

# GENERAL MOTORS

## IATF 16949 - Customer Specific Requirements



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\* Denotes customer-specific content

## 1 Scope

### 1.1 Scope General

**IATF16949:2016, First Edition**, Oct 1, 2016, “Automotive Quality Management System Standard,” **ISO9001:2015, 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 IATF16949 shall meet the following conditions:

- The certification scope must include both IATF16949 and the accompanying IATF16949 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 an IATF Oversight office.

All **IATF16949:2016** requirements, including the requirements of this document, shall be addressed in the organization’s quality management system.

The English language version of IATF16949:2016 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.

## 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 **IATF16949:2016** and this document shall be interpreted as the Procuring Division of General Motors for suppliers pursuing third party registration to **IATF16949:2016** 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 PRR is written with a documented impact towards the GM final customer, GM manufacturing plant, and 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 **IATF16949:2016**, 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**

### **4.1 Understanding the organization and its context**

### **4.2 Understanding the needs and expectations of interested parties**

### **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.

##### **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 IATF16949:2016 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**

This clause applies to suppliers of the organization who are providers of: a) production materials, b) production, service, and accessory parts, or c) heat treating, plating, painting or other finishing services.

This clause does not apply to indirect or providers of services that add no manufacturing value which include, but is not limited to distributors, logistics, sequencers, parts packagers, tooling and equipment.

#### **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 IATF16949:2016 plus meet these additional requirements:

1. The organization (2<sup>nd</sup> party) must be IATF16949:2016 certified and not on probation or suspension.
2. The organization (2<sup>nd</sup> party) must utilize 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/TS16949:2009 and/or IATF16949:2016 audits under the supervision of a qualified lead auditor.

The organization (2<sup>nd</sup> party) must audit annually each qualifying supplier and maintain records of the audit. Qualifying supplier is defined by those suppliers determined to need second-party auditing per clause 8.4.2.4.1 Second-Party Audits.

The duration of these audits must conform to the full application of the Audit Day Requirements table of the current edition of Automotive Certification Scheme for IATF16949 Rules for Achieving and Maintaining IATF Recognition.

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 IATF16949:2016 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 3<sup>rd</sup> party auditors.

NOTE 1: ISO9001:2015 and IATF16949:2016 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 IATF16949:2016 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 Certification Body (CB) of record to the organization shall take the decision to place the organization on immediate suspension \* upon receiving notice of GM New Business Hold – Quality.

*\*See Automotive Certification Scheme for IATF16949, Rules for Achieving and Maintaining IATF Recognition.*

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 of record and to the affected customer(s) within 10 business days of the date of the letter of notification of probation. The corrective action plan of the organization shall be consistent with the affected customer(s) 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 of record shall take the decision to conduct an on-site assessment of appropriate length to verify effective implementation of all corrective actions.

If suspension is not lifted within four months of its issuance, the Certification Body of record shall revoke the IATF16949 certificate of the organization. Exceptions to this revocation 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:** The permitted suspension period for General Motors Europe (GME) is six (6) months.

**NOTE 2:** When an organization is placed in NBH after a recertification site audit but before the certificate for recertification 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 Certification

Organizations shall achieve and maintain BIQS or QSB certification. The organization who's BIQS or QSB certification is revoked (withdrawn) or expired shall notify it's Certification Body within 5 business days after revocation or expiration.

Lack of the organization having a BIQS or QSB certification shall result in a major finding by the organization's Certification Body.

For a Certification Body to close this major finding during the verification audit, the organization shall have either 1) achieved BIQS certification 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 certification.

**NOTE 1:** Exclusions to BIQS certification are shown as WAVD (waived) or NAN (No Audit Needed).

**NOTE 2:** The GM system will indicate the designation of WDRN (Withdrawn) for expired or revoked status.

### **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. For CSII activities that are open during an audit, the organization’s certification body shall verify that an effective corrective action process 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 are closed between surveillance audits.

**NOTE:** The GM special status conditions of CS II (Controlled Shipping – Level 2) is a performance indicators of an organization’s product realization problems. Such status should have resolution, or credible resolution and corrective plans in place, which are confirmed by the customer.

### **Process Specific Audits**

The organization shall audit specific manufacturing processes (see chart below) annually to determine its 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:** 2nd Party assessment must be performed by a competent auditor. An auditor is competent if they meet the following requirements:

- They shall 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/TS16949:2009 and/or IATF16949:2016 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.

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

### **9.1.3 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.

#### **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 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 method 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 including in the problem solving process.
5. Timely closure of corrective action(s) including exit criteria.
6. Initial containment is well documented by the use of 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.

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 method 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 2 <sup>nd</sup> paragraph
		8.4.2.4.1	Changed formatting, added "performing QMS audits" in first paragraph; in 2 <sup>nd</sup> paragraph the wording was changed to clarify who a qualifying supplier is; added 4 <sup>th</sup> paragraph
		8.4.2.5	Added accessory parts
		8.5.1.1	Added 2 <sup>nd</sup> and 3 <sup>rd</sup> paragraphs
		8.5.1.2	Added 2 <sup>nd</sup> , 3 <sup>rd</sup> , and 4 <sup>th</sup> 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: 1 <sup>st</sup> paragraph - Added withdrawn which is the same as revoked, added expired. Added 3 <sup>rd</sup> 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