Quality System Manual

Joe Coatter _____ 9/23/15

President - Joe Coatter Date

Bill Gareis _____ 9/23/15

ISO/TS Management Representative - Bill Gareis Date

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QUA-0003
4.2.2

SECTION I Quality System Manual Introduction

SECTION II ISO 9001 and ISO/TS 16949 Requirements

2.0 Scope of the Quality Management System

This Quality Management System has been developed to address the requirements of the ISO 9001 and ISO/TS 16949 Standards and outlines the systems and procedures that constitute the Quality Management System implemented at the Jaco Manufacturing Co.

The requirements contained within the ISO 9001 Standard will be applied for ALL Customers, while the additional automotive requirements of the ISO/TS 16949 Standard will only be applied for those customers who require specific Standard compliance.

Jaco Manufacturing Co. will make every attempt to apply the additional requirements of the ISO/TS 16949 Standard to all customers, but only when determined to be feasible and a value added approach to the current business operations.

Throughout this Quality System Manual, the following fonts will be utilized to designate the differences between the various standard requirements:

ISO 9001 Requirements:	Black Font
ISO/TS 16949 Requirements:	Green Font

Jaco Manufacturing Co. is committed to the policies and procedures described and referenced throughout this Quality System Manual.

With reference to the noted Standards, the following Scopes of Registration are applied:

ISO 9001:2008 without Design

Custom injection molding

ISO/TS 16949:2009 without Product Design

Custom injection molding

Key Processes (QUA-0001) of the Jaco Manufacturing Co. Quality Management System include, but are not limited to:

Customer Service
Management Responsibility
Resource Management
Purchasing
Tooling Design and Development
Product Realization/Manufacturing
Measurement, Analysis and Improvement
Document and Data Control
Receiving and Receiving Inspection
Shipping

2.1 Company Background

JACO Manufacturing Company has been built on a reputation of customer service, practical applications experience and innovative engineering. We manufacture a number of products for the plastics industry including:

* Custom and insert molding with part sizes up to 32 oz and unmatched repeatability, we offer a wide range of materials including high performance resins. JACO's in-house mold design, tooling and production ensure high quality.

* A full line of JACO plastic compression fittings, which typically cost less than metallic fittings and are available in four different resins for various corrosion-resistance requirements. All common configurations are available in 1/8" through 7/8" tube O.D. sizes including limited metric sizes. Assembly is fast and easy with JACO's sure-grip design.

To ensure top performance from all our products, we utilize a continuous improvement philosophy in all our systems throughout the organization. JACO's unique in-house capabilities are your assurance of quality parts, timely service and competitive pricing.

Our past reputation for excellence has laid the groundwork for our operations today. We maintain a commitment to continually enhance and improve the high quality of our products. We look forward to serving all your injection molding needs.

For more information regarding Jaco Manufacturing Co., please visit our web site at www.jacomfg.com

2.2 Quality Policy

The Top Management Team has developed a Quality Policy statement based on the philosophy of customer satisfaction and quality management, with the goal of providing high quality products and customer service to our customers.

The Jaco Manufacturing Co. Quality Policy reads as follows:

At Jaco, we are all personally committed to meet, and driven to exceed, our customers' expectations.

Each employee is charged with the responsibility and authority to produce product to defined specifications and customer requirements.

Through the application of the Key Ideas of the Quality Policy (i.e. Quality Product, Customer Satisfaction and Continual Improvement) it is expected that each employee understands and meets our customer's expectations.

The Quality Policy has been communicated to all employees via meetings and a variety of handouts and postings. Continuous evaluation during internal audits ensures the implementation and maintenance of the Quality Policy as well as the employees understanding of how they help contribute to the achievement of the Quality Objectives.

Annually, the Top Management Team will define goals and objectives that will be utilized to measure the suitability and effectiveness of the Quality Management System. The goals and objectives will be tracked and formally evaluated during the Management Reviews as a basis for continuous improvements.

2.3 Quality Management System Exclusions

All requirements of the ISO 9001 and ISO/TS 16949 Standards have been addressed with the exception of those elements that are currently excluded to the Jaco Manufacturing Co. business operations.

With this, the following requirement was determined to be 'Excluded'

- Product Design portions of section 7.3

Customers are responsible for product design, verification and validation.

2.4 Quality Management System Documentation Structure

The structure of the quality management system documentation is as follows:

Tier I — Quality System Manual (QSM)

The governing document that defines the scope and processes of the Quality Management System.

The objectives of this manual are to provide our company personnel and customers with a single source of information regarding Jaco Manufacturing Co. policies and procedures for assuring and controlling product and service quality, the continual improvement of the quality management system and compliance to requirements defined within referenced Standards.

This manual establishes Jaco Manufacturing Co. management policy concerning quality and refers to Quality System Procedures (QSP).

These procedures have been developed to ensure the quality of deliverables in strict accordance with contractual and jurisdictional requirements. The policies contained within this manual and the methodologies defined within each referenced procedure are applicable to all contracts performed by Jaco Manufacturing Co.

Nothing within this manual relieves Jaco Manufacturing Co. of its responsibility for complying with the provisions of awarded contracts including work performed by Jaco Manufacturing Co. suppliers and subcontractors.

In the event of any inconsistency between this document and specific contract requirements, the contract requirements shall prevail.

Tier II — Quality System Procedures (QSP)

Documents that define Who, What, and When

Quality System Procedures (QSP) are stand-alone documents necessary to ensure the effective planning, operation and control of Jaco Manufacturing Co. processes. Quality System Procedures cross-reference other procedures and make reference to either third or fourth tier documents.

The extent of detail contained within each procedure has been based on the complexity of the work processes that are being used, the interaction of the processes involved, and the prerequisite skills and training needed by Jaco Manufacturing Co. personnel to perform each activity defined.

Tier III Work Instructions (WI), Control Plans, and other Process Control Documents

Documents that specifically define how to complete an assigned task

Control Plans have been defined as written descriptions of the system for controlling parts and processes. Control Plans are comprehensive documents of product and process characteristics, process controls, tests and measurement systems that will occur during product realization.

Control Plans have been developed based on the methodology of the AIAG APQP/CP Manual.

Tier IV Forms

Documents that promote the recording of data and information to support compliance with either ISO 9001 and ISO/TS16949 Standards or any documented Quality Management System requirements.

Other documents that are controlled but are not considered part of the four-tier structure include External Documents.

External Documents are those documents that Jaco Manufacturing Co. has no authority to update or revise, but need to be controlled within the Quality Management System.

These documents may include, but are not limited to the ISO 9001 and ISO/TS 16949 Standards, Industry Specifications, Reference Manuals and copies of documents provided by Jaco Manufacturing Co. customers.

3.0 Control of the Quality System Manual

The Quality System Manual will be reviewed and approved by the President and the ISO/TS Management Representative of the facility.

The Quality System Manual is a controlled document that is maintained by the Management Representative and distributed via the Document Master List (QUA-0004).

Copies other than those listed may be distributed but are not considered controlled copies. These copies are provided for reference purposes only to sources such as Customers and Third Party Assessment Body's.

3.1 Quality System Manual Revision History

Revision History Log

Rev	Date	Change Description
1	6-5-2012	Released new Quality Manual
2	6-11-2012	Revised Key Processes – Clarified section 2.3 exclusions -
3	7-10-2012	Added procedures not referenced – all procedures are now referenced in QSM
4	10-23-2012	Placed Bill Gareis as ISO/TS Management Representative (title page)
5	11-5-2012	Changed Procedure #'s from element # to 1 thru 26 document # (QSP #)
6	6-26-2013	Revised section 7.4.1.2
7	09-23-2015	Page 3 - Removed the word "Maintenance" from #3 on Key Processes.

4.0 Quality Management System

4.1 General Requirements

The Jaco Manufacturing Co. Quality Management System

a) has determined the processes needed for the quality management system and their application throughout the facility via the System Process Model Diagram (QUA-0002)
b) has determined the sequence and interaction of these processes via the System Process Model Diagram (QUA-0002);
c) has determined the criteria and methods needed to ensure that both the operation and control of these processes are effective through the use of documented Quality Management Procedures, Control Plans, and Work Instructions. Internal monitoring processes such as Internal Audits and Management Review Meetings further assist in ensuring system effectiveness;
d) ensures the availability of resources and information necessary to support the operation and monitoring of these processes via Management Review Meetings, Contract Review, and Quality Planning activities;
e) monitors, measures (where applicable), and analyzes these processes via the Goals and Objectives Matrix (QUA-1025), Management Review Meetings, Internal Audits, Corrective and Preventive Actions, and the general analysis of data;
f) implements actions necessary to achieve planned results and the continual improvement of these processes through Management Review Meetings, Internal Audits, Corrective and Preventive Actions, and the Analysis of Data.

The Key Processes (QUA-0001) are managed by the facilities Top Management who provide information, instruction and support to employees.

In the event that Jaco Manufacturing Co. chooses to outsource any process that affects product conformity with defined requirements, Purchasing Representatives will define the type and extent of control over such processes through the initial qualification and continual monitoring of suppliers (see section 7.4 of this QSM and QSP # 11 Purchasing).

At the present time, outsourced services may include but are not limited to calibration, preventive maintenance, secondary finishing operations, and testing services.

4.1.1 General Requirements- Supplemental

This control does not absolve the Jaco Manufacturing Co. Inc. facility of the responsibility to ensure conformance to customer requirements (QSP # 11).

4.2 Documentation Requirements

4.2.1 General

The quality management system documentation has been effectively implemented and includes

a) documented statements supporting the quality policy and quality objectives
b) this Quality System Manual
c) documented procedures and records addressing the requirements of the ISO and ISO/TS Standards
d) other process control documents (i.e. additional Quality Management Procedures, Control Plans and Work Instructions), including records, determined to be necessary to ensure the effective planning, operation and control of its processes

4.2.2 Quality Manual

Jaco Manufacturing Co. has established and maintains a Quality System Manual that includes

a) The scope of the quality management system.

   Since there are no defined exclusions, details of and justification for the 'Non Applicable' sections of the Quality Management System have been defined in section 2.3 of this Quality System Manual.

b) either reference to the documented procedures or detailed descriptions of the processes and methods to be employed

c) a description of the interaction between the processes of the quality management system as defined in the System Process Model Diagram (see section 4.1b of this Quality System Manual and/or QUA-0002)

4.2.3 Control of Documents

Jaco Manufacturing Co. controls all documents associated with the effective management and maintenance of the Quality Management System.

Documents under formal control include the Quality System Manual, Quality System Procedures, Control Plans, Work Instructions, Forms and External Documents.

Quality System Procedure (QSP # 1 Control of Documents) has been established to define the control of these documents. The procedures include methods

a) to approve documents for adequacy prior to use
b) to review and update as necessary and re-approve documents
c) to ensure that changes and the current revision status of documents are identified
d) to ensure that relevant versions of applicable documents are available at points of use
e) to ensure that documents remain legible and readily identifiable
f) to ensure that documents of external origin determined to be necessary by Jaco Manufacturing Co. to ensure the planning and operation of the Quality Management System are identified and their distribution controlled (see QUA-0004)
g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose

Records are considered a special type of document that when completed will contain data to support compliance with planned arrangements and/or the requirements of the referenced Standards.

Records will be controlled through the Control of Records Procedure (QSP # 2).

4.2.3.1 Engineering Specifications

All Automotive Customer Specifications are reviewed within 10 business days (per QSP # 1) to ensure that any new or updated requirements are adequately communicated and implemented into the relevant procedure(s) and/or PPAP documentation (i.e. FMEA, Control Plans, etc.), and distributed to those personnel who need to be aware of the updated requirements.

Records of the dates in which the changes are implemented in production will be maintained in accordance with (QSP # 2) Control of Records.

4.2.4 Control of Records

Records are maintained and controlled in order to demonstrate conformance to specified requirements and the effective operation of the quality management system.

Jaco Manufacturing Co. records (as defined in the Document Master List (QUA-0004) will remain legible, readily identifiable and retrievable.

Quality System Procedure (QSP # 2) has been established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

4.2.4.1 Records Retention

All Quality Records retention times will satisfy statutory (i.e. Federal, State and Municipal Codes, such as EEOP, Minimum Wage Act), regulatory (i.e. EPA, OSHA) and customer specific requirements.

5.0 Management Responsibility

For the purpose of the Quality Management System, Jaco Manufacturing Co. has defined 'Top Management' as:

President
Quality Manager / Supervisor
Customer Service Manager / Supervisor
Manufacturing Manager / Supervisor
Shipping/Receiving/Inventory Control/IT Manager / Supervisor
Maintenance Manager / Supervisor
Engineering Manager / Supervisor (ISO/TS Management Representative)
Tooling Manager / Supervisor

5.1 Management Commitment

Top Management provides 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. This information is normally communicated via

- training sessions;
- postings and bulletin boards;
- e-mail notifications;
- employee meetings; and posting of the
- Internal Communications Memo (QUA-0005)

b) establishing the Quality Policy (see section 5.3 of this Quality System Manual)
c) ensuring that quality objectives are established (see section 5.4.1 of this Quality System Manual)
d) conducting management reviews (see section 5.6 of this Quality System Manual)
e) Ensuring the availability of resources (i.e. equipment, training, and manpower needs) is normally addressed through Management Review Meetings in which discussions are held regarding the provision of resources and the facility infrastructure.

5.1.1 Process efficiency

Top Management reviews the Production Realization Processes and support processes to assure the effectiveness and efficiency of the QMS through:

- the results of Manufacturing Process Audits (see section 8.2.2.2 of this QSM),
- the Goals and Objectives Matrix (QUA-1025),
- general Quality Issues,
- Customer Complaints

These reviews are formally conducted during Management Review Meetings, but may also be addressed as part of the day-to-day business activities to assure the effectiveness and efficiency of our processes.

5.2 Customer Focus

Top Management ensures that customer requirements are determined and are met with the aim of enhancing customer satisfaction.

Customer Requirements may be determined through Quotations, Purchase Orders, Specifications; Customer provided Supplier Quality Manuals, as well as Customer Satisfaction and Dis-satisfaction data.

To ensure that the defined customer requirements are being met, Top Management will rely on data from the Goals and Objectives Matrix (QUA-1025) and customer feedback (i.e. Customer Report Cards, and general customer communications).

Actions will be taken as necessary to ensure that customer requirements are continually met and enhanced (re: QSP # 20 Customer Satisfaction).

5.3 Quality Policy

The Quality Policy of the Jaco Manufacturing Co. has been defined in section 2.2 of this Quality System Manual.

Top Management ensures that the Quality Policy

a) is appropriate to the purpose of organization (see section 2.0 of the Quality System Manual)
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 (see section 5.4.1 of this Quality System Manual)
d) is communicated and understood throughout the organization via meetings and a variety of handouts and postings. Routine interviews and evaluations during internal audits assure the continued implementation, maintenance, understanding and effectiveness of the Quality Policy.
e) is reviewed for continuing suitability during the Management Review Meetings (QSP # 4 Management Review)

5.4 Planning

5.4.1 Quality Objectives

Top Management ensures that quality objectives, including those needed to meet requirements for product, are established at relevant functions and levels within the organization.

Annually, Top Management will define goals and objectives that will be utilized to measure the suitability and effectiveness of the Quality Policy.

The goals and objectives will be tracked and collected by the responsible managers and be formally evaluated by Top Management during the Management Review Meetings as a basis for continual improvement.

To ensure that the quality objectives are measured and are consistent with the Quality Policy, Top Management utilizes a Goals and Objectives Matrix (QUA-1025).

If goals and objectives are not met, either action items are assigned or statements justifying the non-action are recorded in the Management Review Meeting Minutes.

5.4.1.1 Quality Objectives- supplemental

Goals and Objectives will be identified in the Business Plan and utilized to assist in determining the suitability and effectiveness of the Quality Policy.

The Daily, Weekly, Monthly (as well as the Management Review) Meetings will include discussions related to:

- Status of current Goals and Objectives
- Quality Policy
- Customer Satisfaction / Expectations
- Actions taken to improve upon expectations within defined time periods

5.4.2 Quality Management System Planning

Jaco Manufacturing Co. has defined Quality Management System Planning as 'Systems Level' Quality Planning.

Systems Level Quality Planning will be initiated when new or revised programs are introduced to the existing Quality Management System.

Plans to ensure the effective implementation of the new or revised system will be reviewed and discussed during Management Review Meetings (QSP # 4). The Quality Planning Procedure (QSP # 3) may also be consulted for specific processing of Quality Planning activities.

The initiation of System Level Planning Projects may include information from the monitoring of goals and objectives, updated organizational processes, and the assignment of quality management system projects (including Manufacturing Process Design Projects).

Top Management ensures that…

a) the planning of the quality management system is carried out in order to meet the general requirements stated in Quality System Manual section 4.1, as well as the applicable quality objectives.

b) Top Management will ensure that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

Top Management has defined the responsibilities and authorities of all employees who manage, perform and verify work affecting quality throughout the documented quality management system, the Organizational Chart (ADM-0001) and the established Job Descriptions.

A Responsibility Matrix (ADM-0002) has also been created to assist in identifying the responsibilities of all personnel with respect to the requirements of the ISO/TS Standard.

Top Management has communicated the responsibilities and authorities via the distribution of controlled quality management system documents and the Responsibilities Matrix (ADM-0002).

5.5.1.1 Responsibility for Quality

The Quality Manager (Management Representative)will be informed on all products, process or system related deficiencies, which are determined not to meet specified requirements within one business day.

Communication of the deficiencies may include, but are not limited to, verbal means, inspection documents, reports, questionable products, and/or tags.

Personnel on all shifts who are responsible for conformity to product requirements are empowered to stop production at any time to identify potential problems and have them corrected by authorized individuals.

An Organizational Chart (ADM-0001) has been established to outline the structure and reporting responsibilities of Jaco Manufacturing Co. personnel.

5.5.2 Management Representative

The President of the organization has appointed the Jaco Manufacturing Co. Engineering Manager as the Management Representative. In this position, the Engineering Manager, irrespective of other responsibilities, has the responsibility and authority for

a) ensuring that processes needed for the quality management system are established, implemented and maintained. This is accomplished through the Management Representatives authority for internal audits, corrective actions, quality planning, and document control activities
b) reporting to Top Management on the performance of the quality management system and any need for improvement through Management Review Meetings (QSP # 4)
c) ensuring the promotion of awareness of customer requirements throughout the facility through, but not limited to, the presentation of customer satisfaction and

dis-satisfaction data, various employee meetings and the Internal Communications Memo (QUA-0005).

The appointment to the position of Management Representative is expressed via the review and approval of this Quality System Manual.

5.5.2.1 Customer Representative

The Engineering Manager, Tool Room Manager, Sales Manager and Quality Manager (Management Rep) are responsible for ensuring that the Customer's requirements are being met.

This general responsibility includes:

- Assisting in the selection of special characteristics,
- Assisting Top Management in the development of Quality Objectives specifically related to improving Customer Requirements,
- Providing related training to ensure Customer requirements are being met,
- Involvement with corrective and preventive actions related to customer concerns
- Assisting with any Customer Design and Development Activities
- Acting as the customer's liaison in matters that relate to customer requirements

5.5.3 Internal Communication

Top Management has established and maintains appropriate communication channels via the Organizational Chart (ADM-0001).

The effectiveness of the Quality Management System is communicated during various employee meetings and postings (including the Internal Communications Memo (QUA-0005).

5.6 Management Review

5.6.1 General

Top Management reviews the Quality Management System at a minimum of one time per calendar year to ensure its continuing suitability, adequacy and effectiveness.

The Management Review Meeting will include the assessment of opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

5.6.1.1 Quality Management System Performance

The Management Review Meeting will include the review of Key Processes via the Goals and Objectives Matrix (QUA-1025) as a means for ensuring and promoting continuing suitability, effectiveness and improvement.

Measures will include Quality Objectives keyed to the Quality Policy and the evaluation of the Cost of Poor Quality.

Evidence of the achievement of the Quality Objectives and Customer Satisfaction with relation to products supplied, will be documented in the Management Review Meeting Minutes.

Quality Objectives are consistent with those documented in the Business Plan.

The Business Plan will be developed annually by the Executive Committee and may include, but is not limited to the following topics:

- Quality Objectives (i.e. key internal and operational performance measures)
- Market Related Issues (i.e. new markets, opportunities, current and future customer expectations, current business)
- Financial Planning and Costs (i.e. sales forecast, growth projections, capacity planning)

5.6.2 Review Input

Inputs to Management Review Meetings include information on

a) Internal Audits results;
b) customer feedback;
c) review Quality Policy
d) process performance and product conformity;
e) status of preventive and corrective actions;
f) follow-up actions from previous management reviews;
g) changes that could affect the quality management system, and
h) recommendations for improvement
i) review of plant layouts to optimize material travel, handling and value added floor space to facilitate synchronous material flow (per QSM 6.3.1)
j) review of the Contingency Plan (per QSM 6.3.2)

5.6.2.1 Review Input - supplemental

- Input to the Management Review Meetings will include the analysis of actual and potential field failures and their impact on quality, safety, or the environment.

Per section 7.3.4.1 of this Quality System Manual, the status of current Design Projects, as well as Quality Planning activities associated with Manufacturing Process Design, will be reported on. Information presented may include Quality Risks, Costs, Lead Times, etc.

5.6.3 Review Output

Output from the Management Review Meetings will include 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.

A Quality System Procedure (QSP # 4) further defines the Management Review Meeting topics and the structured agenda.

6.0 Resource Management

6.1 Provision of Resources

Resource requirements have been defined as equipment, manpower, and training needs.

Resource requirements are formally addressed during Management Review Meetings but may be identified and provided for during normal day-to-day operations.

Any associate may request additional resources while the Department Managers/Supervisors, and other members of Top Management have the defined responsibility and authority to determine if the need for the resource(s) is valid, required and feasible.

When determining these resources, consideration will be given to:

- Current business opportunities and constraints;
- Mechanisms that will encourage innovative continual improvement;
- Methods to enhance existing competency; and
- Future resource requirements.

Requested resources may be needed…

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

6.2 Human Resources

6.2.1 General

Personnel performing work affecting conformity to product requirements will display competence to perform tasks based on appropriate education, training, skills and experience.

Competence has been defined as the demonstrated ability to apply knowledge and skills, while skills have been identified as proficiency and dexterity in performing tasks.

6.2.2 Competence, training and awareness

The Department Managers/Supervisors, with assistance from Top Management, will

a) define the necessary competence for personnel performing work affecting conformity to product requirements via Job Descriptions.

   The Job Descriptions will include recommended minimum qualifications (such as education, experience and skills) to enter a position.

   Additional training will assist in providing the necessary knowledge and skills needed for an employee to be considered competent in their respective job task.

b) identify and provide training to support initial qualifications, promote and achieve employee competencies and promote employee development
c) evaluate the effectiveness of the training provided
d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

This may be accomplished through any of the following methods:

- Training (including Orientation and/or other training programs)
- A variety of Quality and/or Safety Meetings
- Internal Audit Activities

e) maintain appropriate records of education, training, skills and experience via the Quality System Procedure (QSP # 2) Control of Records

Quality System Procedure (QSP # 5) has been developed to more clearly define the methods of qualification, training and determining training effectiveness.

6.2.2.1 Tooling Design Skills

Personnel with tooling design responsibility (including personnel having an effect on quality) will be verified as being competent to achieve customer design requirements and skilled in applicable design and development tools and techniques.

Necessary skills may include, but are not limited to the following:

- Die Design
- CAD (Modeling)
- Injection Molding Machine Operations
- Troubleshooting
- Blue Print Reading (GD&T)
- PPAP, FMEA, and APQP/CP

6.2.2.2 Training

The organization will identify training needs and ensure competencies for all personnel performing activities affecting conformity to product requirements.

Through the monitoring of internal process performance data, quality objectives, and customer satisfaction data, training needs will be identified and provided for, as appropriate, to improve upon customer satisfaction and dis-satisfaction levels.

Personnel performing specific tasks will be qualified, as required, with particular attention to satisfy any customer requirements.

Training will be in accordance with and to the satisfaction of customer requirements.

6.2.2.3 Training on the Job

On the job training will be provided to all new employees, employees who have changed positions, as well as contracted and/or agency personnel, whose work may affect conformity to product requirements, specific customer requirements, and/or statutory or regulatory issues.

Personnel whose work has an affect on conformity to product requirements will be informed of the consequences if nonconforming products (quality deficiencies) are released to the customer.

Typically, internal consequences may include items that affect the Cost of Quality (i.e. material costs, rework costs, scrap costs, sorting costs, and replacement material costs) and overall Customer Dissatisfaction.

External consequences may include loss of business and field failures potentially affecting consumer safety.

6.2.2.4 Employee Motivation and Empowerment

Jaco Manufacturing Co. has implemented programs to motivate personnel in order to assist in achieving quality objectives, continual improvements, and creating an environment to promote innovation.

The intent of these programs will be to promote quality and technology awareness throughout the whole organization.

Programs currently in place include, but are not limited to:

- Employee inclusion / involvement with the Corrective Action, Preventive Action, and Continual Improvement Processes
- Safety Suggestions
- Suggestions communicated to Managers/Supervisors
- Various employee functions (i.e. Luncheons)
- Training Programs
- Profit Sharing Plan

Internal Audit activities and comments on the Job Descriptions will be utilized to determine whether or not personnel are aware of the importance of their job tasks and how they help contribute to the achievement of the quality objectives.

All related training, development and promotional activities are more clearly defined in (QSP # 5 Competence, Training and Awareness).

6.3 Infrastructure

To provide a foundation for operations and to ensure the achievement of product conformity to requirements, along with representatives of Top Management, will determine, provide and maintain the infrastructure needed to achieve conformity to product requirements through evaluations performed during Management Review Meetings and Quality Planning activities.

Infrastructure includes, as applicable

a) buildings, workspace, and associated utilities

b) process equipment (hardware and software)

c) supporting services (subcontracted operations, including information systems)

6.3.1 Plant, Facility and Equipment Planning

Jaco Manufacturing Co. will utilize a multi-disciplinary approach (cross-functional teams) for the development of plant, facility and equipment plans.

This is further discussed in the Quality System Procedure – Quality Planning (QSP # 3).

The review of Plant Layouts during Management Review Meetings is intended to facilitate synchronous material flow. Meeting topics will address actions to:

- optimize material travel,
- improve product handling, and
- identify value-added use of floor space

Methods such as the review of Goals and Objectives and Internal Audit activities (QSP # 21) have been developed and implemented to evaluate and monitor the effectiveness of the existing operations.

6.3.2 Contingency Plans

A Contingency Plan has been prepared to reasonably protect the customer's supply of product in the event of emergency, such as utility interruptions, labor shortages and key equipment failures.

The Contingency Plan will be reviewed during the Management Review Meetings.

The Contingency Plan is as follows:

- The Human Resources Manager is responsible for labor shortages. JACO is non-union and does not suffer strike-related labor issues. Local newspapers: The Plain Dealer and Sun News are utilized as advertising avenues.
- The Maintenance Department is responsible to repair molding presses.
- There are two air compressors: the main and back-up.
- JACO uses its own water tower. City water may be used as a backup.
- Multiple power circuits supply the plants. Power may be re-routed in the event of a circuit failure.

6.4 Work Environment

The Manufacturing Manager, along with other representatives of Top Management, has determined and will continue to manage the work environment needed to achieve conformity to product requirements, per (QSP# 6) Work Environment.

Examples of how Jaco Manufacturing Co. manages Work Environment include, but are not limited to:

- ❑ Safety and Housekeeping Audits (HNR-3001)
- ❑ Employees are also recommended to provide input with regards to the improvement of the overall work environment.
- ❑ Safety rules and guidance are provided in the Jaco Manufacturing Co. Employee Manual which includes the use of protective equipment which has been allocated for Jaco Manufacturing Co. personnel.
- ❑ The heat, lighting, humidity, noise level, cleanliness and proper air flow within our office and shop facilities will be monitored and actions taken to ensure the positive enhancement of our personnel's performance.

6.4.1 Personnel safety to achieve conformity to product requirements

Special considerations are directed toward minimizing potential risks and promoting product safety, during Manufacturing Process Design activities (i.e. FMEAs).

All new and/or revised manufacturing processes consider employee safety as an integral part of the input and output stages of the project. This includes training with relation to the safe and proper operation of manufacturing equipment and product handling.

In addition to the Safety Measures tracked through the Goals and Objectives Matrix (QUA-1025), the Safety Committee helps to ensure that all existing safety programs are working and are effective.

6.4.2 Cleanliness of premises

The Manufacturing areas, Quality Offices, and General Office environments are maintained in a state of order and cleanliness appropriate to the products being produced and activities being performed.

Cleanliness of the premises is evident via the Safety and Housekeeping Audits (HNR-3001).

7.0 Product Realization

7.1 Planning of Product Realization

Jaco Manufacturing Co. has defined planning of product realization as the day-to-day 'product/process' level of quality planning.

'Product/Process' planning takes place when a new product or process is introduced, or if a product or process is significantly revised.

In planning product realization, the Engineering and Quality Manager (Management Rep),will determine the need for Quality Planning via discussions of Customer Requirements (Feasibility Reviews) and the monitoring of process data reviewed during the Management Review Meetings.

In the event that…

- new or revised requirements cannot be met through the existing production operations and/or the quality management system, or
- significant process changes are required

Top Management will initiate the Quality Planning activities.

The Management Personnel, assigned, which would include cross-functional department representation, will carry out quality planning activities in accordance with the Quality Planning Checklist (QUA-0006).

For the projects, Management Personnel will assess the following quality planning questions:

a) the need for new and/or revised quality objectives and requirements for the product;
b) the need to revise or 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 level of planning may be the generation of new or revised quality management system documents (i.e. Quality System Manual, Quality System Procedures, Work Instructions, Control Plans, and/or Forms).

The AIAG APQP/CP Manual may be referenced, as needed throughout this process.

Quality Planning activities are further defined in (QSP # 3) Quality Planning.

7.1.1 Planning of product realization - supplemental

Any referenced Customer Requirements or Technical Specification will be included in the planning of product realization and ultimately referenced in the new or revised Quality Management System documentation.

7.1.2 Acceptance Criteria

Acceptance criteria for all inspection and test activities may be defined within the Control Plans, Customer Specifications, Part Prints, Quality Inspection Sheets and Process Control Documents.

When required by contract, the Customer will approve the methods of inspection and associated acceptance criteria.

The acceptance criteria for attribute data sampling is zero defects.

7.1.3 Confidentiality

Jaco Manufacturing Co. ensures the confidentiality of customer contracted products under development and related product information through the Control of Records (QSP # 2) and using the form (HNR-3010) Confidentiality Agreement.

Access to Customer Records will be limited to authorized personnel only.

In the event Customers visit our facility, care is taken to ensure that other Customer Samples, Specifications, and Property are secured in order to maintain confidentiality.

7.1.4 Change Control

Jaco Manufacturing Co. has developed procedures (i.e. QSP # 1 & QSP # 3) to control and react to changes that impact product realization (product and manufacturing processes).

When either the Customer, Jaco Manufacturing Co. or the Supplier initiates changes, the processes associated with PPAP, Quality Planning, and/or Document Control will be applied to ensure compliance with Customer Requirements.

The effects of any changes, including those caused by a supplier will be assessed, verified, and validated prior to implementation.

For proprietary designs; impact on form, fit, and function will be reviewed with the Customer so that all effects can be properly evaluated.

When required by the customer, additional verification and/or identification requirements will be met.

7.2 Contract Review (Customer-Related Processes)

7.2.1 Determination of requirements related to the Product

Initial determination of Customer Requirements is established at the Quotation Phase of the Project.

The Engineering Manager, with assistance from Management Personnel and Customer Service, will ensure that all customer requirements are adequately defined, documented and that Jaco Manufacturing Co. has the ability to meeting any and all requirements prior to entering into a contract with the Customer.

To accomplish this, the responsible personnel will determine:

a) requirements specified by the customer (as stated in either their Quotation Documentation, Purchase Orders, or reference to Customer Specific Supplier Manuals/Specifications)
b) requirements not stated (may be accomplished through conversations with the customer to determined the end use of the product),
c) statutory and regulatory requirements applicable to the product (this includes all applicable government, safety and environmental regulations applied to the acquisition, storage, handling, recycling, elimination or disposal of materials), and
d) any additional requirements considered necessary by Jaco Manufacturing Co. (i.e. credit checks, confirmation of a purchase agreement to assure financial responsibility).

7.2.1.1 Customer designated special characteristics

Upon receipt of requests for quote and/or customer orders, the Engineering and Quality representatives will inquire and obtain any specific customer requirements relating to the designation, documentation and control of any special characteristics.

Special Characteristics will be designated on all related Manufacturing Documentation as a means of ensuring the control and adherence to customer requirements.

7.2.2 Review of requirements related to the Product

The Engineering Manager, with assistance from Customer Service, will review the requirements related to the product.

This review shall be conducted prior to organization's commitment to supply a product to the customer (e.g. acceptance of contract or orders, acceptance of changes to contract or orders) and shall ensure that

a) product requirements are defined,

- What is being requested by the customer;
- What product requirements apply;
- What design or development activities are involved;
- If any statutory or regulatory entity would apply that is not already accounted for, and what their requirements would be;
- What materials are required;
- What facilities would be required to achieve the work;
- What costs would be incurred by Jaco Manufacturing Co. to accomplish the work

b) contract or order requirements differing from those previously expressed are resolved, and

c) Jaco Manufacturing Co. has the ability to meet all of the requirements specified by the Customer

Records of the results of these reviews and actions arising from the reviews shall be maintained in accordance with the Control of Records Procedure (QSP # 2).

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by Customer Service prior to acceptance.

All customer orders received by verbal means will require either a Purchase Order Number or Jaco Management Approval in order to begin processing the order requirements.

All customer orders are considered accepted contracts after being approved by Customer Service as evident via entry into the Computer System and the generation of Order Acknowledgements.

Any customer-initiated changes to an existing contract or order shall be subject to the same review and approval process as an original contract or order with one exception. Based on the requested change, Jaco Manufacturing Co. shall advise the customer of any cost or schedule impact and shall require approval of these changes from the customer prior to acceptance and implementation.

Changes to contracts or orders initiated by Jaco Manufacturing Co. must be submitted to, and approved by, the relevant customer prior to being implemented. This may include the review of any cost and/or production schedule impacts.

7.2.2.1 Review of requirements related to the product – supplemental

Jaco Manufacturing Co. is authorized to access various Customer Purchasing Portals to obtain Customer Orders. In these instances, Customer Service Personnel will print out the Customer Orders and review the information in the same fashion as described in section 7.2.2 of this Quality System Manual.

Jaco Manufacturing Co. does not currently offer direct Internet Sales.

Therefore, all requirements contained within section 7.2.2 of this Quality System Manual will be applied to all Customer Orders.

7.2.2.2 Organization Manufacturing Feasibility

The Engineering Manager, with assistance from the Management Personnel or their designees will investigate, confirm and document the manufacturing feasibility of the proposed products during the contract review process.

The Feasibility Reviews will be documented using the Team Feasibility Commitment Form (QUA-0009) or the customer designated form.

As part of the feasibility review, considerations will be given to the risks (concerns) associated with the prospective project.

7.2.3 Customer Communication

The organization has established and maintained methods for the effective communication with customers in relation to product information, customer contracts, and customer feedback/complaints.

a) Product information is controlled and communicated to the customers via brochures, product literature, quotations, and the company web-site

b) Contracts and their handling (including amendments) are communicated to the customer through (QSP # 8) Contract Review.
c) Customer Feedback and Complaints are communicated from the Customer to the Jaco Manufacturing Co. Customer Service and/or Quality Manager (Management Rep). This activity is further defined in (QSP # 9) Customer Communication & Customer Complaints.

7.2.3.1 Customer communication - supplemental

Jaco Manufacturing Co. has the ability to communicate necessary information, including data, in a customer specified language and/or format (i.e. electronic data exchange).

7.3 Design and Development

Jaco Manufacturing Co. does not have design and development responsibilities for the finished Customer Product / Part.

Jaco Manufacturing Co. is contracted to design and build a tool which will be utilized during in-house manufacturing operations in order to produce finished customer parts.

Sections 7.3.2.2 and 7.3.3.2 specifically address Manufacturing Process Design and will be applied for any new or revised processes or equipment introduced to the system. This would include any required Production Part Approval activities. Manufacturing Process Design activities are typically coordinated on the Quality Planning Checklist (QUA-0006).

The remaining sections will be applied to the Tool Design and any associated APQP and PPAP activities needed in order for Jaco Manufacturing Co. to manufacture the finished customer part in-house.

7.3.1 Design and Development Planning (Tooling)

Upon receipt and review of the customer input requirements, the Engineering Manager along with the Tooling Manager will initiate the APQP Program (QSP # 7) which controls the stages of the Design and Development activities.

The plan will include information relative to

a) determining the type of tool
b) determining if the tooling is going to be built internally or contracted to an outside source
c) the design and development stages
d) determining if any review activities need to be performed
e) the review, verification, and validation requirements
f) the responsibilities for the design and development activities

Responsibilities for the Design and Development activities may be extended to include subcontractors and require Jaco Manufacturing Co. interface between the different groups / functions involved with the project.

Each individual plan will be updated as the project evolves.

Manufacturing Process Design Planning will be accomplished via established Quality Planning Checklists and associated Management Meetings.

7.3.1.1 Multi-disciplinary approach

During the planning phase, a multidisciplinary approach (cross-functional team) will be utilized to prepare for product realization (i.e. Tool Design). The team will be responsible for the:

- Development/finalization and monitoring of special characteristics (as either dictated by the customer or selected by Jaco Manufacturing Co.)
- Development and review of FMEAs, including actions to reduce potential risks
- Development and review of control plans

7.3.2 Design and Development Inputs (Tooling)

Inputs have been defined as any communications with the customer.

This may include, but is not limited to, request for quotes, purchase orders, sample parts, models, specifications, math data, etc.

As part of the review process, Engineering will ensure that the inputs contain information relative to:

a) functional and performance requirements
b) applicable statutory and regulatory requirements
c) information derived from previous similar projects
d) any other requirements essential to the design and development activity (including customer specific requirements)

All inputs will be reviewed for adequacy prior to any planning and development activities to ensure that any incomplete, ambiguous and/or conflicting information is resolved.

7.3.2.1 Product Design Input (Tooling)

The review of inputs will also include:

- A review of customer specific requirements such as special characteristics, identification, traceability, and packaging
- The use of information from previous design projects, competitor analysis, supplier feedback, internal input, and field data
- Targets for conformity to product requirements, life, reliability, durability, maintainability, timing and cost

7.3.2.2 Manufacturing Process Design Input

Jaco Manufacturing Co. will identify, document and review the manufacturing process design input requirements including:

- Product design output data
- Targets for productivity, process capability and cost
- Customer requirements
- Experience from previous developments

Records of the results of this review may be maintained on the established Quality Planning Checklists or through associated meetings.

Error proofing methodologies are considered a critical component of the manufacturing process design and will be utilized as necessary based on potential risks.

7.3.2.3 Special Characteristics (Tooling)

Jaco Manufacturing Co. will identify all special characteristics for products produced during Manufacturing Operations and:

- Include all special characteristics in the control plan
- Comply with customer specified definitions and symbols

- Identify process control documents including drawings, FMEAs, Control Plans, and operator instructions with the customers special characteristic symbol or the organizations equivalent symbol or notation to include those process steps that affect special characteristics

7.3.3 Design and Development Outputs (Tooling)

Outputs for the Tooling Design and Development activities (i.e. Tool Drawings) will be reviewed as part of the Design and Development Plan and include information and materials to support:

a) compliance with all defined input requirements

- 2D drawing(s)
- 3D CAD Geometry

b) communications of appropriate information to purchasing, production, quality and service provisions (as applicable) - Information regarding the tool build and any other pertinent information

c) reference to final customer product / part acceptance criteria

d) identification of the characteristics of the tooling that are essential for its safe and proper use

All Design and Development Outputs will be in a form suitable for verification against Design and Development Input Requirements and will be approved prior to release.

7.3.3.1 Product Design Outputs – Supplemental (Tooling)

All Tooling / Product Design Outputs will be expressed in terms that can be verified against the input requirements.

Additional Tool / Product Design Outputs may include the following (as required by the customer):

- Design FMEA's and reliability results
- Special Characteristics and specifications
- Error proofing
- Product drawings or mathematical data
- Product Design Review Results

7.3.3.2 Manufacturing Process Design Output

The manufacturing process design output will be expressed in terms that can be verified against manufacturing process design input requirements and validated.

The manufacturing design output may include:

- Updated facility layouts
- Records of Training
- Specifications and drawings (i.e. tooling, die and part prints)
- Flow Chart for Injection Molding Operations
- Manufacturing Process FMEAs
- Control Plans
- Work Instructions
- Process approval acceptance criteria (as defined by the Customer)

- Data for quality, maintainability (i.e. tool refurbishing- sharpening, polishing, and perishable tooling control) and measurability (part Cpk & run at rate)
- methods of rapid detection and feedback of product and/or manufacturing process nonconformities

7.3.4 Design and Development Review (Tooling)

Tooling / Product Design and Development Reviews will be performed at established stages via the APQP Program.

Each review activity will be performed in order to:

a) Evaluate the ability of the design and development activities to meet requirements
b) Identify any problems and propose actions for resolution

Participants in these review activities will include representatives from all functions involved or concerned with the stage of the project being reviewed.

Records of the results of the reviews will be maintained in accordance with the Design Plan and Control of Records Procedure (QSP # 2).

7.3.4.1 Monitoring (Tooling)

Measurements at specified stages of the tool design and development will be defined, analyzed and documented in the Design Records.

The status of current Design Projects, as well as Quality Planning activities associated with Manufacturing Process Design, will be reported on during Management Review Meetings.

Information presented during Management Reviews may include Quality Risks, Costs, Lead Times, etc.

7.3.5 Design and Development Verification (Tooling)

Tooling / Product Design and Development Verification activities will be performed in accordance with the established Design Plan.

Verification of the Tool has been defined as the evaluation of Sample Parts manufactured with the designed Tool, measured against all defined input requirements.

Records of the results of the verification activities and any subsequent actions taken will be documented in the Design Package and maintained in accordance with (QSP # 2).

7.3.6 Design and Development Validation (Tooling)

Tooling / Product Validation is performed by Jaco Manufacturing Co. Customers in accordance with the established Design Plan.

The Validation stage consists of built tooling and established processes being performed in accordance with planned arrangements to ensure that resulting products and processes conform to define user requirements and will be capable of meeting the Customer requirements

The Validation Activities performed by the customer will ensure that the Tooling designed and developed at Jaco Manufacturing Co. is capable of producing the final customer product per the requirements and specifications provided at the input stage of these activities.

The design is considered validated upon receipt of Customer approval of the part(s) produced from the completed Tooling

Records of the Validation activities, or any resulting action items, will be maintained per (QSP # 2).

7.3.6.1 Design and Development Validation – Supplemental

Tooling Validation will be performed in accordance with customer requirements including program timing as evident in the APQP Program

7.3.6.2 Prototype Program

When required by customers, prototypes (product samples) and Control Plans will be developed.

If required, Jaco Manufacturing Co. will be responsible for monitoring and providing the Prototypes (Product Samples) to the customer in a timely fashion to assure the completion of any performance testing and conformity of product in accordance with customer requirements.

In the event that Prototype activities are subcontracted, Jaco Manufacturing Co. will

- maintain the primary responsibility for conformance with requirements
- maintain technical leadership of the project
- ensure that the subcontracted tooling and manufacturing processes will be utilized in production.

7.3.6.3 Product Approval Process

Jaco Manufacturing Co. will conform to the designated product and manufacturing approval requirements recognized by the customer.

This normally includes compliance with the requirements contained within the AIAG PPAP Manual. See Quality System Procedure (QSP # 10 - PPAP).

As required by our Customers, the requirements for product and manufacturing process approval will be applied to Jaco Manufacturing Co. Suppliers.

7.3.7 Control of Design and Development Changes (Tooling)

Tooling Design and Development changes will be tracked and identified within the APQP Program.

All changes will be subject to the same review, verification and validation activities as associated with the original Tool Design and Development activities.

Consideration will be given to the effect of the change on any constituent parts and product already delivered.

Records of Tooling Design and Development changes will be properly identified and maintained per (QSP # 2).

7.4 Purchasing

7.4.1 Purchasing Process

Jaco Manufacturing Co. ensures that purchased product (i.e. raw materials, components, and packaging materials) and subcontracted services conform to specified purchase requirements.

The type and extent of control applied to the supplier and the purchased product are dependent upon the effect of the purchased product on subsequent product realization and the final product quality.

All suppliers are evaluated for initial, as well as ongoing performance, via (QSP # 11) and the following paragraphs of this Quality System Manual.

The Management Personnel, along with assistance from Purchasing and Quality, will evaluate and select suppliers based on their ability to supply products, materials and services in accordance with facility requirements.

The specific criteria for selection, evaluation and re-evaluation are more clearly defined in section 7.4.3.2 of this QSM, (QSP # 11), and the Jaco Manufacturing Co. Supplier Quality Requirements.

Records of the results of initial and ongoing evaluations and any necessary actions arising from these evaluations will be maintained in accordance with the Control of Records Procedure (QSP # 2).

7.4.1.1 Statutory and Regulatory conformity

All purchased products and materials used in the production realization process will conform to applicable statutory and regulatory requirements.

For example, MSDS are required for any shipments of restricted, toxic, or hazardous substances.

7.4.1.2 Supplier quality management system development

Jaco Manufacturing Co. has established and implemented a system to promote the development of our suppliers with the goal of compliance to the requirements of the ISO/TS 16949 Standard.

Suppliers will be prioritized based on their current quality management systems, their overall quality performance, and the importance of the product/service supplied.

For those suppliers providing materials and/or services used for our automotive customer's products, the primary quality remains with the supplier and cannot be altered. These suppliers must be or working towards third party registration to ISO 9001.2008 by an accredited third party certification body, unless waived by the customer. These suppliers are referred to as Type "A" suppliers.

Suppliers who provide products and/or services that are not as critical as a type 'A' Supplier to part quality and where Jaco assumes responsibility and

verification of the quality, such as tool fabricators, these suppliers are referred to as Type "B" suppliers and may not be ISO 9001 registered. Jaco qualifies these suppliers through supplier assessments, on-site visits, and inclusion of the supplier in the APQP or other critical planning processes.

Supplier development activities are more clearly defined in (QSP # 11).

7.4.1.3 Customer approved sources

When specified in the customer contract, Jaco Manufacturing Co. will purchase products, materials and/or services from the customer approved sources.

The use of customer-designated sources does not relieve Jaco Manufacturing Co. of the responsibility for ensuring the quality of purchased products.

Customer approved sources will be added to the Jaco Manufacturing Co. Approved Supplier List and will be subject to the same ongoing performance monitoring activities as supplier's that have been approved via other means (see QSP # 11).

7.4.2 Purchasing Information

Purchasing information will clearly describe the material, product, and/or service 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

Purchasing activities are more clearly defined in (QSP # 11).

7.4.3 Verification of Purchased Product (Receiving Inspection)

Jaco Manufacturing Co. has established and implemented inspection and other activities necessary for ensuring that purchased product meets specified purchase requirements.

Purchased product may be subject to receiving inspection activities as defined in the associated Procedures, Work Instructions and/or Control Plans.

Where Jaco Manufacturing Co. or its customer intends to perform verification at the supplier's premises, the purchasing documents will state the intended verification arrangements and method of product release.

7.4.3.1 Incoming product conformity to requirements

In order to assure the quality of purchased product, Jaco Manufacturing Co. will perform one of the following incoming inspection activities:

- Receipt of and evaluation of statistical data (verification of supplier quality/test data against Jaco Manufacturing Co. Standards)
- Receiving inspection and/or testing performed on a sampling basis
- Evaluation of Certificates of Analysis against defined and documented Specifications
- Material/Part evaluation by a designated Laboratory to confirm data provided by the supplier and ensure conformity to product requirements

Inspection methods other than the aforementioned must be agreed and approved by the customer

7.4.3.2 Supplier Monitoring

Jaco Manufacturing Co. monitors the ongoing performance of its suppliers as a means of ensuring that the suppliers are consistently providing products and services that meet specified purchase order requirements.

The methods and criteria for monitoring include, but may not be limited to:

- Delivered product conformity to requirements
- Customer complaints and/or disruptions including field returns from the end user
- Delivery schedule performance (including incidents of premium freight)
- Special status customer notification related to quality or delivery issues.

Jaco Manufacturing Co. will promote supplier monitoring of the performance of their manufacturing processes (QSP # 11).

7.5 Production Provisions

At the present time, 'Service Provisions' are not applicable to the Jaco Manufacturing Co. Scope of Operations and therefore have not been identified in this section of the Quality System Manual.

In the event that Servicing Provisions become a necessary requirement of the Quality Management System, this section of the Quality System Manual will be updated and related procedures developed.

7.5.1 Control of Production Provision

Jaco Manufacturing Co. has planned and carries out production provisions under controlled conditions. Controlled conditions are identified in the System Process Model Diagram (QUA-0002) and the Injection Molding Flow Chart (QUA-2011), Production Provisions will include: Reference (QSP # 12) Control of Production:

a) Production Documents that describe the characteristics of the product, such as:

- Work Orders and Work Instructions (which contain, at minimum, information relative to first piece inspection requirements, information relative to ongoing inspection requirements and frequencies.
- Control Plans, and
- other Quality Management System documents

b) the availability of work instructions (as necessary),

c) the use of suitable production equipment capable of producing products to defined specifications. This is accomplished through, but not limited to the following:

- Existing Equipment is managed via (QSP # 13), Preventive Maintenance Procedure
- New Equipment will be qualified in accordance with the Quality Planning activities (QSP # 3) and the Production Part Approval Processes.
- Equipment qualifications are supported through research, trials, capability studies, and discussions held during various meetings.

d) the availability and use of monitoring and measuring equipment (QSP # 18),

e) the implementation of monitoring and measurement through inspection and testing as defined in the Inspection, Measuring and Test Equipment, (QSP # 18) and related Quality Inspection Sheets, Work Instructions and Control Plans
f) The implementation of product release and delivery activities will be stated on production documentation and associated reports

7.5.1.1 Control Plan

As required by the Customer, Control Plans will be developed at the system, sub-system and component levels for the product supplied.

Production Control Plans will be developed for Manufacturing Operations and take into consideration all Manufacturing Process FMEA outputs.

Pre-Launch Control Plans will be developed per Customer Request.

Control Plans will include:

- A list of controls used for the manufacturing process
- Methods for monitoring controls exercised over special characteristics defined by both the customer and Jaco Manufacturing Co.
- Customer required information (if any)
- The initiation of reaction plans when the process becomes unstable or not statistically capable.

Control Plans will be reviewed and updated when any change occurs affecting product, manufacturing process, measurement, logistics, supply sources, or FMEA.

7.5.1.2 Work Instructions

Jaco Manufacturing Co. has prepared work instructions for all employees having responsibility for the operation of processes that impact conformity to product requirements.

Work Instructions are accessible at the designated Work Stations.

Work Instructions are derived from the production realization processes (i.e. FMEAs, Control Plans, and Quality Planning Activities).

7.5.1.3 Verification of job set-ups

Work Instructions, or other associated documents, are available to address Job Set-ups

Job Set-ups will be verified…

- at the start of each job via First Piece Dimensional Inspections,
- in the event the tool is damaged, repaired and/or replaced during a current job run

With respect to material change overs, the nature of the process is to have a continual flow of acceptable material. Materials will be added throughout the job run to keep material levels and temperatures consistent. Therefore, the need for any additional job set up verification is not required.

Statistical methods of verification may be utilized, where applicable.

7.5.1.4 Preventive and predictive maintenance

Jaco Manufacturing Co. has identified Key Process Equipment and provides resources for machine/equipment maintenance (QSP # 13).

An effective planned total preventive maintenance system has been established and includes:

- Planned maintenance activities
- Packaging and preservation of equipment, tooling and gauging (as necessary)
- Availability of replacement parts for key manufacturing equipment
- Documenting, evaluating and improving upon maintenance objectives

Predictive Maintenance methods have been established to continually improve the effectiveness and the efficiency of the production equipment.

Predictive Maintenance activities may include, but are not limited to:

- the analysis of previously Scheduled and Un-scheduled Maintenance activities,
- Infrared Analysis
- Vibration Analysis
- Oil Analysis

Outside Services providing the Predictive Maintenance activities are maintained via the Approved Supplier List (see QSP # 11).

7.5.1.5 Management of production tooling

Jaco Manufacturing Co. has developed and maintains a Tooling Management Program for dies and any identified perishable tooling)

The Tooling Management Program (QSP # 14) includes:

- Maintenance and repair facilities and personnel
- Storage and recovery
- Set-up instructions
- Tool-change programs for any perishable tooling

Tool Changes are subjective and cannot be predetermined based on the material variation of the tools. With this, Quality Personnel and Operators perform periodic product inspections in order to confirm tool capability and quality of product. As necessary, tools are removed, evaluated and either repaired or replaced.

At the completion of each job, the die is removed, and provided to the Tool Room with a mold maintenance request form for any repair, as required.

Tool Room personnel will perform the necessary repairs and document their actions on the mold maintenance request. Once completed, the Die is considered available for use for the next production order.

- Tool / Die modification documentation including engineering change level
- Tool identification including status (i.e. die numbers, service status identifier)

If any of the aforementioned activities are to be outsourced, the outsourced activities and suppliers will be controlled and monitored via the Purchasing Procedure (QSP # 11).

7.5.1.6 Production scheduling

Production will be scheduled in order to meet customer requirements.

The majority of production scheduling is order driven, while some parts are built to stock based on customer order history.

All production scheduling is supported by an information system that permits access to production information at key stages of the process.

Information relative to the key stages of each product in production is attainable from the Production Control Database.

7.5.1.7 Feedback of information from service

Since Service activities are not included in the Scope of Operations, this particular requirement has been determined to be 'Not Applicable' at this time.

In the event servicing becomes a necessary requirement, actions will be taken to address the requirements contained within this section of the ISO/TS 16949 Standard.

Information relative to all customer complaints and concerns will be addressed in accordance with (QSP # 9) Customer Complaints.

7.5.1.8 Service agreement with customer

As previously stated, Jaco Manufacturing Co. Scope of Business Operations does not offer servicing beyond the manufacture and delivery of completed product.

With this, the requirements of this section of the ISO/TS 16949 Standard are considered not applicable.

7.5.2 Validation of Processes for Production Provision (Special Processes)

Jaco Manufacturing Co. will validate all production processes where resulting output cannot be verified through subsequent monitoring or measurement (QSP # 18) and, as a consequence product deficiencies will only be apparent after the product is in use or has been delivered.

The current manufacturing processes transform raw materials such as Raw Plastic into molded finished products through a variety of injection molding, assembly and finishing stages.

Even though the output of each stage of the injection molding, assembly and finishing processes can be verified through normal inspection and testing techniques (i.e. visual and dimensional), Jaco Manufacturing Co. has identified Injection Molding operations

as a ‘special process’ since destructive and/or specialized verifications may be required to confirm the integrity of the product.

To ensure the suitability of existing ‘special processes’ as well as the introduction of new processes, the following validation activities and documentation will be completed for each of the identified special processes:

a) defined criteria for the review and approval of the processes,

   This is initially determined during Quality Planning activities and communicated to manufacturing personnel via the Quality Instruction Sheet, Control Plans, or other production documentation.

b) approval of equipment and personnel via Quality Planning, Calibration, and Training

   The requirements for any qualifications of process operations, including associated equipment and personnel will be initially determined through (QSP # 3) Quality Planning and (QSP # 5) Training.

c) Use of specific methods and procedures as defined within the documented QMS and external documents defining common industry practice

d) Records of the equipment and/or employee qualifications and test results will be maintained in accordance with the Control of Records Procedure (QSP # 2).

e) Re-validation of equipment and employees will be handled though ongoing testing and inspection of the product, as well as ongoing employee training and re-qualifications of personnel.

Validation activities will ultimately demonstrate the ability of these processes to achieve planned results.

Where applicable, process changes which affect the characteristics of a product will be identified, recorded, evaluated, reviewed, authorized and controlled to ensure that the changes made benefit Jaco Manufacturing Co. while satisfying the needs and expectations of the relevant customer(s).

After changes have been made to a process, and to verify that the change made had the desired effect, both the process and any resulting product shall be re-validated.

7.5.2.1 Validation of processes for production provision- Supplemental

Production process re-validation activities will be accomplished through the annual review of the Goals and Objectives related to individual process measures (i.e. scrap, up-time, returns).

As required by the Customer, Annual Layouts of a representative sample of products will also validate production processes.

7.5.3 Identification and Traceability

Jaco Manufacturing Co. has identified all products by suitable means (i.e. tags, markings, labels, supplier/customer markings) throughout the product realization process. Reference (QSP # 15) Identification & Traceability.

Jaco Manufacturing Co. identifies the product status with respect to monitoring and measurement requirements via labels, tags, inspection stamps, and/or associated quality records.

Products whose identification and inspection status cannot be verified will be handled in accordance with the Control of Nonconforming Product (QSP # 23).
When traceability is a specified customer and/or industry requirement, Jaco Manufacturing Co. will control the unique identification of the product and maintain records (i.e. traceability via the Lot Numbers documented on the labels for each product).

7.5.3.1 Identification and traceability - supplemental

All products will be properly identified to support identification and traceability.

7.5.4 Customer Property

Jaco Manufacturing Co. may accept customer owned raw materials, tooling, inspection fixtures, and/or returnable containers for processing to complete any customer contract and product realization requirements (re: QSP # 16). Customer owned property may also include intellectual data and personal data.

Specific requirements for communicating customer property issues will be established at the Quotation Phase and conveyed to the Quality and Manufacturing Departments, as applicable.

While under Jaco Manufacturing Co. control, the customer property will be identified, verified, protected and safeguarded as if it were actually owned by Jaco Manufacturing Co.

If any customer property is lost, damaged or otherwise found to be unsuitable for use,

- the situation will be reported to the customer for disposition,
- items found to be nonconforming shall be tagged and recorded as defined within procedure (QSP # 23), and
- records of the communication and any resulting dispositions will be maintained in accordance with the Control of Records Procedure (QSP # 2).

7.5.4.1 Customer owned tooling

Customer owned packaging, dies, fixtures and/or equipment provided by the customer will be permanently marked so that the ownership of each item is visible and apparent.

7.5.5 Preservation of Product

Jaco Manufacturing Co. will preserve the product during internal processing and delivery to intended destination in order to maintain conformity to requirements.

As applicable, preservation will include identification, handling, packaging, storage and protection. Preservation will also be applied to constituent parts of the product. Reference (QSP # 17) Preservation of Product.

Unless specified by contract, Jaco Manufacturing Co. policy is that the protection of the quality of the product ceases once the product is loaded onto the delivery vehicle and signed for by the transportation service (e.g. FOB Jaco Manufacturing Co. Dock).

If required by customer, the responsibility for the quality of product may be extended to include delivery to destination (e.g. FOB Customer Dock).

As business practices dictate, Jaco Manufacturing Co. will assist in the investigation of any customer claims resulting from possible subcontractor transit damage.

7.5.5.1 Storage and inventory

In order to detect deterioration, the condition of product in stock will be assessed during Annual Inventory.

During the Annual Inventory, products/materials that are subject to deterioration and/or shelf life requirements will be assessed for current condition.

In the event, products/materials are found to be beyond shelf life requirements or have obvious signs of deterioration, the condition will be reported via the Control of Nonconforming Product (QSP # 23).

An Inventory Management System has been established to:

- optimize inventory turns over time
- assure stock rotation (i.e. FIFO)

Any obsolete products will be controlled via the associated Control of Nonconforming Product (QSP # 23).

7.6 Control of Monitoring and Measuring Equipment

Jaco Manufacturing Co. has determined the monitoring methods and measurement requirements for production realization activities and has identified the monitoring and measuring equipment needed to provide evidence of product conformity to defined customer and/or industry requirements.

Jaco Manufacturing Co. has established processes to ensure that monitoring and measurement activities can be carried out in a manner that is consistent with the monitoring and measurement requirements.

In order to validate monitoring and measurement results, measuring equipment shall:

a) be calibrated or verified, or both, at specified intervals, or prior to use, against measuring standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded;
b) be adjusted or re-adjusted as necessary;
c) have identification in order to determine it's calibration status
d) be safeguarded from adjustments that would invalidate the measurement result;
e) be protected from damage and deterioration during handling, maintenance and storage.

In addition, Jaco Manufacturing Co. will assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. Appropriate actions will be taken on the equipment and any product affected.

At the present time, Jaco Manufacturing Co. does not utilize any monitoring and measurement software to determined product acceptance.

In the event, monitoring and measurement software is introduced, specific instructions will be developed to control the monitoring and measuring software to prove its ability to provide suitable inspection results.

Records of the results of calibration and verification will be maintained in accordance with the Control of Records Procedure (QSP # 2).

Quality System Procedure (QSP # 18) has been developed to address the calibration requirements.

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.

Measurement system analysis, which may include but is not limited to bias, linearity, stability, repeatability and reproducibility studies, are conducted on all measurement systems referenced in the Control Plans.

The analytical methods and acceptance criteria used will conform to those specified by customer. Other methods may be utilized but only after obtaining approval from the customer.

7.6.2 Calibration / Verification records

Calibration and/or verification records will provide evidence of conformity of product to established requirements. Records will include the calibration of employee owned and customer owned equipment, as applicable.

The Calibration and/or verification records will include:

- Equipment identification
- Reference to the master calibration device
- Revisions following product changes
- As received 'Out of Specification' readings
- Assessment of the impact of out of specification conditions
- Statements of conformity after calibration
- Notification to customer in the event suspect product or material that may have been released

7.6.3 Laboratory requirements

7.6.3.1 Internal Laboratory

The Jaco Manufacturing Co., facility operates a Testing, Dimensional, and Calibration Laboratory.

Jaco's Laboratory has a defined Laboratory Scope, which includes its capabilities to perform inspection, testing and calibration activities. The Laboratory Scopes are defined in procedure (QSP # 19).

The Laboratories include technical requirements specific to:

- Procedures appropriate to the purpose of the related task
- Competency and Qualifications of Laboratory personnel

- Calibration of Equipment and Testing of the Product
- Capabilities to perform specified activities correctly (as defined in the laboratory scope QSP # 19) including traceability to relevant process standards
- A review of Calibration and Testing records

7.6.3.2 External Laboratory

External, Commercial, or Independent Laboratory facilities that may be utilized for inspection, testing or calibration activities beyond Jaco Manufacturing Co. Internal Laboratory capabilities will have defined scopes.

Jaco Manufacturing Co. will maintain copies of the External Laboratory Scope Statements along with the following information:

- Evidence of their customer acceptance, or
- Evidence of accreditation to ISO/IEC 17025 or national equivalent (i.e. A2LA)

8.0 Measurement, Analysis and Improvement

8.1 General

Jaco Manufacturing Co. has planned and implemented the monitoring, measurement, analysis, and improvement processes needed

a) to demonstrate conformity to product requirements through the evaluation of product inspection and test data, and statistical techniques associated with product characteristics (i.e. Process Picture Maps, Control Plans, and Work Instructions).
b) to ensure conformity of the quality management system through Internal Audit activities, Management Review Meetings and its associated agenda items (QSP # 4 and QSP # 21)
c) to continually improve the effectiveness of the quality management system during the Management Review Meetings, associated opportunities for improvement, and any resulting action items

In order to obtain this information, Top Management will determine the applicable collection methods, including statistical techniques and the extent of their use during Management Review Meetings.

8.1.1 Identification of statistical tools

When required for additional control, problem resolution or problem identification, Statistical Tools will be identified, implemented, and maintained as determined by the Quality Manager (Management Rep).

Statistical Techniques may either be applied to product realization or administrative elements of the Quality Management System.

The selection of the most appropriate statistical tool for production related activities will be determined during Quality Planning activities and will be identified in the associated Control Plan and/or Work Instruction (i.e. Control Charts, X-Bar & R).

Administrative statistical techniques will be identified during Management Review Meetings (i.e. Run Charts, Histograms, Bar Charts and Pie Charts)

8.1.2 Knowledge of basic statistical concepts

Jaco Manufacturing Co. ensures that basic statistical concepts (such as variation, control, stability, process capability, and over-adjustment) are understood and utilized throughout the organization.

Production employees having the responsibility for the control and maintenance of particular statistical techniques will be provided the necessary training.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

As one of the measurements of the performance of the quality management system, Customer Satisfaction will be analyzed via data from:

- Customer Report Cards,
- direct contact / interviews / communication with the customer

All data will be collected, compiled and trends identified with respect to customer satisfaction. The information will be reviewed during Management Review Meetings at which time potential actions (corrective action or continual improvements) may be initiated

The methods for obtaining and using customer satisfaction information are more clearly defined in (QSP # 20).

8.2.1.1 Customer Satisfaction - supplemental

Customer Satisfaction may also be monitored through the continual evaluation of performance data related to the production realization process.

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 (including incidents of premium freight)
- Customer notifications related to quality or delivery issues

8.2.2 Internal Audit

Jaco Manufacturing Co. has established and maintains a comprehensive internal audit program.

This program has been implemented to ensure that regular, systematic and constructive quality evaluations are performed to ensure the on-going effective operation of the quality management system.

Documented Procedure (QSP # 21) has been established to control the planning, implementing, and conduct of internal audits.

Internal audits are performed in order to verify whether quality activities and related results comply with planned arrangements and to determine the effectiveness of the quality management system.

At a minimum, each key process will be audited one time per year. During the auditing of the key processes, consideration will be given to all requirements of the ISO 9001 and ISO/TS 16949 Standards, as applicable.

The Internal Audit Schedule will be based on the status and importance of the activity/process to be audited. The audit frequency will be increased or decreased based on performance data, management directives, and internal/external nonconformances, including the results of previous internal audits.

Internal audits will be carried out by personnel who are independent of those having direct responsibility for the activity/process being audited. The Quality Manager (Management Rep) will select independent auditors to perform objective and impartial audits, and ensure that Internal Auditors do not audit their own work.

The results of the internal audits will be recorded and brought to the attention of the personnel having responsibility in the area audited.

The management personnel responsible for the area being audited will ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate any identified nonconformities and their causes.

Follow-up activities will be performed and include the verification of the corrective actions taken and the reporting of verification results (see QSP # 25) Corrective Action.

8.2.2.1 Quality Management System Audit

As previously stated, all applicable requirements of the ISO & ISO/TS Standards will be addressed throughout the performance of the key process auditing.

8.2.2.2 Manufacturing Process Audit

As indicated on the Process-Part Audit Master Schedule (QUA-1021), each manufacturing process will be subject to being audited during the normal course of systems audits.

This auditing will assure that specific manufacturing activities are being complied with.

8.2.2.3 Product Audit (Dock Audits)

Jaco Manufacturing Co. conducts audits of the packaged final product to verify conformance to all specified customer requirements.

This may include but is not limited to a verification of product dimensions, functionality, packaging, and labeling.

Frequencies in which these audits are performed are based on either Customer Requirements or developed at the discretion of the Top Management.

The Dock Audit Requirements and Frequencies are captured on a Dock Audit Requirements Log (QUA-1039) and may also be referenced on associated copies of the Control Plans, and Quality Inspection Sheets.

Records of the Product / Dock Audits will be maintained in accordance with the Quality Records Procedure (QSP # 2).

8.2.2.4 Internal Audit Plans

The Internal Audit Plan (QUA-1020) will ensure that all key processes, related activities, and shifts are subject to the Internal Audit activities.

The Internal Audit Plan will be developed annually and updated as the audits are performed to ensure that additional emphasis is placed on those processes with less than satisfactory results.

The audit frequency will be increased as a result of any internal/external nonconformities or customer complaints.

8.2.2.5 Internal Auditor Qualification

Internal Auditors will be qualified to perform audits based on an auditor training and qualification process, which may include:

- The review of relevant standards (i.e. IS0 9001, ISO/TS 16949)
- A review of the Jaco Manufacturing Co. documented quality management system
- The performance of an internal audit under the supervision of a qualified auditor
- Outside consultant training conducted on Jaco's premises

Auditors who have attended an Internal Auditor Course will only be required to become familiar with the Jaco Manufacturing Co. documented Quality Management System and associated processes (see the System Process Model Diagram- QUA-0002).

Records of Qualified Auditors are maintained in accordance with the Control of Records Procedure (QSP # 2).

8.2.3 Monitoring and Measurement of Processes

Jaco Manufacturing Co. has applied suitable methods for monitoring and, where applicable, measurement of the quality management system processes.

These methods shall demonstrate the ability of the processes to achieve planned results.

Methods of monitoring the Key Processes of the Jaco Manufacturing Co. Quality Management System include:

- Internal Audits,
- Management Review Meetings,
- the review of Corrective, Preventive and Continual Improvement Projects, and
- the review of the Goals and Objectives Matrix (QUA-1025).

When planned results are not achieved, actions may be taken to ensure conformity of the process.

8.2.3.1 Monitoring and measurement of manufacturing processes, reference (QSP # 22).

For all new manufacturing processes introduced to the quality management system, process studies will be performed to ensure and verify process capabilities and provide additional input for process control (see

Manufacturing Process Design and Development discussed in section 7.3 of this Quality System Manual and the Quality Planning Procedure (QSP # 3).

The results of the process studies will be documented on a Quality Planning Checklist and reference or contain information which supports required production activities, measurements, inspections, and maintenance instructions.

The documents may include but are not limited to objectives for manufacturing process capability, reliability, maintenance, availability, and acceptance criteria.

Jaco Manufacturing Co. will maintain process capability or performance as specified by our customer's part approval process requirements.

Jaco Manufacturing Co. ensures that the associated Control Plans, Work Instructions, and process flow diagrams are implemented and include:

- Measurement techniques
- Sampling plans
- Acceptance criteria
- Reaction plans when acceptance criteria are not met

Significant process events (such as machine repair) will be recorded on the associated quality documents.

Jaco Manufacturing Co. initiates reaction plans from the control plan for characteristics that are either not statistically capable or are unstable. These reaction plans will include the containment of product and 100% inspection.

A corrective action plan will be completed indicating specific timing and assigned responsibilities to assure that the process becomes stable and capable.

When required contractually, the corrective action plan will be reviewed with and approved by the customer.

Records will be maintained of the effective dates of all process changes.

8.2.4 Monitoring and Measurement of Product

Jaco Manufacturing Co. will monitor and measure the characteristics of the product to verify that product requirements have been met.

Monitoring and Measuring activities will be carried out at appropriate stages of the product realization process in accordance with the planned arrangements defined in the Quality Inspection Sheets, Control Plans, Work Instructions and/or other Process Control Documents.

Evidence of conformity with the acceptance criteria as well as the personnel authorizing the product release for delivery to the customer will be maintained as quality records.

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

8.2.4.1 Dimensional (Layout) Inspection and Functional Testing

When required by the customer, Dimensional (Layout) Inspection and Functional Testing to applicable customer engineering material and performance standards will be performed for each product as specified on the control plan.

Results of the Dimensional (Layout) and Functional Testing will be maintained and be available to the customer upon request.

8.2.4.2 Appearance Items

As required by the Customer, products designated as 'Appearance Items' will have:

- appropriate resources including lighting for evaluation
- master limit samples
- maintenance and control of masters and the evaluation equipment
- verification that personnel making appearance evaluations are competent and qualified to do so

8.3 Control of Nonconforming Product

All Jaco Manufacturing Co. personnel have the responsibility to ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery.

The controls and related responsibilities and authorities for dealing with nonconforming product are defined in Procedure – Control of Nonconforming Product (QSP # 23).

Jaco Manufacturing Co. has defined potential dispositions of nonconforming product as:

- Reject (Scrap)
- Rework to meet specified requirements
- Use as is (under Customer Authorized Deviation)

Records of the nature of nonconformities and any subsequent actions taken, including deviations obtained, will be maintained in accordance with the Control of Records Procedure (QSP # 2).

When nonconforming product is re-worked it will be subject to re-verification (inspection and test) to demonstrate conformity to the requirements prior to release.

When nonconforming product is detected after delivery or use has started, Jaco Manufacturing Co. will take actions appropriate to the effects, or potential effects, of the nonconformity via the Corrective Action Procedure (QSP # 25).

8.3.1 Control of nonconforming product - supplemental

All products with an un-identified or suspect status will be classified and handled as if it were nonconforming material.

8.3.2 Control of reworked product

Instructions for re-work requirements are defined on the Nonconformance Report Tag.

Re-inspection activities will be documented on a Nonconformance Report Tag.

8.3.3 Customer Information

Customers will be informed within 24 hours of identification that nonconforming product has accidentally been shipped.

A record of this communication by the Quality Manager (Management Rep) will be maintained via general correspondence in accordance with the Control of Records Procedure (QSP # 2).

8.3.4 Customer waiver

Customer deviations will be obtained prior to further processing whenever the product or manufacturing process is found to be different from that which is currently approved.

Jaco Manufacturing Co. maintains records of the expiration date and quantity authorized for all product deviations.

Once the authorized deviation expires, Jaco Manufacturing Co. will ensure compliance with the original or superseding specifications and requirements.

All product shipped under an authorized deviation will be identified to indicate the product deviation on each shipping container.

The process of obtaining authorized deviations may also be applied to purchase products, which do not conform to specified requirements. Jaco Manufacturing Co. will agree with any request from it's suppliers before submission to the customer.

8.4 Analysis of Data

The Quality Manager (Management Rep)and representatives from Top Management have the defined responsibility for determining, collecting and analyzing data to demonstrate the suitability and effectiveness of the quality management system.

Based on the data evaluated, continual improvement activities may be initiated to enhance the effectiveness of the quality management system.

The overall analysis of this data will provide Top Management with information relating to:

a) Customer Satisfaction - data evaluated to support Customer Satisfaction

b) Conformity to product requirements through inspection and test data

Jaco Manufacturing Co. ensures compliance with customer product requirements through the performance of receiving, in-process and final inspection activities.

In addition, a variety of statistical techniques are utilized to confirm the suitability or our processes and product conformity.

c) Characteristics and trends of processes and products including opportunities for preventive action.

d) Suppliers

8.4.1 Analysis and use of data

Trends in Quality and Operational performance are compared with progress towards objectives (as detailed on the Goals and Objectives Matrix) and lead to action to support:

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

Quality and Operational performance data may include but is not limited to:

- Productivity
- Cost of Poor Quality
- Process Efficiency and Effectiveness
- Production Output
- Quality Performance
- Equipment Utilization
- Customer Complaints

Data collected and analyzed may be compared with those of competitors and/or appropriate benchmarks.

8.5 Improvement

8.5.1 Continual Improvement

The Top Management Team, will implement actions to continually improve the effectiveness of the quality management system.

Continual Improvement may be viewed as opportunities for improvement based on the review of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management reviews.

8.5.1.1 Continual Improvement of the organization

Jaco Manufacturing Co. has implemented and maintains a documented procedure (QSP # 24) to control the application and handling of Continual Improvement Projects through completion.

8.5.1.2 Manufacturing process improvement

Manufacturing process improvements continually focus on the control and the reduction of variation in product characteristics and manufacturing process parameters.

8.5.2 Corrective Action

Corrective Actions are initiated to address ‘known’ process and/or product nonconformances.

Jaco Manufacturing Co. will initiate corrective actions to eliminate the causes of these nonconformities in order to prevent their recurrence.

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

A documented procedure (QSP # 25) has been established to define requirements for

a) reviewing nonconformities (including customer complaints)
b) determining the causes of nonconformities (root cause investigation),

c) evaluating the need for action to ensure that nonconformities do not recur (short-term or interim action),
d) determining and implementing action needed (deciding upon the long-term actions),
e) recording the results/implementation of action(s) taken, and
f) verifying the effectiveness of the corrective action(s) taken.

8.5.2.1 Problem Solving

Disciplined problem solving methods will be applied to assist in identifying the root cause of the nonconformance and assist in determining the corrective actions to be taken.

Problem solving methods may include but are not limited to:

- 8-D
- Brainstorming
- Root Cause Analysis
- 5 Why's
- Evaluation of similar corrective actions
- Fishbone Diagrams

In the event that the customer prescribes their own problem solving method, Jaco Manufacturing Co. will adhere to the customers prescribed methodology.

8.5.2.2 Error-proofing

Error proofing is the result of systematic evaluations of problems with actions taken to re-design the system or the process to assure that the possibility of nonconformances does not recur.

Error proofing methodology is always taken into consideration as part of the Corrective Action process.

8.5.2.3 Corrective Action Impact

Corrective Actions taken will be applied to other similar processes and products, as applicable, in order to eliminate the recurrence of similar nonconformities.

8.5.2.4 Rejected Product Test / Analysis

Jaco Manufacturing Co. will analyze rejected parts returned from the customer's manufacturing plants, engineering facilities, and/or dealerships.

Jaco Manufacturing Co. will minimize the cycle time of this process.

Records of the product test /analysis will be made available to the customer upon request and maintained in accordance with the Control of Records Procedure (QSP # 2).

Based on the results of the product test /analysis, corrective actions may be initiated to prevent recurrence of the nonconforming situation.

8.5.3 Preventive Action

Preventive Actions are initiated based on trends in data evaluated that may indicate the 'potential' for nonconformities in the process or with the product.

Top Management will determine the actions to be taken to eliminate the causes of these 'potential' nonconformities in order to prevent their occurrence.

Preventive actions will be appropriate to the effects of the potential nonconformities.

A documented procedure (QSP # 26) has been established to define the requirements for:

a) determining the potential nonconformities and their causes,
b) evaluating the need for action to prevent occurrence of nonconformities (project approval),
c) determining and implementing action(s) needed (steps to be taken),
d) recording the results of action taken (implementation), and
e) Reviewing preventive action taken (verification of the effectiveness in achieving the preventive action goal).

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