

## **SYSTEMS POLICY MANUAL**

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### **REVISION HISTORY**


<u>Revision Date</u>	<u>Revision Number</u>	<u>Description</u>
01/03/05	1	Released
02/27/05	2	Removed Clause 7.3 / Revised Clause 8.2.2 / Added Exclusion comment under Application / Removed note #2 from Clause 7.1
07/27/05	3	Removed Bullet #5 & #6 under Quality Objectives
09/15/05	4	Updated to ISO/TS 16949
09/25/06	5	Added justification to exclusion / revised process map / revised preventive action page to include drawing / revised approval page
03/14/07	6	Revised Process Map / Added GM to Approval sign-off
01/25/08	7	Revised Process Map
4/8/08	8	Removed dates under Standards / Guidelines
6/4/08	9	Revised Process Map
12/30/08	10	Updated to reflect new ISO 9001:2008 requirements

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**Approval Document**

We have reviewed and agree with the procedures and policies described in this manual, and are committed to follow all aspects of the quality management system.

General Manager:  1/5/09

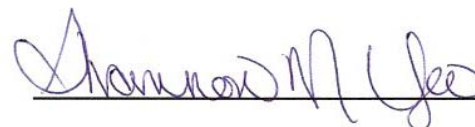
Operations:  1/5/09

Quality:  1/5/09

Sales:  1/5/09

Purchasing:  1-5-09.

Manufacturing:  1/5/09

Shipping/Receiving:  1/5/09

All top management personnel are to sign and date confirming their acceptance of the manual.

## **DISTRIBUTION AND CONTROL**

A.G Manufacturing's Quality Management System documentation is primarily contained as an on-line document. The documentation is accessible at most stand-alone computer stations.

Any printed pages of the policy manual, procedures, and work instructions are labeled uncontrolled.

A Printed uncontrolled copy is maintained by the Quality department.

## **GENERAL**

This manual describes the policies and company-wide control systems of A.G Manufacturing's quality management system. This system meets the requirements of ISO 9001 (2008), TS-16949 (2002), Chrysler, Ford and General Motors supplements.

A.G Manufacturing manufactures electrical distribution systems.

All products manufactured are included in the Quality Management System.

This manual describes A.G Manufacturing's mission and policy statements as it relates to the quality standards of the company. These are supported by our procedures and work instructions to insure that our customer and applicable regulatory requirements are identified, communicated, and achieved to ensure customer satisfaction is attained, and our Quality Management System is continually improved.

This manual is our primary reference document for all our quality related activities, and is used to communicate our commitment to quality and to drive our Quality Management System

The Quality Management System follows the elements of ISO 9001, TS-16949 (2002), and also references other key documents that were used. Where further detail is required, there are procedural documents that support our Work Instructions.

Our Quality Management System Representative is our Quality Manager. They are responsible for insuring that processes are established, implemented, and maintained according to ISO 9001:2008, TS-16949 (2002) and that the objectives are met.

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## **APPLICATION**

All of the activities at AG Manufacturing are considered within the scope of the Quality Management System to ISO 9001, TS-16949 (2002) with the exclusions of clauses 7.3.2.1 and 7.3.3.1. These exclusions do not affect AG Mfg. ability or responsibility to provide product that meets customer and applicable regulatory requirements. As a build to print facility AG Manufacturing is not responsible for design related issues.

Where "typical", "example", or "e.g." are used, any suggestions provided are for guidance only. Paragraphs marked "NOTE" are for guidance in understanding or clarifying the associated requirement. The word, "should," appearing in a NOTE is for guidance only.

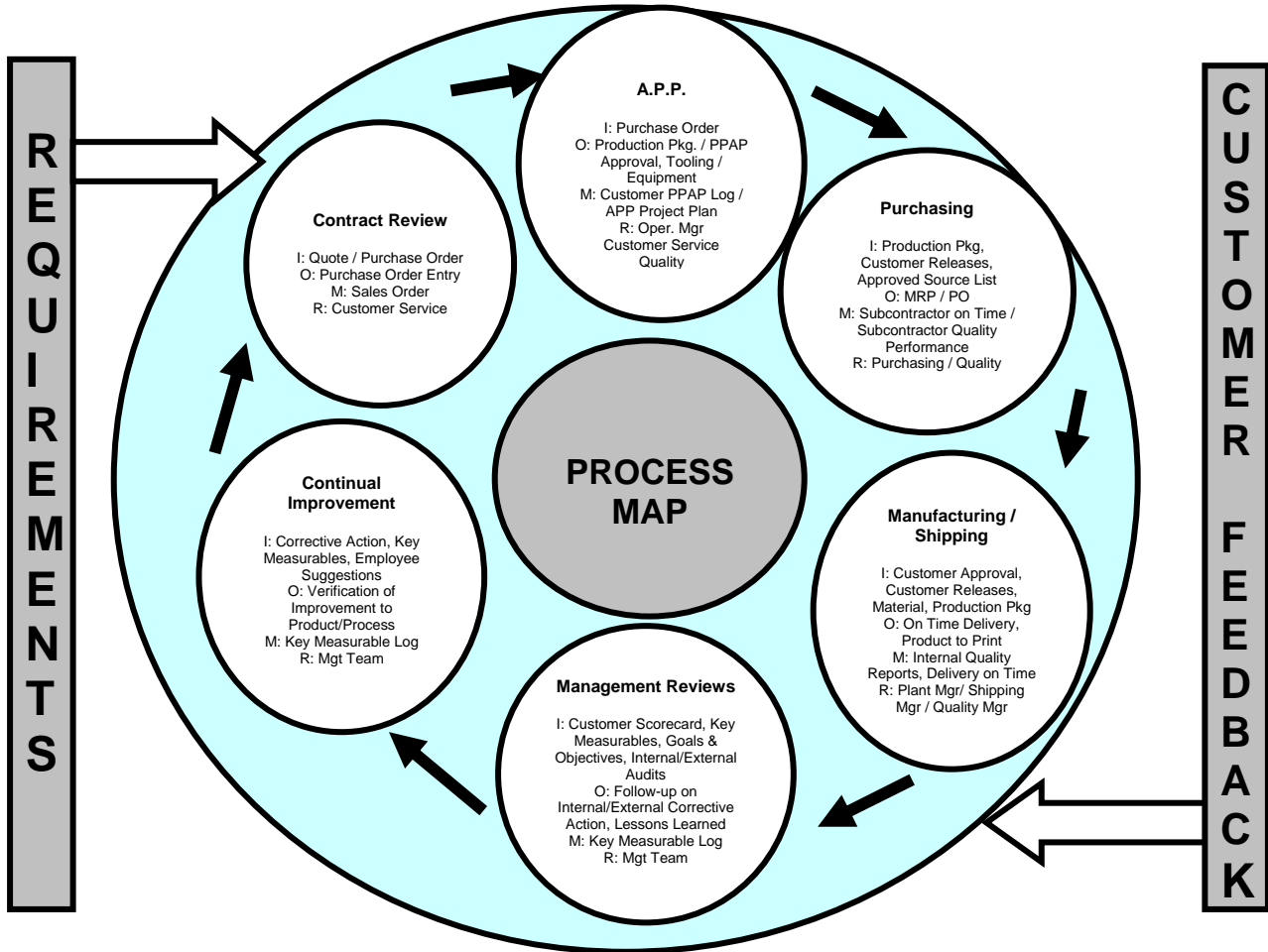
Where "R&A" is used, the abbreviation stands for "Responsibility and Authority".

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## **BACKGROUND HISTORY**

A.G Manufacturing – Established in 2004

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**Legend**  
I: Input  
O: Out Put  
M: Measurable  
R: Responsibility & Authority

## **QUALITY POLICY**

- Heighten customer satisfaction by providing products and services which meet or exceed the customer's requirements.
- Monitor the quality system for effectiveness, through continuous reviews.
- Strive to continually improve through cross functional participation.

## **OBJECTIVES**

- Provide quality products and services by striving to meet our customer's expectations.
- Maintain a formal quality management system meeting all ISO 9001, TS-16949 (2002), standards.
- Conduct continuous process improvement and problem prevention activities.
- Empower employees to effect continual improvement through team participation.

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## **NORMATIVE REFERENCE**

### **Standards / Guidelines**

ISO 9001: 2008 Quality Management Systems - Requirements  
ISO / TS 16949 – Technical Specification  
Advanced Product Quality Planning (APQP)  
Failure Mode and Effects Analysis (FMEA)  
Measurement System Analysis (MSA)  
Production Part Approval Process (PPAP)  
Statistical Process Control (SPC)

*When a Customer issues specific requirements in addition to ISO/TS 16949:2002, those requirements will be adhered to.*

## **CUSTOMER SPECIFIC REQUIREMENTS**

### **Standards / Guidelines**

*(As others become available they will be controlled and kept on file)*

GM Customer Specifics – ISO/TS 16949  
Chrysler Customer Specifics – ISO/TS 16949  
Ford Motor Company Customer Specifics – ISO/TS 16949

## **Quality Management System Requirements**

### Scope and Purpose

The system described in this section of the SPM conforms to the requirements of the TS 16949 standard: Clause 4—Quality Management System Requirements. This policy defines the corporate commitment to quality.

### Responsibility and Authority (R&A)

The R&A for overall administration of quality activities are shared by all the departments within the company. Employees have the responsibility to complete activities in support of the quality policy, quality documentation and customer requirements. Employees have been granted authority in order to meet specified requirements.

## **4. Management System Requirements**

### 4.1 General Requirements

#### 4.1.1 Quality:

A quality management system has been established, documented, implemented, maintained and is continually improved in accordance to the requirements of this International Standard. To implement the system, the organization has:

- a) determined the processes required for the quality management system and their application throughout the organization;
- b) determined the sequence and interaction of these processes;
- c) determined the criteria and methods needed to ensure that both the operation and control of these processes are effective;
- d) ensured the availability of resources and information necessary to support the operation and monitoring of these processes;
- e) monitored, measured (where applicable), and analyzed these processes; and,
- f) implemented actions necessary to achieve planned results and continual improvement of these processes.

These processes are managed in accordance with ISO/TS 16949:2002.

Control is ensured over any outsource processes that affect product conformity to requirements. Control of such applicable processes is identified within the quality management system. Where AG Manufacturing chooses to outsource any process that affects product conformity with requirements, the organization ensures control over such processes. Type and extent of control of such outsource process shall be defined within the quality management system.

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*NOTE 1: Processes needed for the quality management system referred to above include processes for management activities, provision of resources, product realization, measurement, analysis and improvement*

*NOTE 2: An “outsourced process” is a process that is needed for the quality management system in which AG Manufacturing chooses to have performed by an external party.*

*NOTE 3: Ensuring control over outsourced processes does not absolve AG Manufacturing of the responsibility of conforming to all customer, statutory and regulatory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such as*

- a) the potential impact of the outsourced process on AG Manufacturing’s capability to provide product that conforms to requirements.*
- b) the degree to which the control for the process is shared.*
- c) the capability of achieving the necessary control through the application of 7.4*

## **4.2 Documentation Requirements:**

### **4.2.1 General**

Management system documentation includes:

- a) documented statements of a quality policy and quality objectives;
- b) a Manual;
- c) documented procedures and records required by ISO/TS 16949:2002 and
- d) documents, including records determined by the organization to be necessary to ensure the effective planning, operation and control of processes

*NOTE 1: Where the term “documented procedure” appears within this manual, this means that the procedure is established, documented, implemented and maintained. A single document may address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.*

*NOTE 2: The documentation can be in any form or type of medium.*

### **4.2.2 Systems Manual**

A Systems Manual has been established and maintained that includes:

- a) the scope of the quality management system, including details of and justification for any permissible exclusions;
- b) the documented procedures established for the quality management system, or reference to them; and,

- c) a description of the interaction between the processes of the quality management system.

#### **4.2.3 Control of Documents:**

Documents and records required by the quality management system are controlled.

A documented procedure has been established to define the controls needed to:

- a) approve documents for adequacy prior to issue;
- b) review and update as necessary and re-approve documents;
- c) ensure that changes and the current revision status of documents are identified;
- d) ensure that relevant versions of applicable documents are available at points of use;
- e) ensure that documents remain legible and readily identifiable;
- f) ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled; and,
- g) prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

#### **4.2.3.1 Engineering Specification**

AG Manufacturing has a process to assure the timely review, distribution and implementation of all customer engineering standards/specifications and changes based on the customer's required schedule. AG Manufacturing maintains a record of the date on which each change is implemented in production. Implementation includes updated documents. Timely review does not exceed two working weeks.

*NOTE: A change in these standards/specifications requires an updated record of customer production part approval when these specifications are referenced on the design record or if they affect documents of production part approval process, such as control plan, FMEAs, etc.*

#### **4.2.4 Control of Records:**

Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled.

A documented procedure has been established to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.

Records shall remain legible, readily identifiable and retrievable.

*NOTE 1: "Disposition" above includes disposal.*

*NOTE 2: "Records" also include customer- specified records.*

#### **4.2.4.1 Records Retention**

AG Manufacturing defines retention periods for quality management system related documents and records to satisfy regulatory and customer requirements as a minimum.

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## **Management Responsibility**

### Scope and Purpose

The system described in this section of the SPM conforms to the requirements of the TS 16949 standard: Clause 5—Management Responsibility. This policy defines the corporate commitment to quality.

### Responsibility and Authority (R&A)

The R&A for overall administration of the quality activities are shared by all departments within the company. Employees have the responsibility to complete activities in support of the quality policy, quality documentation and customer requirements. Employees have been granted authority in order to meet specified requirements.

## **System Requirements**

### **5 Management Responsibility:**

#### **5.1 Management Commitment**

Top management has provided evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by:

- a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements;
- b) establishing the quality policy;
- c) ensuring that quality objectives are established;
- d) conducting management reviews; and,
- e) ensuring the availability of resources.

##### **5.1.1 Process Efficiency**

Top management monitors the product realization processes and the support processes to assess their effectiveness and efficiency.

#### **5.2 Customer Focus:**

Top management has ensured that customer requirements are determined and fulfilled with the aim of enhancing customer satisfaction.

**5.3 Quality Policy:**

Top management has ensured the quality policy is:

- a. appropriate to the purpose of the organization;
- b. includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system;
- c. provides a framework for establishing and reviewing quality objectives;
- d. communicated and understood within the organization; and,
- e. reviewed for continuing suitability.

**5.4 Planning****5.4.1 Quality Objective:**

Top management has ensured quality objectives, including those needed to meet requirements for product, are established at relevant functions and levels within the organization. The quality objectives are measurable and consistent with the quality policy. Top management has defined the quality objectives and measurements, which are included in the business plan and are used to deploy the quality policy.

**5.4.2 Quality Management System Planning:**

Top management has ensured that:

- a) the planning of the quality management system is carried out in order to meet the requirements of the general requirements of this international standard (section 4.1); and,
- b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

**5.5 Responsibility and Authority****5.5.1 Responsibility and Authority:**

Top management has ensured the responsibilities and authorities are defined and communicated within the organization.

**5.5.1.1 Responsibility for Quality**

Management with responsibility and authority for corrective action are promptly informed of products, processes or concerns, which do not conform to requirements. Personnel responsible for compliance have the authority to stop production or activity to correct the problem. Production operations across all shifts (if applicable) are staffed with personnel in charge of, or delegated responsibility for, ensuring product quality.

## **5.5.2 Management Representative:**

### **5.5.2.1 Quality Management Representative**

Top management has appointed a member of AG Manufacturing's management who, irrespective of other responsibilities, has responsibility and authority that includes:

- a) ensuring processes needed for the quality management system are established, implemented and maintained;
- b) reporting to top management on the performance of the quality management system, and any need for improvement;
- c) ensuring the promotion of awareness of customer requirements throughout the organization.

Currently, the appointed Management Representative is the Quality Manager.

*NOTE: The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.*

### **5.5.2.2 Customer Representative**

Top Management has designated an individual to represent the needs of the customer to address quality requirements, such as selection of special characteristics, setting quality objectives and related training, corrective and preventive actions, product design and development.

## **5.5.3 Communication:**

Top management has ensured appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

AG Manufacturing has established and maintains procedures for:

- a. internal communication between the various levels and function of the organization;
- b. Receiving, documenting and responding to relevant communication from external interested parties.

## **5.6 Management Review:**

### **5.6.1 General**

Top management reviews the quality management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness. This review includes assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Records of management reviews are maintained.

**5.6.1.1 Quality Management System Performance**

These reviews include all elements of the quality management system and its performance trends as an essential part of the continual improvement process. Part of the management review includes the monitoring of quality objectives, and the regular reporting and evaluation of the cost of poor quality. These results are recorded to provide, as a minimum, evidence of the achievement of the objectives specified in the quality policy, the objectives specified in the business plan, and customer satisfaction with product supplied.

**5.6.2 Management Review Input:**

Input to management review includes information on:

- a) results of audits;
- b) customer feedback;
- c) process performance and product conformity;
- d) status of preventive and corrective actions;
- e) follow-up actions from earlier management reviews;
- f) planned changes that could affect the quality management system, and;
- g) recommendations for improvement

**5.6.2.1 Review Input – Supplemental**

Input to management review shall include an analysis of actual and potential field-failures and their impact on quality, safety, or the environment.

**5.6.3 Management Review Output:**

Output from management review includes any decisions and actions related to:

- a) improvement of the effectiveness of the quality management system and its processes;
- b) improvement of product related to customer requirements; and,
- c) resource needs.

## **Resource Management**

### Scope and Purpose

The system described in this section of the SPM conforms to the requirements of the TS 16949 standard: Clause 6—Resource Management. This policy defines the corporate commitment to quality.

### Responsibility and Authority (R&A)

The R&A for overall administration of quality activities are shared by all the departments within the company. Employees have the responsibility to complete activities in support of the quality policy, quality documentation and customer requirements. Employees have been granted authority in order to meet specified requirements.

## **6. Resource Management**

### **6.1 Provision of Resources:**

Resources have been determined and provided to:

- a) implement and maintain the quality management system and continually improve its effectiveness; and,
- b) enhance customer satisfaction by meeting customer requirements.

### **6.2 Human Resources:**

#### **6.2.1 General**

Personnel performing work affecting conformity to product requirements are competent on the basis of appropriate education, training, skills and experience.

NOTE: Conformity to product requirements can be affected directly or indirectly by personnel performing any task within the quality management system.

#### **6.2.2 Competence, Training and Awareness:**

The organization has:

- a) determined the necessary competence for personnel performing work affecting conformity to product requirements,
- b) where applicable provided training or taken other action to achieve the necessary competence.
- c) evaluated the effectiveness of the actions taken;
- d) ensured that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives;
- e) maintained appropriate records of education, training, skills and experience.

### **6.2.2.1 Product Design Skills**

AG Manufacturing will ensure that personnel with product design responsibility are qualified to achieve design requirements and are skilled in applicable tools and techniques. Applicable tools and techniques are identified by the organization.

**Note: At this time AG Mfg. is not Product Design Responsible**

### **6.2.2.2 Training**

AG Manufacturing has established and maintains documented procedures for identifying training needs and achieving competence of all personnel performing activities affecting product quality and impacting the environment. Personnel performing specific assigned tasks are qualified on the basis of education, training, skills and/or experience, as required. Attention is given to satisfy customer specific requirements.

*NOTE 1: This applies to all employees having an effect on quality at all levels of the organization.*

*NOTE 2: An example of the customer specific requirements is the application of digitized mathematically based data.*

### **6.2.2.3 Training on the Job**

The organization provides on the job training for personnel in any new or modified job affecting product quality including contract or agency personnel. Personnel whose work can affect quality are informed about the consequences to the customer of nonconformity to quality requirements.

### **6.2.2.4 Employee Motivation and Empowerment**

AG Manufacturing has a process to motivate employees to achieve quality objectives, to make continual improvements, and to create an environment to promote innovation. The process includes the promotion of quality and technological awareness throughout the whole organization.

AG Manufacturing has a process to measure the extent to which its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

## **6.3 Infrastructure:**

The infrastructure needed to achieve conformity to product requirements has been determined, provided and maintained.

Infrastructure examples may include, but not be limited to:

- a) buildings, workspace and associated utilities;
- b) process equipment, (both hardware and software);
- c) supporting services (such as transport, communication or information systems).

### **6.3.1 Plant, Facility and Equipment Planning**

AG Manufacturing uses a multidisciplinary approach for developing plant, facility, and equipment plans. Plant layouts optimize material travel, handling and value-added use of floor space, and facilitates synchronous material flow. Methods have been developed and implemented to evaluate and monitor the effectiveness of existing operations.

*NOTE: These requirements should focus on lean manufacturing principles and the link to the effectiveness of the quality management system.*

### **6.3.2 Contingency Plan**

The organization has a contingency plan to satisfy customer requirements in the event of an emergency such as utility interruptions, labor shortages, key equipment failure and field returns.

## **6.4 Work Environment:**

The work environment needed to achieve conformity to product requirements has been determined and managed.

*NOTE: The term "work environment" relates to those conditions under which work is performed including physical, environmental and other factors (such as noise, temperature, humidity, lighting or weather).*

### **6.4.1 Personal Safety to achieve Product Quality**

Product safety and means to minimize potential risks to employees are addressed in the quality policy and practices, especially in the design and development process and in manufacturing process activities.

### **6.4.2 Cleanliness of Premises**

AG Manufacturing maintains its facilities in a state of order, cleanliness and repair consistent with the product.

## **Product Realization**

### Scope and Purpose

The system described in this section of the SPM conforms to the requirements of the TS-16949 standard: Clause 7—Product Realization. This policy defines the corporate commitment to quality.

### Responsibility and Authority (R&A)

The R&A for overall administration of quality management system activities are shared by the Design, Quality and Operations Team. Employees have the responsibility to complete activities in support of the quality policy, quality system documentation and customer requirements. Employees have been granted authority in order to meet specified requirements.

## **7. Product Realization**

### **7.1 Planning of Product Realization:**

The processes needed for product realization are planned and developed, and are consistent with the requirements of the other processes of the quality management system. In planning product realization, the following has been determined, as appropriate:

- a) quality objectives and requirements for the product;
- b) the need to establish processes and documents, and to provide resources specific to the product;
- c) required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance;
- d) records needed to provide evidence that the realization processes and resulting product meet requirements.

The output of this planning shall be in a form suitable for the organization's method of operation.

*NOTE 1: A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan.*

*NOTE 2: The organization may also apply the requirements given in 7.3 to the development of product realization processes.*

*NOTE 3: Some customers refer to project management or advanced product quality planning as a means to achieve product realization. Advanced product quality planning embodies the concepts of error prevention and continual improvement as contrasted with error detection, and is based on a multidisciplinary approach.*

### **7.1.1 Planning of Product Realization – Supplemental**

Customer requirements and references to its technical specifications are included in the planning of product realization as a component of the quality plan.

### **7.1.2 Acceptance Criteria**

Acceptance criteria is defined by the organization, and where required, approved by the customer. For attribute data sampling, acceptance criteria is zero defects.

### **7.1.3 Confidentiality**

AG Manufacturing ensures the confidentiality of customer-contracted products and projects under development, and related product information.

### **7.1.4 Change Control**

The organization has a process to control and react to changes that have an impact on product realization, including those initiated by the subcontractor. The effects of any changes are assessed, and verification and validation activities are defined, to ensure compliance with customer requirements. Changes are validated before implementation. For proprietary designs, impact on form, fit and function (including performance and/or durability) are reviewed with the customer so that all effects can be properly evaluated. When required by the customer, additional verification/identification requirements, such as those required for new product introduction, are met.

*NOTE 1: Any product realization change affecting customer requirements requires notification to, and agreement from, the customer.*

*NOTE 2: The above requirement applies to product and manufacturing process changes.*

## **7.2 Customer Related Processes:**

### **7.2.1 Determination of Requirements Related to the Product**

Requirements related to the product have been determined, including:

- a) requirements specified by the customer, including the requirements for delivery and post-delivery activities;
- b) requirements not stated by the customer but necessary for specified or intended use, where known;
- c) statutory and regulatory requirements applicable to the product; and
- d) any additional requirements considered necessary

*NOTE 1: Post-delivery activities include for example, actions under warranty provisions, contractual obligations such as maintenance services, supplementary services such as*

*recycling or final disposal and any after-sales product service provided as part of the customer contract or purchase order*

*NOTE 2: This requirement includes recycling, environmental impact and characteristics identified as a result of the organizations knowledge of the product and manufacturing processes.*

*NOTE 3: Compliance to item c) includes all applicable government, safety and environmental regulations, applied to acquisition, storage, handling, recycling, elimination or disposal of materials.*

### **7.2.1.1 Customer Designated Special Characteristics**

AG Manufacturing demonstrates conformity to customer requirements for designation, documentation, and control of special characteristics.

### **7.2.2 Review of Requirements Related to the Product:**

Requirements related to the product are reviewed. This review is conducted prior to committing to supply a product to customers, and ensures that:

- a) product requirements are defined;
- b) contract or order requirements differing from those previously expressed are resolved;
- c) the organization has the ability to meet the defined requirements

Records of the results of review and actions arising from this review are maintained.

Where the customer provides no documented statement of requirements, customer requirements are confirmed before acceptance.

Where product requirements are changed, it is ensured that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

*NOTE: In some situations, such as Internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.*

### **7.2.2.1 Review of Requirements Related to the Product - Supplemental**

Waiving the requirements stated in 7.2.2 for a formal review shall require customer authorization.

### **7.2.2.2 Organization Manufacturing Feasibility**

The organization investigates, confirms and documents the manufacturing feasibility of the proposed products in the contract review process, including risk analysis.

### **7.2.3 Customer Communication:**

Effective arrangements for communication with customers relating to the following are determined and implemented:

- a) product information;
- b) enquiries, contracts or order handling, including amendments;
- c) customer feedback, including customer complaints.

#### **7.2.3.1 Customer Communication – Supplemental**

The organization has the ability to communicate necessary information, including data, in a customer-specified language and format.

### **7.3 Design and Development**

*NOTE: The requirements of 7.3 include product and manufacturing process design and development, and focus on error prevention rather than detection.*

#### **7.3.1 Design and Development Planning:**

Design and Development of the product is planned and controlled, including determination of the following:

- a) stages of the design and development process;
- b) review, verification and validation appropriate to each design and development stage; and,
- c) responsibilities and authorities for design and development.

Interfaces between different groups involved in design and development are managed to ensure effective communication and clear assignment of responsibility.

Planning output is updated, as appropriate, as the design and development progresses.

*NOTE: Design and development review, verification and validation have distinct purposes. They can be conducted and recorded separately or in any combination, as suitable for the product and the organization.*

**Note: At this time AG Mfg. is not Product Design Responsible**

##### **7.3.1.1 Multidisciplinary Approach**

A multidisciplinary approach is used to prepare for product realization including:

- ◆ the development, finalization and monitoring of special characteristics;

- ◆ the development and review of FMEA's including actions to reduce potential risks; and,
- ◆ development and review of control plans.

*NOTE: A multidisciplinary approach typically includes the organizations design, manufacturing, engineering, quality, production and other appropriate personnel.*

### **7.3.2 Design and Development Inputs:**

Inputs relating to process requirements are determined and records maintained, including:

- a) functional and performance requirements;
- b) applicable statutory and regulatory requirements;
- c) applicable information derived from previous similar designs; and,
- d) other requirements essential for design and development.

Inputs are reviewed for adequacy, and requirements are complete, unambiguous, and not in conflict with each other.

*NOTE: Special characteristics (see 7.2.1.1) are included in this requirement.*

### **7.3.2.2 Manufacturing Process Design Inputs:**

Manufacturing process design inputs are identified, documented and reviewed. Manufacturing design inputs may include:

- ◆ product design output data;
- ◆ targets for productivity, process capability, and cost;
- ◆ customer requirements, if any; and,
- ◆ experience from previous process developments.

*NOTE: The manufacturing process design includes the use of error-proofing methods to a degree appropriate to the magnitude of the problems and commensurate with the risks encountered.*

### **7.3.2.3 Special Characteristics:**

Special characteristics are identified and:

- ◆ are to be included in the control plan;
- ◆ comply with customer specified definitions and symbols; and,
- ◆ identify process control documents including drawings, FMEAs, control plans, operator instructions with the customer's special characteristic symbol or the organizations equivalent symbol or notation to include those process steps that affect special characteristics.

*NOTE: Special Characteristics can include product characteristics and process parameters.*

### **7.3.3 Design and Development Outputs:**

The outputs of design and development are in a form suitable for verification against the design and development input, and are approved prior to release. Design and development outputs:

- a) meet the input requirements for design and development;
- b) provide appropriate information for purchasing, production and service provision;
- c) contain or reference product acceptance criteria; and,
- d) specify the characteristics of the product that are essential for safe and proper use.

*NOTE: Information for production and service provision can include details for the preservation of product.*

### **7.3.3.2 Manufacturing Process Design Outputs:**

Manufacturing design outputs are expressed in terms that can be verified against the manufacturing process design input requirements and verified. The manufacturing design input requirements include:

- ◆ specifications and drawings;
- ◆ manufacturing process flow chart/layout;
- ◆ manufacturing process FMEA's;
- ◆ control plan;
- ◆ work instructions;
- ◆ process approval acceptance criteria;
- ◆ data for quality, reliability, maintainability and measurability;
- ◆ results of error-proofing activities, as appropriate; and,
- ◆ methods of rapid detection and feedback of product/manufacturing process non-conformities.

### **7.3.4 Design and Development Review:**

At suitable stages, systematic reviews of design and development are performed in accordance with planned arrangements:

- a) to evaluate the ability of the results of design and development to meet requirements; and,
- b) to identify any problems and propose necessary actions.

Participants in the design and development review include representatives of functions concerned with the design and development stage being reviewed. Records of the results of the reviews and any necessary actions are maintained.

*NOTE: These reviews are normally coordinated with the design phases and include manufacturing process design and development.*

#### **7.3.4.1 Monitoring**

Measurements at specific stages of design and development are defined, analyzed and reported with summary results as an input to management review.

*NOTE: These measurements include quality risks, costs, lead-times, critical paths and others, as appropriate.*

#### **7.3.5 Design and Development Verification:**

Verification is performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions are maintained.

#### **7.3.6 Design and Development Validation:**

Design and development validation is performed in accordance with planned arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practical, validation is completed prior to delivery or implementation of the product. Records of the results of validation and any necessary actions are maintained.

*NOTE 1: The validation process normally includes an analysis of field reports for similar products.*

*NOTE 2: The requirements of 7.3.5 and 7.3.6 above apply to both product and manufacturing processes.*

##### **7.3.6.1 Design and Development Validation – Supplemental**

Design and development validation is performed in accordance with customer requirements including program timing.

##### **7.3.6.2 Prototype Program**

When required by the customer, the organization will have a prototype program and prototype control plan. Wherever possible, the same subcontractors, tooling and manufacturing processes are used which will be used in production. All performance-

testing activities are monitored for timely completion and conformance to requirements. While services may be outsourced, the responsibility and technical leadership for the project is not.

#### **7.3.6.3 Product Approval Process:**

A procedure has been developed for product and process approval, which conforms to customer's recognized format and process.

*NOTE: Product approval should be subsequent to the verification of the manufacturing process.*

This product approval process is also applied to subcontractors.

#### **7.3.7 Control of Design and Development Changes:**

Design and development changes are identified and records are maintained. The changes are reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes includes evaluation of the effect of the changes on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions are maintained.

*NOTE: Design and development changes include all changes during the product program life (see 7.1.4)*

### **7.4 Purchasing**

#### **7.4.1 Purchasing Process:**

Purchasing processes are controlled to ensure purchased product conforms to specified purchase requirements. The type and extent of control are applied to subcontractors and purchased product is dependent upon the effect of the purchased product on subsequent product realization or the final product.

Subcontractors are evaluated and selected based on their ability to supply product in accordance with requirements. Criteria for selection, evaluation and re-evaluation and any necessary actions arising from the evaluation are maintained.

*NOTE 1: Purchased products above include all products and services that effect customer requirements such as sub-assembly, sequencing, sorting, rework and calibration services.*

*NOTE 2: When there are mergers, acquisitions or affiliations associated with subcontractors, the organization should verify the continuity of the subcontractor's quality management system and its effectiveness.*

#### **7.4.1.1 Regulatory Conformity**

All purchased products or material used in the product satisfy applicable regulatory requirements.

As a first step, subcontractors to the organization shall be third party registered to ISO 9001:2000 by an accredited third party certification body unless otherwise specified by the Customer.

#### **7.4.1.2 Subcontractor Quality Management System Development**

AG Manufacturing performs subcontractor quality management system development with the goal of subcontractor compliance to the Technical Specification.

AG Manufacturing's Subcontractor Requirements Manual is located on the AG Mfg. Web-site and may be accessed by any one of our subcontractors.

*NOTE: The prioritization of subcontractors for development depends upon, for example, the subcontractor's quality performance and the importance of the product supplied.*

#### **7.4.1.3 Customer - Approved Sources**

Where specified by the contract, the organization uses purchased products, materials or services from approved sources.

The use of customer-designated sources, including tool/gage subcontractors, does not relieve the organization of the responsibility for ensuring the quality of purchased products.

#### **7.4.2 Purchasing Information:**

Purchasing information describes the product to be purchased, including where appropriate:

- a) requirements for approval of product, procedures, processes, and equipment;
- b) requirements for qualification of personnel; and,
- c) quality management system requirements.

The adequacy of specified purchasing requirements prior to their communication to subcontractors is ensured.

#### **7.4.3 Verification of Purchased Product:**

Inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements are established and implemented. Where verification

of purchased product is intended at subcontractors' premises, including customer verification of such product, the verification activity and the method of product release are stated in the purchasing information.

#### **7.4.3.1 Incoming Product Quality**

The organization has a process to assure the quality of purchased product, utilizing one or more of the following methods:

- ◆ receipt of, and evaluation of, statistical data by the organization;
- ◆ receiving inspection and/or testing such as sampling based on performance;
- ◆ second or third party assessments or audits of subcontractor sites, when coupled with records of acceptable quality performance;
- ◆ part evaluation by a designated laboratory; and,
- ◆ another method agreed upon with the customer.

#### **7.4.3.2 Subcontractor Monitoring**

Subcontractor performance is monitored through the following indicators:

- ◆ delivered part quality performance;
- ◆ customer disruptions including field returns;
- ◆ delivery schedule performance (including incidents of premium freight); and,
- ◆ special status customer notifications related to quality or delivery issues.

AG Manufacturing may choose additional indicators.

AG Manufacturing promotes subcontractor monitoring of the performance of their manufacturing processes.

### **7.5 Production and Service Provision**

#### **7.5.1 Control of Production and Service Provision:**

Production and service operations are planned and carried out under controlled conditions, including, as applicable:

- a) the availability of information that describes the characteristics of the product;
- b) the availability of work instructions, as necessary;
- c) the use of suitable equipment;
- d) the availability and use of monitoring and measuring equipment;
- e) the implementation of monitoring and measurement;
- f) the implementation of product release, delivery and post-delivery activities.

### **7.5.1.1 Control Plan**

Control plans are developed at the system, subsystem, component, and/or material level, for the product supplied, including those processes producing bulk materials as well as parts;

- ◆ the Control Plan is in place for pre-launch and production that takes into account the design FMEA(where applicable) and manufacturing process FMEA outputs;
- ◆ the Control Plan lists the controls for the manufacturing process control, includes methods for monitoring of control exercised over special characteristics defined by both the customer and the organization, and includes customer required information, if any, and initiates the specified reaction plan when the process becomes unstable or not statistically capable;
- ◆ Control Plans are reviewed and updated when any change occurs affecting product, manufacturing process, measurement, logistics, supply sources or FMEA

*NOTE: Customer approval may be required after review or update of the control plan.*

### **7.5.1.2 Work Instructions**

The organization has documented work instructions for all employees having responsibilities for the operation of processes. These instructions are available at the work stations. These instructions are derived from sources such as the quality plan, control plan, and the product realization process.

### **7.5.1.3 Verification of Job Set-up**

Job set ups are verified whenever performed, such as an initial run of a job, material changeover, or job change. Work instructions are available for set up personnel, and statistical methods of verification are used where applicable.

*NOTE: Last-off-part comparisons are recommended.*

### **7.5.1.4 Preventive and Predictive Maintenance**

AG Manufacturing has identified key process equipment and has provided resources for machine/equipment maintenance, and has developed an effective planned maintenance system. At a minimum, this system includes:

- ◆ planned maintenance activities,
- ◆ packaging and preservation of equipment, tooling, and gauging,
- ◆ availability of replacement parts for key manufacturing equipment, and
- ◆ documenting, evaluating and improving maintenance objectives.

The organization utilizes predictive maintenance methods to continually improve the effectiveness and efficiency of production equipment.

#### **7.5.1.5 Management of Production Tooling**

AG Manufacturing provides resources for tool and gauge design, fabrication and verification activities.

Tooling management includes:

- ◆ Maintenance, repair facilities and personnel;
- ◆ storage and recovery;
- ◆ set up;
- ◆ tool change programs for perishable tools;
- ◆ tool design modification documentation, including engineering change level;
- ◆ tool modification and revision to documentation;
- ◆ tool identification, defining the status, such as production, repair or disposal; and,
- ◆ a system to monitor these activities if any work is outsourced.

*NOTE: This requirement also applies to the availability of tools for vehicle service parts.*

#### **7.5.1.6 Production Scheduling**

Production is scheduled in order to meet customer requirements, such as just in time supported by an information system that permits access to production information at key stages of the process and is order-driven.

#### **7.5.1.7 Feedback of information from Service**

AG Manufacturing communicates information on service concerns to manufacturing, engineering and design functions.

*NOTE: The intent of the addition of "service concerns" to this subclause is to ensure that the organization is aware of nonconformities that occur external to its organization.*

#### **7.5.1.8 Service Agreement with Customer**

AG Manufacturing has no servicing agreements with customers.

#### **7.5.2 Validation of Processes for Production and Service Provision:**

Processes for production and service are validated and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered. Validation demonstrates the ability of these processes to achieve planned results. Arrangements are established for these processes including, as applicable:

- a) defined criteria for review and approval of the processes;

- b) approval of equipment and qualification of personnel;
- c) use of specific methods and procedures;
- d) requirements for records; and,
- e) revalidation.

#### **7.5.2.1 Validation of Processes for Production and Service Provision – Supplemental**

The requirements of 7.5.2 shall apply to all processes for production and service provisions.

#### **7.5.3 Identification and Traceability:**

Product is identified, where appropriate, by suitable means throughout product realization. The status of the product is identified with respect to measurement and monitoring requirements throughout product realization. Where traceability is a requirement the unique identification of product is controlled and records maintained.

*NOTE: In some industry sectors, configuration management is a means by which identification and traceability are maintained.*

*NOTE: Inspection and test status is not indicated by the location of product in the production flow unless inherently obvious, such as material in an automated production transfer process. Alternatives are permitted, if the status is clearly identified, documented and achieves the designated purpose.*

#### **7.5.3.1 Identification and Traceability – Supplemental**

The words “Where appropriate” in 7.5.3 shall not apply

#### **7.5.4 Customer Property:**

Care is exercised with customer property while it is under control or being used. Customer property provided for use or incorporation into product is identified, verified, protected and safeguarded. Any customer property that is lost damaged or otherwise found to be unsuitable for use is reported to the customer and records maintained.

*NOTE: Customer property can include intellectual property and personal data.*

*NOTE: Customer-owned returnable packaging is included in this clause.*

#### **7.5.4.1 Customer-Owned Production Tooling**

Customer-owned tools, manufacturing, test, inspection tooling and equipment is permanently marked so ownership of each item is visible and can be determined.

**7.5.5 Preservation of Product:**

The preservation of product during internal processing and delivery to the intended destination is preserved in order to maintain conformity to requirements. As applicable, preservation shall include identification, handling, packaging, storage and protection. Preservation also applies to the constituent parts of a product.

**7.5.5.1 Storage and Inventory**

In order to detect deterioration, the condition of product in stock is assessed at appropriate intervals. The organization uses an inventory management system to optimize inventory turn over time and assure stock rotation. Obsolete product is controlled in a similar manner to nonconforming product.

**7.6 Control of Monitoring and Measuring Equipment:**

The monitoring and measurements to be undertaken, and the monitoring and measuring equipment needed to assure conformity of product requirements are determined. Processes are established to ensure that monitoring and measurement can be carried out and are carried out in a manner consistent with the monitoring and measurement requirements. Where necessary to ensure valid results, measuring equipment is:

- a) calibrated or verified or both at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards;
- b) adjusted or re-adjusted as necessary;
- c) have identification in order to determine its calibration status;
- d) safeguarded from adjustments that would invalidate the measurement result; and,
- e) protected from damage and deterioration during handling, maintenance and storage.

The validity of the previous measuring results are assessed and recorded when the equipment is found not to conform to requirements. Appropriate action is taken on the equipment and any product affected.

Records of the results of calibration and verification are maintained.

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application is confirmed. This is undertaken prior to initial use and reconfirmed as necessary.

*NOTE: Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.*

*NOTE: A number or other identifiers traceable to the device calibration record meets the intent of requirement c) above.*

### **7.6.1 Measurement System Analysis**

Statistical studies are conducted to analyze the variation present in the results of each type of measuring and test equipment system. This requirement applies to measurement systems referenced in the Control Plan. The analytical methods and acceptance criteria used conform to those in customer reference manuals on measurement systems analysis.

### **7.6.2 Calibration / Verification Records**

Records of the calibration/ verification activity for all gauges, measuring and test equipment, including employee and customer-owned gauges, includes:

- ◆ equipment identification, including the measurement standard against which the equipment is calibrated;
- ◆ revisions following engineering changes;
- ◆ any out-of-specification readings as received for calibration/verification;
- ◆ an assessment of the impact of out-of-specification condition; and,
- ◆ statements of conformance to specification after calibration/verification, and notification to the customer if suspect product or material has been shipped.

### **7.6.3 Laboratory Requirements**

#### **7.6.3.1 Internal Laboratory**

AG Manufacturing does not maintain an internal laboratory.

#### **7.6.3.2 External Laboratory**

Any external/commercial/independent laboratory facilities used for inspection, test or calibration services shall have a defined laboratory scope that includes the capability to perform the required inspection, test, or calibration, and the laboratory shall be accredited to ISO/IEC 17025 or national equivalent, or there shall be evidence that the external laboratory is acceptable to the customer.

*NOTE 1: Such evidence may be demonstrated by customer assessment, for example, or by customer-approved second-party assessment that the laboratory meets the intent of ISO/IEC 17025 or national equivalent.*

*NOTE 2: When a qualified laboratory is not available for a given piece of equipment, calibration services may be performed by the equipment manufacturer. In such cases, the organization should ensure that the requirements listed in 7.6.3.1 have been met.*

## **Measurement, Analysis and Improvement**

### Scope and Purpose

The system described in this section of the SPM conforms to the requirements of the TS-16949 standard: Clause 8—Measurement, Analysis and Improvement. This policy defines the corporate commitment to quality.

### Responsibility and Authority (R&A)

The R&A for overall administration of quality activities are shared by the Quality and Operations Team. Employees have the responsibility to complete activities in support of the quality policy, quality documentation and customer requirements. Employees have been granted authority in order to meet specified

## **8. Measurement, Analysis and Improvement**

### **8.1 General Requirements:**

The organization has planned and implemented the monitoring, measurement, analysis and improvement processes needed to:

- a) demonstrate conformity to product requirements;
- b) ensure conformity of the quality management system; and,
- c) continually improve the effectiveness of the quality management system.

This includes determination of applicable methods, including statistical techniques, and the extent of their use.

#### **8.1.1 Identification of Statistical Tools**

Appropriate statistical tools for each process are determined during advanced product quality planning and included in the Control Plan.

#### **8.1.2 Knowledge of Basic Statistical Concepts**

AG Manufacturing ensures that statistical concepts, such as variation, control, process capability and over-adjustment are understood and utilized throughout the organization.

### **8.2 Monitoring and Measurement**

#### **8.2.1 Customer Satisfaction:**

As one of the measurements of the performance of the quality system, the organization monitors information relating to customer perception as to whether customer requirements have been met. The methods for obtaining and using this information are determined.

*NOTE: Monitoring customer perception can include obtaining input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims and dealer reports.*

*NOTE: Consideration should be given to both internal and external customers.*

### **8.2.1.1 Customer Satisfaction – Supplemental**

Customer satisfaction with the organization is monitored through the continual evaluation of the performance of the realization processes. Performance indicators are based on objective data and include, but are not limited to:

- ◆ delivered part quality performance;
- ◆ customer disruptions including field returns;
- ◆ delivery schedule performance ; and,
- ◆ customer notifications related to quality or delivery issues.

The organization monitors the performance of manufacturing processes to demonstrate compliance with customer requirements for product quality and efficiency of the process.

### **8.2.2 Internal Audit:**

Periodic internal audits are conducted at planned intervals to determine whether the quality management system:

- a) conforms to the planned arrangements, to the requirements of this International Standard, and to the quality management system requirements established by the organization; and,
- b) is applicable to help the company effectively operate the business; and,
- c) is effectively implemented and maintained.

An audit program is planned that takes into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods are defined. Selection of auditors and conduct of audits ensures objectivity and impartiality of the audit process. Auditors do not audit their own work.

A documented procedure has been established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.

Records of the audits and their results are maintained.

The management responsible for the audited area ensures that any necessary corrections and corrective actions are taken without undue delay to eliminate detected

nonconformities and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results.

*NOTE: See ISO 19011 for guidance*

#### **8.2.2.1 Quality Management System Audit**

AG Manufacturing audits its quality management system to verify compliance with ISO/TS 16949:2002 and any additional quality management system requirements.

#### **8.2.2.2 Manufacturing Process Audit**

Each manufacturing process is audited to determine its effectiveness.

#### **8.2.2.3 Product Audit**

AG Manufacturing audits product at appropriate stages of production and delivery to verify conformance to all specified requirements, such as product dimensions, functionality, packaging, and labeling at a defined frequency.

#### **8.2.2.4 Internal Audit Plans**

Internal audits cover all quality management related processes, activities and shifts, and is scheduled according to an annual plan. When internal/external nonconformities or customer complaints occur, the audit frequency is appropriately increased.

*NOTE: Specific checklists should be used for each audit.*

#### **8.2.2.5 Internal Auditor Qualification**

Internal auditors are qualified to audit the requirements of ISO/TS 16949:2000. Third party training is required for lead auditors. Internal audit maybe qualified by conducting an audit under the supervision of the lead auditor

### **8.2.3 Monitoring and Measurement of Processes:**

Suitable methods are applied for monitoring and, where applicable, measurement of the quality management system processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action are taken, as appropriate.

#### **8.2.3.1 Monitoring and Measurement of Manufacturing Processes**

The organization performs process studies on all new manufacturing processes to verify process capability and to provide additional input for process control. The results of process studies are documented with specifications, where applicable, for means of production, measurement and test, and maintenance instructions. These documents

include objectives for manufacturing process capability, reliability, maintainability and availability, as well as acceptance criteria.

The organization maintains manufacturing process capability or performance as specified by the customer part approval process requirements. The organization ensures that the Control Plan and the Process Flow Diagram are implemented, including adherence to the;

- ◆ specified measurement techniques,
- ◆ sampling plans,
- ◆ acceptance criteria, and
- ◆ reaction plans when acceptance criteria are met.

Significant process events such as tool change and machine repair are noted on the control charts.

The organization initiates a reaction plan from the Control Plan for characteristics that are either unstable or non-capable. These reaction plans include containment and 100% inspection of product as appropriate. A corrective plan is then completed; indicating specific timing and assigned responsibilities to assure that the process becomes stable and capable. These plans are reviewed and approved by the customer when required.

AG Manufacturing maintains records of effective dates of process changes.

*NOTE: When determining suitable methods, it is advisable that the type and extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to product requirements and on the effectiveness of the quality management system is considered.*

#### **8.2.4 Monitoring and Measurement of Product:**

The characteristics of the product are monitored and measured to verify that product requirements are fulfilled. This is completed at appropriate stages of the product realization process in accordance with planned arrangements. Evidence of conformity with the acceptance criteria shall be maintained.

Records indicate the person(s) authorizing the release of product for delivery to the customer

The release of product and delivery of service to the customer does not proceed until all the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority, and where applicable, by the customer.

*NOTE: When selecting product parameters to monitor compliance to specified internal and external requirements, the organization determines the type of product characteristics, leading to*

- *the types of measurement*

- *suitable measurement means, and*
- *the capability and skills required.*

#### **8.2.4.1 Layout Inspection and Functional Testing**

Layout inspections and functional verification to applicable customer engineering material and performance standards are performed for all products at sufficiently frequent intervals as specified on the Control Plan. Records are available for customer review.

*NOTE: Layout inspection is the complete measurement of all product dimensions shown on the design records.*

#### **8.2.4.2 Appearance Items**

AG Manufacturing does not manufacture parts designated as appearance items.

### **8.3 Control of Nonconforming Product:**

Product that does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. A documented procedure has been established to define the controls and related responsibilities and authorities for dealing with nonconforming product.

Where applicable, nonconforming product is dealt with by one or more of the following manners:

- a) by taking action to eliminate the detected nonconformity;
- b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer; and,
- c) by taking action to preclude its original intended use or application.
- d) By taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started

When nonconforming product is corrected, it is subject to re-verification to demonstrate conformity to the requirements.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, are maintained.

#### **8.3.1 Control of Nonconforming Product – Supplemental**

Product with unidentified or suspect status is classified as nonconforming product.

#### **8.3.2 Control of Reworked Product**

Instructions for rework, including re-inspection requirements, are accessible to and utilized by appropriate personnel.

### **8.3.3 Customer Information**

Customers are promptly informed if nonconforming product has been shipped.

### **8.3.4 Customer Waiver**

AG Manufacturing obtains customer concession or permission for deviation prior to further processing whenever the product or manufacturing process is different than what is currently approved. The organization maintains records of the expiration date or quantity authorized. The organization ensures compliance with the original or superseding specifications and requirements when the authorization expires.

This applies equally to purchased product. The organization agrees with any requests from subcontractors before submission to the customer.

## **8.4 Analysis of Data:**

The determination of, collection, and analysis of appropriate data is completed to demonstrate the suitability and effectiveness of the quality management system, and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This includes data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data provides information relating to:

- a) customer satisfaction;
- b) conformance to product requirements;
- c) characteristics and trends of processes and products including opportunities for preventive action; and,
- d) subcontractors.

### **8.4.1 Analysis and Use of Data**

Trends in quality and operational performance are compared with progress toward objectives and lead action to support the following:

- ◆ development of priorities for prompt solutions to customer-related problems;
- ◆ determination of key customer-related trends and correlation to support status review, decision making and longer term planning; and,
- ◆ an information system for the timely reporting of product information arising from usage.

*NOTE: Data should be compared with those of competitors and/or appropriate benchmarks.*

## **8.5 Improvement**

**8.5.1 Continual Improvement:**

The effectiveness of the quality management system is continually improved through the use of the following:

- ◆ quality policy;
- ◆ quality objectives;
- ◆ audit results;
- ◆ analysis of data;
- ◆ technical team projects;
- ◆ corrective and preventive actions; and,
- ◆ management review.

**8.5.1.1 Continual Improvement of the Organization**

AG Manufacturing has a defined process for continual improvement.

**8.5.1.2 Manufacturing / Business Process Improvement**

Continual improvement focuses upon reduction of part production cost through increased control over our processes, reduction of variation and optimization for specific characteristics, identified process parameters, and performance metrics.

*NOTE 1: Controlled characteristics are documented in the control plan.*

*NOTE 2: Continual improvement is implemented once manufacturing processes are capable and stable, or product characteristics are predictable and meet customer requirements.*

**8.5.2 Corrective Action:**

Corrective action is taken to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the impact of the problems encountered.

A documented procedure for corrective action is established defining requirements for:

- a) reviewing nonconformities (including customer complaints);
- b) determining the causes of nonconformities;
- c) evaluating the need for action to ensure that nonconformities do not recur;
- d) determining and implementing action needed;
- e) records of the results of actions taken; and,
- f) reviewing the effectiveness of the corrective action taken.

Preventive action is determined to eliminate the causes of potential nonconformities in order to prevent occurrence. Preventive actions are appropriate to the effects of the potential problems.

#### **8.5.2.1 Problem Solving**

The organization has a defined process for problem solving leading to root cause identification and elimination. If customer-prescribed problem solving exists, the organization uses the prescribed format.

#### **8.5.2.2 Error – Proofing**

AG Manufacturing uses error-proofing methods in its corrective action process.

#### **8.5.2.3 Corrective Action Impact**

AG Manufacturing shall apply to other similar processes and products the corrective action, and controls implemented, to eliminate the cause of nonconformity.

#### **8.5.2.4 Rejected Product Test/Analysis**

AG Manufacturing analyzes parts rejected by the customer's manufacturing plants, engineering facilities and dealerships. The organization minimizes the cycle time of the process. Records of these analyses are kept and made available upon request. The organization performs analysis and, initiates corrective action to prevent recurrence.

NOTE: Cycle time related to rejected product analysis should be consistent with the determination of root cause, corrective action and monitoring the effectiveness of implementation.

#### **8.5.3 Preventive Action**

A documented procedure for preventive action is established defining requirements for:

- a) determining potential nonconformities and their causes;
- b) evaluating the need for action to prevent occurrence of nonconformities;
- c) determining and implementing action needed;
- d) records of results of action taken; and,
- e) reviewing the effectiveness of the preventive action taken.

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