

# 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**, 09/15/15, “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.

#### **Consulting**

For the purposes of **TS16949:2016**, consulting is the provision of training, documentation development, or assistance with implementation of quality systems to a specific customer. If these activities are open to the public, advertised, and not customer specific, they are considered training rather than consulting. Other products, processes or services may be offered directly or indirectly, provided they do not compromise confidentiality or the objectivity or impartiality of its certification process or decisions. Refer to the most current version of Automotive Certification Scheme for **IATF16949 Rules**. Also see **ISO/IEC 17021**.

## **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.

## **Ergonomics**

Ergonomics is the evaluation of the design of a product or process to assure compatibility with the capabilities of human beings. Analysis of motion refers to capabilities of people with respect to tasks (e.g. lifting, twisting, reaching) to prevent or relieve problems of strain, stress, excessive fatigue, etc. Factors involved include anatomical dimensions of the worker, placement of products to be worked upon, placement of buttons/switches, physical loads imposed on the worker, and environmental effects such as noise, vibration, lighting and space

## **Initial Process Study**

Initial Process Studies are short-term studies conducted to obtain early information on the performance of new or revised processes relative to internal or customer requirements. In many cases, preliminary studies should be conducted at several points in the evolution of new processes (e.g. at the equipment or tooling subcontractor’s plant, after installation at the supplier’s plant). These studies should be based on as many measures as possible. When utilizing X-Bar and R charts, at least twenty-five subgroups (minimum of four pieces per sub-group) are required to obtain sufficient data for decision-making.

When this amount of data is not available, control charts should be started with whatever data is available, or contact the authorized customer representative to develop a suitable plan. See also the **Production Part Approval Process (PPAP)** in Section 5.

**NOTE: Initial Process Studies.** The purpose of the initial process study is to understand the process variation, not just to achieve a specific index value. When historical data are available or enough initial data exist to plot a control chart (at least 100 individual samples),  $C_{pk}$  can be calculated when the process is stable. Otherwise, for processes with known and predictable special causes and output meeting specifications,  $P_{pk}$  should be used. When not enough data are available (< 100 samples) or there are unknown sources of variation, contact the authorized customer representative to develop a suitable plan.

### **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.

### **Quality Indices**

See current edition **AIAG Statistical Process Control** reference manual.

### **Organization**

Organizations are defined as providers of: a) production materials, b) production or service 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*.

### **Service parts**

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

### **Suppliers**

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

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

### **Value-Added Production Processes**

Refers to activities or operations that improve the product for which a customer is willing to pay, where given the option.

See also **IATF16949:2015** definition of “manufacturing”, “site”, and “remote location”.

## **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**

# **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**

Note: Examples of such systems for suppliers to GM's North American Operations are: 1) requirement planning information such as the Electronic Data Interchange (EDI) ANSI ASC X12 830 transaction set or the EDIFACT DELFOR message; 2) shipping schedules such as the ANSI ASC X12 862 or 866 transaction sets or the EDIFACT DELJIT message; 3) the ANSI ASC X12 856 transaction set; 4) the EDIFACT DESADV message.

#### **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**

No additional requirements

#### **8.3.3.2 Manufacturing process design input**

No additional requirements

#### **8.3.3.3 Special characteristics**

No additional requirements

### **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 process to identify high risk items at critical operations.

### **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 production materials, or production or service parts. Also included are providers of heat-treating, painting, plating, or other finishing services.

Indirect and service providers are not included in this requirement, e.g. distributors adding no manufacturing value, 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 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.
3. The organization (2<sup>nd</sup> party) must audit annually each qualifying supplier for whom it has performed a 2<sup>nd</sup> party assessment, and maintain records of the audit
4. 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.

### **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 of their supplier. 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/ service parts/ materials. 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.

##### **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.

##### **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

#### **8.5.5.1 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 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). A bypass list for error proofing devices identifies what the bypass method (alternate method) is before a device failure so that when a failure occurs, the list can be referenced for action to be taken. This list shall be available to all associates with the decision responsibility to bypass. Implemented bypasses are reviewed in daily leadership meeting(s) with the goal to return to normal operation. Processes/devices in bypass shall have a quality focused audit performed.

#### **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**

No additional requirements

### 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 whose BIQS or

QSB certification is revoked shall notify its Certification Body within 5 business days after revocation.

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

### **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.

**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

### **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.

#### **9.2.2.4 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.

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).
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 when feasible, 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**

#### **10.3.1 Continual improvement – supplemental**

No additional requirements

Publication date	Change effective date	Section	Change
Dec 1, 2016	Jan 1, 2017	All	Release