------------	---------------

- b) correcting, preventing or reducing undesired effects;
- c) improving the performance and effectiveness of the quality management system.

10.2 Nonconformity and corrective action

10.2.1 When a nonconformity occurs, including any arising from complaints, we:

- a) react to the nonconformity and, as applicable:
 - 1) take action to control and correct it;
 - 2) deal with the consequences;
- b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
 - 1) reviewing and analyzing the nonconformity;
 - 2) determining the causes of the nonconformity;
 - 3) determining if similar nonconformities exist, or could potentially occur;
- c) implement any action needed;
- d) review the effectiveness of any corrective action taken;
- e) update risks and opportunities determined during planning, if necessary;
- f) make changes to the quality management system, if necessary.

Corrective actions will be appropriate to the effects of the nonconformities encountered.


10.2.2 Douglas Autotech retains documented information as evidence of:

- a) the nature of the nonconformities and any subsequent actions taken;
- b) the results of any corrective action.

10.2.3 Problem Solving – supplemental

Douglas Autotech has a documented process for problem solving including:

- a) Defined approaches for various types and scale of problems (e.g., new product development, current manufacturing issues, field failures, audit findings);
- b) Containment, interim actions, and related activities necessary for control of nonconforming outputs (see ISO 9001, Section 8.7);
- c) Root cause analysis, methodology used, analysis, and results;
- d) Implementation of systemic corrective actions, including consideration of the impact or 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).

 PAST, PRESENT, AND FUTURE INNOVATION OF STEERING TECHNOLOGY			
Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 68 of 69

Where the customer has specific prescribed processes, tools, or systems for problem solving, Douglas Autotech will use those processes tools, or systems unless otherwise approved by the customer.

10.2.4 Error- proofing - supplemental

Douglas Autotech has a documented process to determine the use of appropriate error-proofing methodologies. Details of the method used will be documented in the process risk analysis (such as PFMEA) and test frequencies will be documented in the control plan.

The process includes the testing of error-proofing devices for failure or simulated failure. Records will be maintained. Challenge parts, when used, will be identified, controlled, verified, and calibrated where feasible. Error-proofing device failures will have a reaction plan.

10.2.5 Warranty management systems - supplemental

When the organization has been required to provide warranty for their product(s), Douglas Autotech has a warranty management process. Douglas Autotech includes in the process a method for warranty part analysis, including NTF (no trouble found). When specified by the customer, Douglas Autotech implements the required warranty management process.

10.2.6 Customer complaints and field failure test analysis - supplemental

Douglas Autotech performs analysis on customer complaints and field failures, including any returned parts, and initiates problem solving and corrective action to prevent recurrence.

Where requested by the customer, this will include analysis of the interaction of embedded software of the organization's product within the system of the final customer's product.

Douglas Autotech will communicate the results of testing/ analysis to the customer and also within the organization.

10.3 Continual improvement

We continually improve the suitability, adequacy and effectiveness of the quality management system.

Title: Quality Manual ISO 9001:2015 & IATF 16949 Supplement	Document No. I-4.4-C-AD-P- 001 Revision D	Date: 5-6-2020	Page 69 of 69
--	--	--------------------------	---------------

We consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities to be addressed as part of continual improvement.

10.3.1 Continual improvement – supplemental

Douglas Autotec has a documented process for continual improvement. Douglas Autotec includes in this process the following:

- a) Identification of the methodology used, objectives, measurement, effectiveness, and documented information;
- b) A manufacturing process improvement action plan with emphasis on the reduction of process variation and waste;
- c) Risk analysis (such as FMEA).