GENERAL MOTORS

IATF 16949 - Customer Specific Requirements

Posted Date: May 22, 2019

Effective Date: June 1, 2019

SUMMARY OF IATF 16949 SECTIONS WITH CUSTOMER-SPECIFIC CONTENT

* Denotes customer-specific content

1 Scope

1.1 Scope General

IATF 16949:2016, First Edition, Oct 1, 2016, "Automotive Quality Management System Standard," **ISO 9001:2015**, **Fifth Edition**, Sept 15, 2015, "Quality Management Systems – Requirements", and this document defines General Motors fundamental quality system requirements for organizations where automotive customer-specified parts for production and/or service are manufactured. Third party certification to IATF 16949 shall meet the following conditions:

- The certification scope must include both IATF 16949 and the accompanying IATF 16949 GM-Customer Specific Requirements,
- The certification must be conducted in compliance with the IATF recognized automotive certification scheme by a Certification Body currently contracted and recognized by the IATF.

All **IATF 16949:2016** requirements, including the requirements of this document, shall be addressed in the organization's quality management system.

The English language version of IATF 16949:2016 or related reference documents shall be the official version for purposes of third-party registration.

Sanctioned translations shall:

- Be for reference only
- Reference the English language as the official version
- Not contain ISO 9001:2015 text verbatim
- Include an appropriate copyright statement

Any other language translations are not authorized.

Organizations shall refer to the Quality Statement of Requirements (SOR), GM1927-03, for requirements for organizations supplying parts and materials to General Motors.

1.2 IATF 16949:2016 Deviations (Waivers)

Organizations requesting deviations (waivers) for IATF 16949:2016 Certification must contact their GM SQE and complete the GM1927-71 Quad Report for certification waiver and obtain GM Supplier Quality Leadership approval. The completed and approved Quad Report will be stored in GM's Supplier Certification Management System (SCMS) under the requesting Organization's DUNS.

2 Normative references

2.1 Normative and informative references

No additional requirements.

3 Terms and definitions

3.1 Terms and definitions for the automotive industry

Accredited Laboratory
An accredited laboratory is one that has been independently evaluated for technical competence. The criteria for evaluation are based on ISO/IEC 17025, or national equivalent. Accreditation is performed by qualified agencies (public or private) operating in accordance with ISO/IEC 17011.

NOTE: The above definition also applies to the reference manuals in Section 2 of this document and currently in effect.

Active Part
An active part is one currently being supplied to the customer for original equipment or service applications. The part remains active until tooling scrap authorization is given by the appropriate customer activity. For parts with no customer-owned tooling or situations where multiple parts are made from the same tool, written confirmation from the customer Purchasing activity is required to deactivate a part.

NOTE: For bulk material, "active part" refers to the bulk material contracted, not the parts that are subsequently produced from that material.

Aftermarket Parts
Aftermarket parts are replacement parts not procured or released by OEM for service part applications which may or may not be produced to original equipment specifications.

Accessory Parts
Parts manufactured to GM standards, that are procured or released by GM, and are mechanically attached or electronically connected to the vehicle before or after final delivery to the customer.

Bypass
Proactive approach to address potential error proofing failures with a defined and approved process which addresses the risk as defined in the PFMEA, considering safety, severity and overall RPN rating. Bypass process is established before a device failure. Bypass differs from a deviation process as a deviation process is a reactive process.

Customer
References to "customer" in **IATF 16949:2016** and this document shall be interpreted as the Procuring Division of General Motors for organizations pursuing third party registration to **IATF 16949:2016** to satisfy General Motors **sourcing requirements** third party quality system assessment registration.

Service Parts
Replacement parts manufactured to OEM specifications, which are procured or released by the OEM for service part application.

Severity Score
Severity Score for a GM supply organization is impacted when quality SPPS (Supplier Practical Problem Solving) records are written with a documented impact towards the GM final customer, GM manufacturing plant, or GM product (vehicle, powertrain or component). A Severity Matrix is used to equate the Plant and or Customer Impact resulting in a Severity Score.

Organization
Organizations are defined as providers of: a) production materials, b) production, service, and accessory parts, or c) heat treating, plating, painting or other finishing services, directly to General Motors or other customers subscribing to this document.

NOTE: See **IATF 16949:2016**, Section 3, *Terms and definitions*.

Suppliers
Suppliers are defined as organizations that are providers of: a) production materials, b) production, service, and accessory parts, or c) heat treating, plating, painting or other finishing services, directly to an organization who is a provider of General Motors or other customers subscribing to this document.

NOTE: The term "tier supplier(s)" refers to suppliers at any tier level in the automotive supply chain.

4 Context of the organization

No additional requirements.

4.1 Understanding the organization and its context

No additional requirements.

4.2 Understanding the needs and expectations of interested parties

No additional requirements.

4.3 Determining the scope of the quality management system

4.3.1 Determining the scope of the quality management system – supplemental

No additional requirements.

4.3.2 Customer-specific requirements

No additional requirements.

4.4 Quality management system and its processes

4.4.1

No additional requirements.

4.4.1.1 Conformance of products and processes

No additional requirements.

4.4.1.2 Product safety

No additional requirements.

4.4.2

No additional requirements.

5 Leadership

5.1 Leadership and commitment

5.1.1 General

No additional requirements.

5.1.1.1 Corporate responsibility

No additional requirements.

5.1.1.2 Process effectiveness and efficiency

No additional requirements.

5.1.1.3 Process owners

No additional requirements.

5.1.2 Customer focus

No additional requirements.

5.2 Policy

5.2.1 Establishing the quality policy

No additional requirements.

5.2.2 Communicating the quality policy

No additional requirements.

5.3 Organizational roles, responsibilities and authorities

5.3.1 Organizational roles, responsibilities, and authorities – supplemental

No additional requirements**.**

5.3.2 Responsibility and authority for product requirements and corrective actions

No additional requirements.

6 Planning

6.1 Actions to address risks and opportunities

No additional requirements.

6.1.1 and 6.1.2

No additional requirements,

6.1.2.1 Risk analysis

No additional requirements.

6.1.2.2 Preventive action

No additional requirements.

6.1.2.3 Contingency plans

No additional requirements.

6.2 Quality objectives and planning to achieve them

6.2.1 and 6.2.2

No additional requirements.

6.2.2.1 Quality objectives and planning to achieve them – supplemental

No additional requirements.

6.3 Planning of changes

No additional requirements.

7 Support

7.1 Resources

7.1.1 General

No additional requirements

7.1.2 People

No additional requirements

7.1.3 Infrastructure

No additional requirements

7.1.3.1 Plant, facility, and equipment planning

No additional requirements

7.1.4 Environment for the operation of processes

No additional requirements

7.1.4.1 Environment for the operation of processes – supplemental

No additional requirements

7.1.5 Monitoring and measuring resources

No additional requirements

7.1.5.1 General

No additional requirements

7.1.5.1.1 Measurement system analysis

No additional requirements

7.1.5.2 Measurement traceability

No additional requirements

7.1.5.2.1 Calibration/verification records

No additional requirements

7.1.5.3 Laboratory requirements

No additional requirements

7.1.5.3.1 Internal laboratory

No additional requirements

7.1.5.3.2 External laboratory

No additional requirements

7.1.6 Organizational knowledge

No additional requirements

7.2 Competence

7.2.1 Competence – supplemental

No additional requirements

7.2.2 Competence – on-the-job training

No additional requirements

7.2.3 Internal auditor competency

No additional requirements

7.2.4 Second-party auditor competency

No additional requirements

7.3 Awareness

No additional requirements

7.3.1 Awareness – supplemental

No additional requirements

7.3.2 Employee motivation and empowerment

No additional requirements

7.4 Communication

7.5 Documented information

7.5.1 General

No additional requirements

7.5.1.1 Quality management system documentation

No additional requirements

7.5.2 Creating and updating

No additional requirements

7.5.3 Control of documented information

No additional requirements

7.5.3.1 and 7.5.3.2

No additional requirements

7.5.3.2.1 Record retention

The organization's business records shall be retained as specified in GMW15920. Organizations can purchase GMW documents from IHS at www.global.ihs.com

7.5.3.2.2 Engineering specifications

No additional requirements

8 Operation

8.1 Operational planning and control

8.1.1 Operational planning and control — supplemental

No additional requirements

8.1.2 Confidentiality

No additional requirements

8.2 Requirements for products and services

8.2.1 Customer communication

No additional requirements

8.2.1.1 Customer communication — supplemental

No additional requirements

8.2.2 Determining the requirements for products and services

No additional requirements

8.2.2.1 Determining the requirements for products and services - supplemental

No additional requirements

8.2.3 Review of the requirements for products and services

No additional requirements

8.2.3.1

No additional requirements

8.2.3.1.1 Review of the requirements for products and services — supplemental

No additional requirements

8.2.3.1.2 Customer-designated special characteristics

The organization shall follow General Motors **Key Characteristic Designation System Process GMW15049**. Key Characteristics shall be applied as per IATF 16949:2016 8.3.3.3 Special Characteristics.

8.2.3.1.3 Organization manufacturing feasibility

No additional requirements

8.2.3.2

No additional requirements

8.2.4 Changes to requirements for products and services

No additional requirements

8.3 Design and development of products and services

8.3.1 General

No additional requirements

8.3.1.1 Design and development of products and services – supplemental

No additional requirements

8.3.2 Design and development planning

No additional requirements

8.3.2.1 Design and development planning – supplemental

No additional requirements

8.3.2.2 Product design skills

No additional requirements

8.3.2.3 Development of products with embedded software

No additional requirements

8.3.3 Design and development inputs

No additional requirements

8.3.3.1 Product design input

All operations shall be analyzed for risk using a PFMEA. Product requirements shall be identified, and failure modes comprehended in the PFMEA. Risk Priority Number (RPN) values shall be consistently applied using Severity, Occurrence, and Detection ranking tables. Severity shall be based on all risks such as organization risk, customer risk, and end user risk.

8.3.3.2 Manufacturing process design input

No additional requirements

8.3.3.3 Special characteristics

The organization shall have a process to identify critical operations within their manufacturing process.

8.3.4 Design and development controls

No additional requirements

8.3.4.1 Monitoring

No additional requirements

8.3.4.2 Design and development validation

No additional requirements

8.3.4.3 Prototype programme

No additional requirements

8.3.4.4 Product approval process

The organization shall comply with the AIAG Production Part Approval Process (PPAP) manual and GM 1927-03 Quality SOR to meet this requirement.

8.3.5 Design and development outputs

No additional requirements

8.3.5.1 Design and development outputs – supplemental

No additional requirements

8.3.5.2 Manufacturing process design output

The organization shall have a method to identify, control, and monitor the high-risk items on those critical operations.

There shall be rapid feedback and feed forward between inspection stations and manufacturing, between departments, and between shifts.

8.3.6 Design and development changes

No additional requirements

8.3.6.1 Design and development changes – supplemental

All design changes, including those proposed by the organization, shall have written approval by the authorized customer representative, or a waiver of such approval, prior to production implementation. See also AIAG **Production Part Approval Process (PPAP)** manual.

8.4 Control of externally provided processes, products and services

8.4.1 General

8.4.1.1 General - supplemental

No additional requirements

8.4.1.2 Supplier selection process

No additional requirements

8.4.1.3 Customer-directed sources (also known as "Directed–Buy")

No additional requirements

8.4.2 Type and extent of control

No additional requirements

8.4.2.2 Statutory and regulatory requirements

No additional requirements

8.4.2.3 Supplier quality management system development

No additional requirements

8.4.2.3.1 Automotive product-related software or automotive products with embedded software

No additional requirements

8.4.2.4 Supplier monitoring

No additional requirements

8.4.2.4.1 Second-party audits

Second-party auditors performing QMS audits must meet the requirements in clause 7.2.4 Second-Party Auditor Compliance in IATF 16949:2016 plus meet these additional requirements:

1. The organization must be IATF 16949:2016 certified and not on suspension.
2. The Second Party Auditor must be a qualified ISO Lead Auditor, or a qualified internal auditor with evidence of their successful completion of training, and a minimum of five internal ISO/TS 16949:2009 and/or IATF 16949:2016 audits under the supervision of a qualified lead auditor.

The organization may conduct (2nd party) audits of their supplier per their supplier development risk management analysis.

For initial certifications, the first second party audit should use the initial audit days from Table 5.2*. For subsequent second party audits use the recertification days Table 5.2*.

*See ***Automotive Certification Scheme for IATF 16949, Rules for Achieving and Maintaining IATF Recognition, section 5.2, Table 5.2 Minimum audit days.***

The second party audits shall identify an acceptable passing level and include a scoring or ranking to determine which suppliers have passed. The organization shall have documented evidence that they review and follow up on all non-conformances identified in the second-party audit with the intent to close these non-conformances.

8.4.2.5 Supplier development

When a supplier to an organization is so small as to not have adequate resources to develop a system according to IATF 16949:2016 or ISO 9001:2015, certain specified elements may be waived by the organization. The organization shall have decision criteria for determining "specially designated small suppliers". Such decision criteria shall be in writing and applied consistently in the application of this provision. The existence and use of such decision criteria shall be verified by 3rd party auditors.

NOTE 1: ISO 9001:2015 and IATF 16949:2016 Minimum Automotive Quality Management System Requirements for Sub-Tier Suppliers contain fundamental quality management system requirements of value to any size of provider of production materials, production, service, and accessory parts, or heat treating, plating, painting or other finishing services. There are a number of methods to implement a compliant system, so it is recognized that a simpler Quality Management System approach could be used for the smaller suppliers of organizations to which IATF 16949:2016 clause 8.4.2.3 applies.

NOTE 2: "Small" may also refer to volume supplied to automotive.

8.4.3 Information for external providers

8.4.3.1 Information for external providers - supplemental

No additional requirements

8.5 Production and service provision

8.5.1 Control of production and service provision

No additional requirements

8.5.1.1 Control plan

General Motors does not provide waivers to organizations for control plan approval because General Motors signatures on the Control Plan are not required.

The organization shall provide measurement, test, and inspection data which demonstrates that control plan requirements, sample sizes, and frequencies are being met when requested.

Sample sizes and frequencies shall be determined based on risk and occurrence of failure modes, and to ensure that the customer is adequately protected from receiving the product represented by the inspection/tests before the results of the inspection/tests are known.

8.5.1.2 Standardized work – operator instructions and visual standards

Standardized work should include the what, how, and why tasks are performed. All standardized work shall be followed.

Visual standards throughout the facility shall be common, including between facilities building the same platform/product for global quality.

Visual standards shall be clearly communicated to all team members that are affected and referenced in the standardized work.

Visual standards that differentiate “good” from “bad” shall satisfy customer requirements and be controlled.

8.5.1.3 Verification of job set-ups

No additional requirements

8.5.1.4 Verification after shutdown

No additional requirements

8.5.1.5 Total productive maintenance

No additional requirements

8.5.1.6 Management of production tooling and manufacturing, test, inspection tooling and equipment

Where warehouses or distribution centers (distributors) are remote sites, the requirements for management of production tooling may not be applicable.

8.5.1.7 Production scheduling

No additional requirements

8.5.2 Identification and traceability

No additional requirements

8.5.2.1 Identification and traceability — supplemental

No additional requirements

8.5.3 Property belonging to customers or external providers

No additional requirements

8.5.4 Preservation

No additional requirements

8.5.4.1 Preservation - supplemental

No additional requirements

8.5.5.1 Feedback of information from service

No additional requirements

8.5.5.2 Service agreement with customer

No additional requirements

8.5.6 Control of changes

No additional requirements

8.5.6.1 Control of changes – supplemental

The documented process shall require consideration of a production trial run for every product and process change. Results of the trial run shall be documented.

8.5.6.1.1 Temporary change of process controls

The organization shall have a process for both bypass and deviation. The alternative actions identified on the bypass list shall be customer approved and shall be reviewed using the methodology of the PFMEA to identify the risk. This review shall be documented.

8.6 Release of products and services

8.6.1 Release of products and services — supplemental

No additional requirements

8.6.2 Layout inspection and functional testing

Unless specified otherwise by a GM Procuring Division, there is no customer established frequency for layout inspection after receiving production part approval (PPAP).

8.6.3 Appearance items

No additional requirements

8.6.4 Verification and acceptance of conformity of externally provided products and services

No additional requirements

8.6.5 Statutory and regulatory conformity

No additional requirements

8.6.6 Acceptance criteria

No additional requirements

8.7 Control of nonconforming outputs

8.7.1

No additional requirements

8.7.1.1 Customer authorization for concession

No additional requirements

8.7.1.2 Control of nonconforming product – customer-specified process

No additional requirements

8.7.1.3 Control of suspect product

No additional requirements

8.7.1.4 Control of reworked product

No additional requirements

8.7.1.5 Control of repaired product

No additional requirements

8.7.1.6 Customer notification

No additional requirements

8.7.1.7 Nonconforming product disposition

No additional requirements

8.7.2

No additional requirements

9 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

No additional requirements

9.1.1.1 Monitoring and measurement of manufacturing processes

The organization shall have a method for the employee to call or notify for help when an abnormal condition on the equipment or product occurs. A method to call or notify shall be available in all operational areas of the organization.

Sufficient alarm limits shall be established for escalation of abnormal conditions and shall match the reaction plan identified in the product's control plan.

9.1.1.2 Identification of statistical tools

No additional requirements

9.1.1.3 Application of statistical concepts

No additional requirements

9.1.2 Customer satisfaction

No additional requirements

9.1.2.1 Customer satisfaction – Supplemental.

New Business Hold

The organization shall notify their Certification Body within 5 business days of receiving notice of special status condition of GM New Business Hold – Quality. The Certification Body shall take the decision to place the organization on immediate suspension* upon receiving notice of GM New Business Hold – Quality (NBH).

*See ***Automotive Certification Scheme for IATF 16949, Rules for Achieving and Maintaining IATF Recognition, section 8.3.***

1. In the event of certification suspension as a result of an organization receiving notice of General Motors New Business Hold – Quality, the organization shall complete a corrective action plan. The organization shall submit the corrective action plan to the Certification Body and to the affected customer(s) within 10 business days of the effective date of the NBH. The corrective action plan of the organization shall be consistent with the affected customer requirements including correction steps, responsibilities, timing information, and key metrics to identify effectiveness of the action plan.
2. Before any suspension can be lifted, the Certification Body shall take the decision to conduct an on-site special audit of appropriate length to verify effective implementation of all corrective actions. The special audit must be conducted within 90 calendar days from the notice of New Business Hold – Quality.

If suspension is not lifted within the maximum of 110 calendar days from the notice of New Business Hold – Quality, the Certification Body shall withdraw the IATF 16949 certificate of the organization. Exceptions to this withdrawal shall be justified in writing by the Certification Body based upon its on-site review of the effectiveness of the organization's corrective action plan and agreement obtained in writing from the authorized GM customer representative.

NOTE 1: When an organization is placed in NBH after a recertification (or initial) site audit but before the certificate is issued:

- The Certification Body shall issue the certificate in accord with the IATF Rules.
- The Certification Body shall then place the new certificate in immediate suspension with the rules for lifting such suspension appropriately applied.

BIQS Requirements
Organizations shall achieve and maintain BIQS Level of 3, 4 or 5. The organization whose BIQS Level falls below Level 3 shall notify its Certification Body within 5 business days after falling below the stated requirement. If the organization fails to notify their Certification Body, the Certification Body shall issue a minor non-conformance against IATF 16949:2016, clause 9.1.2.1.

The Certification Body shall issue a major non-conformance against IATF 16949:2016, clause 9.1.2.1, when they are notified (or discover) the organization is at a BIQS Level 1 or 2. The Certification Body shall conduct an on-site special audit.
Organizations that have not had their initial IATF 16949 certification and are BIQS Level 1 or 2 shall not be issued a non-conformance.

To close this major non-conformance during the on-site special audit, the organization shall have either 1) achieved BIQS metrics of Level 3, 4 or 5; or 2) a documented action plan, confirmed by the GM SQE or SQE designee, detailing the steps, improvements, with target dates, being made to achieve BIQS Level 3, 4 or 5.
NOTE: The GM system Sourceability Report will indicate a BIQS Level of 1 or 2 for those organizations not meeting the BIQS requirements.

CSII (Controlled Shipping Level 2)
The organization shall notify its Certification Body within 5 business days after being placed in Controlled Shipping – Level 2 (CS II) Status. The Certification Body is not required to issue a non-conformance for an organization placed in CSII status.

For CSII activities that are open during an audit, the organization's Certification Body shall verify that an effective corrective action is in process and, if closed, that the corrective actions have been implemented and read across to the entire organization's site for similar processes and/or products. The organization's Certification Body shall also investigate any CSII activities that have occurred and were closed between surveillance audits.

> **NOTE**: The GM condition of CS II (Controlled Shipping – Level 2) is a performance indicator of problems in an organization's product realization process. The CSII condition should have resolution, or credible resolution and corrective plans in place, which are confirmed by the customer.

9.1.3 Analysis and evaluation

No additional requirements

9.1.3.1 Prioritization

No additional requirements

9.2 Internal audit

9.2.1 AND 9.2.2

No additional requirements

9.2.2.1 Internal audit programme

No additional requirements

9.2.2.2 Quality management system audit

No additional requirements

9.2.2.3 Manufacturing process audit

The organization shall incorporate an internal layered process audit process to assess compliance to standardized processes, to identify opportunities for continuous improvement, and to provide coaching opportunities. The layered process audit is led by Management who are competent to conduct the audits. The process shall include:

1. A schedule including frequency of audits and locations of planned audits.
2. Audit layers must be used and include different levels of employees, including top management.
3. Customer complaints or rejections trigger a layered audit on the process that was cause of the issue.
4. All departments within the organization.
5. All findings are recorded and measured for improvement.
6. Findings that cannot be corrected during the audit shall move to an action plan for monitoring to closure.
7. Records of audits shall be maintained.
8. Layered audit questions shall be reviewed periodically and changed if needed to focus on the organization's weaknesses.
9. Layered process audit shall be done as part of corrective action verification activities.

In addition to layered process audits the organization shall audit specific manufacturing processes (see chart below) annually to determine their effectiveness. Applicability and effectiveness of these processes shall be determined utilizing the most current version CQI standard (see chart below). The effectiveness evaluation shall include the organization's self-assessment, actions taken, and that records are maintained.

NOTE 1: The assessment must be performed by a competent auditor. An auditor is competent if they meet the following requirements:

- They shall be a qualified ISO 9001:2015 Lead Auditor, or a qualified internal auditor with evidence of their successful completion of training, and a minimum of five internal ISO/TS 16949:2009 and/or IATF 16949:2016 audits under the supervision of a qualified lead auditor.
- They shall have a minimum of 5 years' experience working with the process that is being audited or a combination of experience and education in the specific process.

NOTE 2: Audit findings must be addressed in an action plan, with champion(s) assigned and reasonable closure dates.

CQI Standards:

Heat Treating Processes	CQI-9 Heat Treat System Assessment
Plating Processes	CQI-11 Plating System Assessment
Coating Processes	CQI-12 Coating System Assessment
Welding Process	CQI-15 Weld System Assessment
Plastics Molding Processes	CQI-23 Molding System Assessment
Solder Processes	CQI-17 Soldering System Assessment
Casting Process	CQI-27 Casting System Assessment

9.2.2.4 Product audit

The organization shall perform quality focused checks on each shift.

The organization shall have a process for final inspection and/or Customer Acceptance Review & Evaluation (CARE). GP-12 shall be performed as required during launch and until released by the organization's assigned SQE or designate and per GM 1927-28 Early Production Containment (GP-12).

1. Final inspection shall be performed on all finished product prior to shipping. This inspection can be 100% inspection or less based on risk.
2. GP-12 inspection checks shall be included at an upstream inspection station (final inspection/CARE).
3. Quality checks shall be included in standardized work. Point, touch, listen, and count inspection methods are incorporated.
4. Successive production/quality checks shall be increased in cases of high risks such as model launch, pass through components and characteristics pass through, major changes, shut down (see clause 8.5.1.4) or customer feedback.

9.3 Management review

9.3.1 General

No additional requirements

9.3.1.1 Management review - supplemental

No additional requirements

9.3.2 Management review inputs

No additional requirements

9.3.2.1 Management review inputs – supplemental

No additional requirements

9.3.3 Management review outputs

No additional requirements

9.3.3.1 Management review outputs – supplemental

No additional requirements

10 Improvement

10.1 General

10.2 Nonconformity and corrective action

No additional requirements

10.2.1 and 10.2.2

No additional requirements

10.2.3 Problem solving

The organization's documented problem-solving process shall include:

1. Tracking of issues through closure.
2. Daily review of issues by a multi-disciplined team including plant management.
3. Daily reviews are documented.
4. All levels of the organization are included in the problem-solving process.
5. Robust method to identify the verifiable root cause(s) of each issue.
6. Timely closure of corrective action(s) including exit criteria.
7. Initial containment is well documented using a containment worksheet or similar

10.2.4 Error-proofing

Error proofing devices shall be tested to failure or simulated failure at the beginning of each shift at a minimum, otherwise according to the control plan. In the event of error proofing device failure, a reaction plan that includes containment should be included in the control plan.

The organization shall keep a list of all error proofing devices and identify which can be bypassed and which cannot (also see clause 8.5.6.1.1). The bypass determination shall consider safety, severity and overall RPN rating.

10.2.5 Warranty management systems

No additional requirements

10.2.6 Customer complaints and field failure test analysis

No additional requirements

10.3 Continual improvement

No additional requirements

10.3.1 Continual improvement – supplemental

The organization shall have a process for effective review of PFMEA of all manufacturing parts and processes to occur annually at a minimum. This review shall consider, at a minimum, critical, safety, and high-risk items. The organization shall incorporate tools such as reverse PFMEA or other similar methods to assist in the PFMEA review. PFMEA review output shall include an updated PFMEA, record of the changes made (or record that no changes were made), and identification of the team involved in the review.

Critical, safety, and high-risk items (such as priority from Risk Limiting Method, high RPN or equivalent) shall have an action plan which includes recommended actions, responsibility, and timing.

Reviewing a PFMEA for corrective action process does not meet the requirement of annual review unless there is evidence that critical, safety, and high-risk items are considered in addition to the corrective action issue. A proactive review approach is required.

Publication date	Change effective date	Section	Change
Dec 1, 2016	Jan 1, 2017	All	Release
Sept 6, 2017	Nov 1, 2017	1.1	Changed release date format of ISO 9001:2015
		3.1	Added Accessory Parts definition; added accessory parts to definitions of Organizations and Suppliers
		8.3.3.1	Added requirements
		8.3.3.3	Moved requirements from 8.3.5.2
		8.3.5.2	Added requirements
		8.4.2.3	Added Accessory Parts; added "This clause does not apply to" the beginning of the 2nd paragraph
		8.4.2.4.1	Changed formatting, added "performing QMS audits" in first paragraph; in 2nd paragraph the wording was changed to clarify who a qualifying supplier is; added 4th paragraph
		8.4.2.5	Added accessory parts
		8.5.1.1	Added 2nd and 3rd paragraphs
		8.5.1.2	Added 2nd, 3rd, and 4th paragraphs
		8.5.6.1.1	Added requirements for review of risk and
		9.1.1.1	Added requirements
		9.1.2.1	BIQS Certification section: 1st paragraph - Added withdrawn which is the same as revoked, added expired. Added 3rd paragraph and the 2 notes.
		9.2.2.3	Added item #9
		9.2.2.4	Added per GM1927-28
		10.2.3	Item #5 added "including exit criteria"
		10.3.1	Added requirements
May 21, 2019	June 1, 2019	1.2	Added IATF 16949:2016 Deviations (Waivers)
		3.1	Replaced PRR with SPPS
		7.5.3.2.1	Added note on how to purchase
		8.4.2.4.1	Removed probation from #1; 2nd paragraph Updated, The organization may conduct (2nd party) audits of their supplier per their supplier development risk management analysis; 3rd paragraph updated duration statement added *See ***Automotive Certification Scheme for IATF 16949, Rules for Achieving and Maintaining IATF Recognition, section 5.2, Table 5.2 Minimum audit days.***

		8.4.2.5	Note 1 added MAQMSR
		9.1.2.1	**New Business Hold** 1st paragraph added supplier notification requirement to CB; #2 replaced assessment with special audit and timing note for special audit; 2nd paragraph added maximum days from notice; replaced revoke with withdraw; replaced revocation with withdrawal; deleted **NOTE 1**: The permitted suspension period for General Motors Europe (GME) is six (6) months.
			BIQS Requirements Updated Section
			CSII (Controlled Shipping Level 2) Note: replaced special status with performance indicator; Added, the Certification Body is not required to issue a non-conformance.
		9.2.2.3	Added Welding Process CQI 15 Weld System assessment
		10.2.3	Updated #4 ***All levels of the organization are included in the problem-solving process; Added new #5*** Robust method to identify the verifiable root cause(s) of each issue
		10.2.4	1st paragraph added in the event of error proofing device failure, a reaction plan that includes containment should be included in the control plan
		8.4.2.3	Updated; corrections were made between May 1st and May 22nd; Clause number typographic error corrected June4th