Tri-Gon Precision, Inc.

820 Sahwatch Street
Colorado Springs, CO, 80903-4104

QUALITY MANUAL

ISO 9001:2008

Change Record

Rev	Date	Responsible Person	Description of Change
1.0	**1/28/2013**	**Sandra Gonzales**	**Quality Manual Approved**

QUALITY MANUAL INDEX

SECTION / TITLE
CLAUSE

1. General

The purpose of this quality manual is to describe the policies and company-wide control structure of the quality management system (QMS) used to achieve the corporate quality policy and objectives at Tri-Gon Precision, Inc.

The true measure of quality at Tri-Gon Precision, Inc. is customer satisfaction. Because customer satisfaction and the quality of our products are and will continue to be the keys to our competitiveness for years to come, it is increasingly vital for us at Tri-Gon Precision, Inc. to understand and use our quality management system to do the best job, the first time, every time. To ensure that our quality management system will continue to provide a solid foundation for success, it is essential that we continually improve our quality management system and related processes.

Scope of Registration

The company's scope of registration for ISO 9001:2008 is:

With great pride and a commitment to excellence our team at Tri-Gon Precision, Inc. is dedicated to manufacturing intricate quality components that exceed our customer's expectations. It is through this commitment that we consistently deliver a 100% quality product to our customer per purchase order requirements. Meanwhile, providing added-value services to each and every customer.

Exclusion: 7.3 Design and Development. As such the exclusion does not affect Tri-Gon Precision, Inc.'s ability, or responsibility, to provide product that meets customer and applicable regulatory requirements.

Not applicable: 7.5.2 Validation of Processes for Production and Service Provision

The quality management system described in this Quality Manual addresses the requirements of the ISO Quality Standards as defined in ISO 9001:2008.

All references made to ISO 9001 in this manual refer to the 2008 version of the Standard.

3. Terms and Definitions

The terms and definitions provided below are frequently used to describe aspects of the quality management system at Tri-Gon Precision, Inc.

Customer: Any internal or external organization or person that receives a product, information or service from Tri-Gon Precision, Inc.

Customer Satisfaction: is defined as "customer's perception of the degree to which the customer's requirements have been fulfilled."

Nonconformity: Situation where a requirement was not fulfilled.

Organization: Refers to Tri-Gon Precision, Inc. throughout this Quality Manual.

Process: Set of interrelated or interacting activities, which transform inputs (information, materials, etc.) into outputs (goods or service).

Product: The output (results-goods or service) generated by a process.

Quality: Degree to which a set of inherent characteristics fulfills requirements.

Supplier: Any organization or person that provides a product or service to Tri-Gon Precision, Inc.

Standard: The ISO 9001:2008 version of the International Standard.

Verification: confirmation, through the provision of objective evidence, that specified requirements have been fulfilled. (Note: the term "verified" is used to designate the corresponding status. Confirmation can comprise activities such as: performing alternative calculations, comparing a new specification with a similar proven specification, undertaking tests and demonstrations, and reviewing documents prior to issue.)

Validation: confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled. (Note: the term "validated" is used to designate the corresponding status. The use conditions for validation can be real or simulated.)

Additional terms and definitions provided in ISO 9000:2008 also apply throughout this quality manual.

4. Quality Management System

4.1. General Requirements

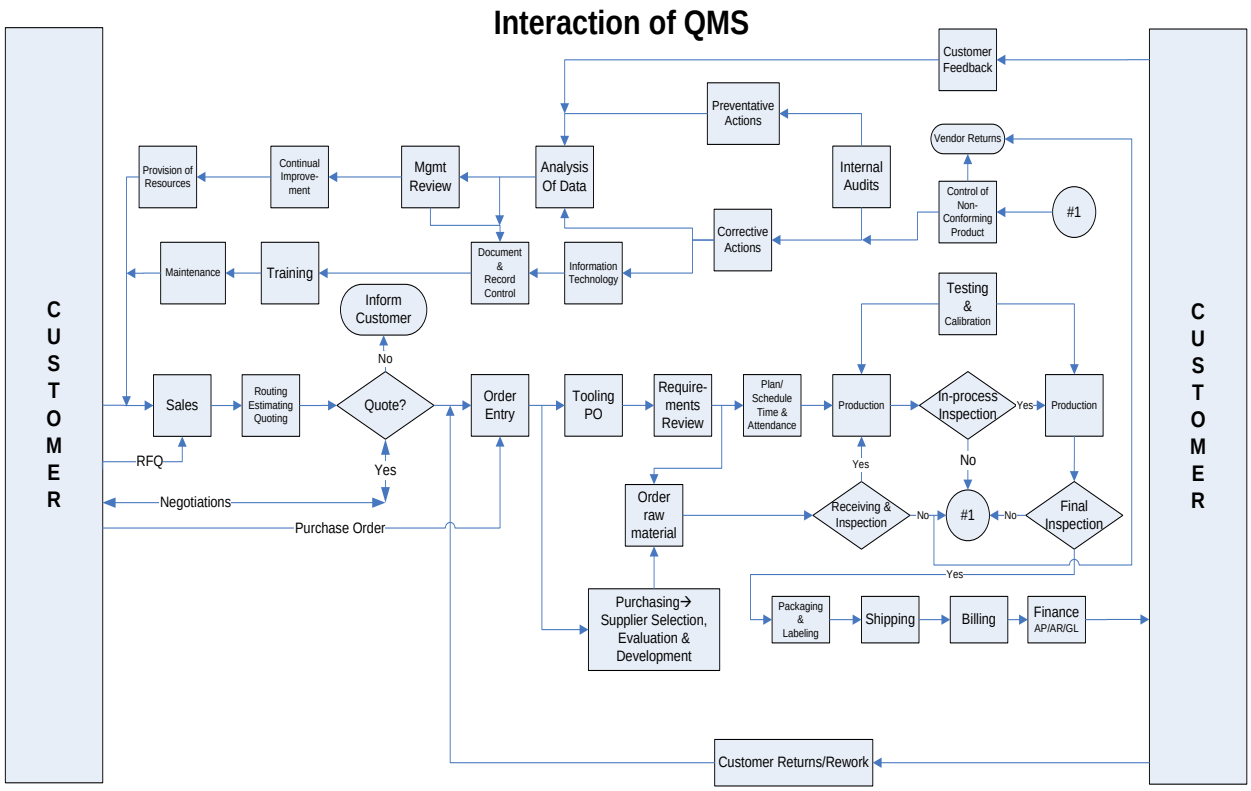
Tri-Gon Precision, Inc.'s quality management system has been established, documented, implemented and maintained as a way to continually improve the performance of our organization. The quality manual describes our quality policy and general company-wide structure and procedures for maintaining the quality management system that meets the Standard's requirements.

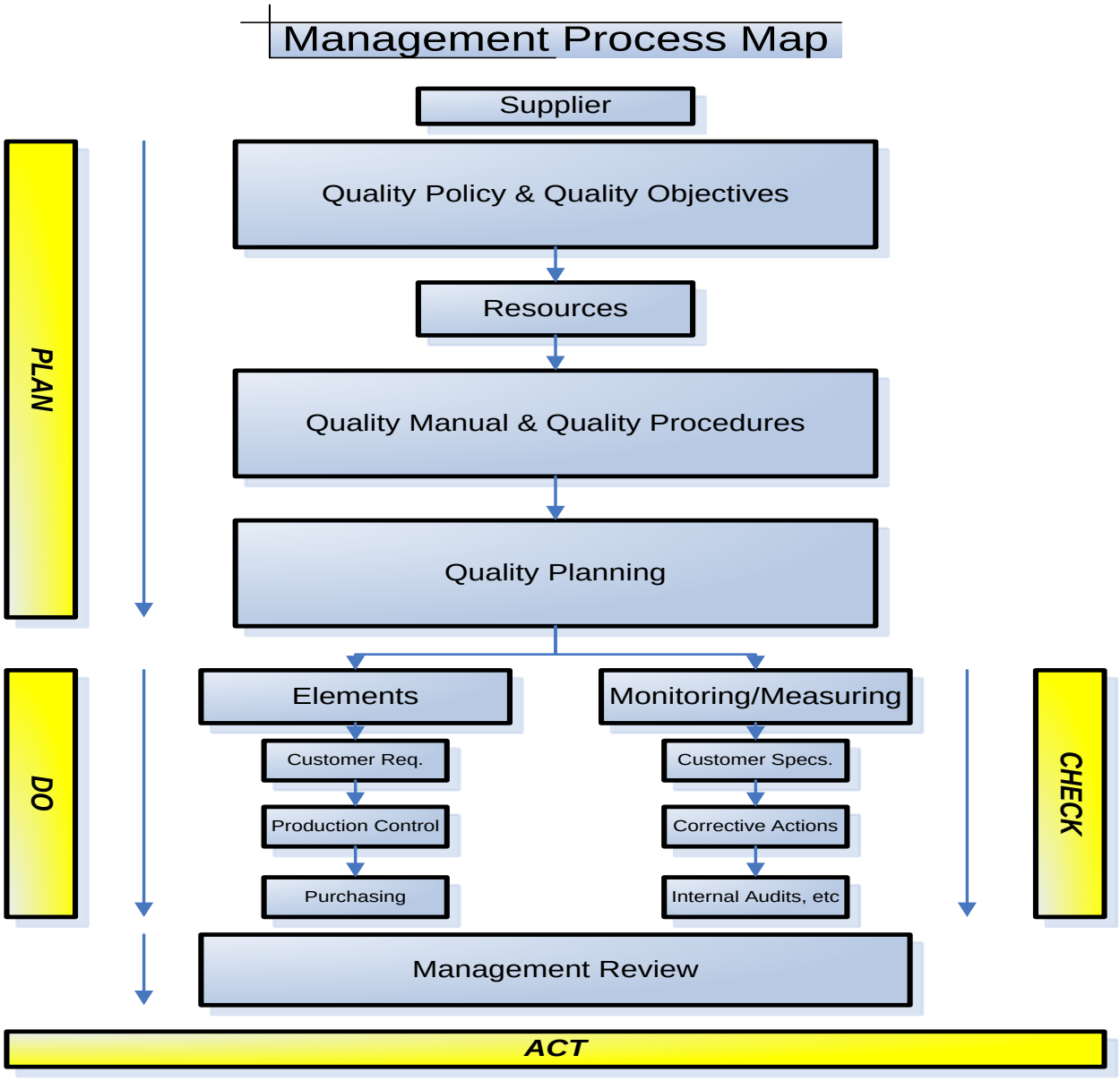
Tri-Gon Precision, Inc.'s quality management system is based upon a "process approach" to quality management, demonstrated by our commitment to:

- Identify the processes needed for the effective operation of our quality management system and their application throughout the organization.
- Determine the sequence and interaction of our quality management system processes.
- Determine the criteria and methods needed to ensure the effective operation and control of these processes.
- Ensure the availability of resources and information necessary to support the operation and monitoring of these processes.
- Implement action necessary to achieve planned results and continual improvement.

Tri-Gon Precision, Inc. manages these processes in accordance with the requirements of ISO 9001. QMSM-1001 Process Interaction provides a global view of the process linkages and interactions described in our Quality Management System. This document, applied together with QMSM-1002 Management, shows the management process of our quality management system processes. These maps are shown below:

Figure 4.1A


Interaction of QMS
CUSTOMER
CUSTOMER
Customer Feedback
Preventative Actions
Vendor Returns
Provision of Resources
Continual Improve-ment
Mgmt Review
Analysis Of Data
Internal Audits
Control of Non-Conforming Product
#1
Corrective Actions
Maintenance
Training
Document & Record Control
Information Technology
Testing & Calibration
Inform Customer
No
Sales
Routing Estimating Quoting
Quote?
Order Entry
Tooling PO
Require-ments Review
Plan/ Schedule Time & Attendance
Production
In-process Inspection
Yes
Production
RFQ
Yes
No
Negotiations
Purchase Order
Order raw material
Receiving & Inspection
No
#1
No
Final Inspection
Yes
Purchasing→ Supplier Selection, Evaluation & Development
Packaging & Labeling
Shipping
Billing
Finance AP/AR/GL
Customer Returns/Rework


Management Process Map
Supplier
Quality Policy & Quality Objectives
Resources
Quality Manual & Quality Procedures
Quality Planning
PLAN
DO
CHECK
Elements
Monitoring/Measuring
Customer Req.
Production Control
Purchasing
Customer Specs.
Corrective Actions
Internal Audits, etc
Management Review
ACT

Tri-Gon Precision, Inc. maintains control over all outsourced processes that affect conformity with product requirements and/or the quality management system. Methods for control are identified below and in documented procedures, where appropriate.

4.2. Documentation Requirements

4.2.1 General Documentation Requirements

Tri-Gon Precision, Inc. maintains a documented quality management system as a means to ensure that products and services conform to the specified requirements. Reference: QMSP-1001 Control of Documents.

Quality System documents are available to all employees through the E2 Shoptech Quality Module. There is no individual distribution of documents; i.e., no system of controlled 3-ring binders.

The following four levels of documentation are utilized and maintained to meet the requirements of ISO 9001 and where it is necessary, to ensure adequate control.

Level 1: Quality Manual

The Quality Manual includes Tri-Gon Precision, Inc.'s quality policy, quality objectives and the general company-wide structure, scope and methods for maintaining the quality management system. The quality manual references the related quality management system procedures followed to meet the specified policies and approaches.

Level 2: Quality Management System Procedures and Processes.

The content of Level 2 defines the company operation and processes for each element of ISO 9001 and constitutes the company's norm for implementing all activities, referencing Level 3 documentation when required.

Level 3: Process Maps

Process maps are used to show the individual processes in the system.

Level 4: Forms, Assembly & Test Procedures and Engineering documents.

This level contains Forms, and Assembly & Test Procedures.

Level 5: Records

Records are used by Tri-Gon Precision, Inc. to provide assurance and evidence that the required product or service quality was achieved, and that the company's quality management system has been implemented correctly.

4.2.2 Quality Manual

At Tri-Gon Precision, Inc., the quality manual is the foundation of our quality management system. In our quality manual, we describe the scope of the Quality Management System and reference documented procedures necessary to meet the specified polices and approaches utilized by Tri-Gon Precision, Inc. The interactions of the quality management system processes are depicted in Figure 4.1A, found in Section 4.1.

Our quality manual is a controlled document which is reviewed and approved by top management, and is controlled as specified below.

4.2.3 Control of Documents

Tri-Gon Precision, Inc. identifies and controls documents and data in any media that relate to the requirements of ISO 9001, as described in QMSP-1001 Control of Documents. These documents are established, documented, implemented and maintained in accordance with ISO 9001 procedures addressing the following issues:

- Approval of documents for adequacy prior to release.
- Review and revision of documents, including the processes for re-approval and re-issuing of documents.
- Identification of changes to and the current revision status of documents.

Records are a special type of document and are controlled as specified below.

4.2.4 Control of Records

Tri-Gon Precision, Inc. quality management system is documented through the use of records, as described in QMSP-1002 Quality Records Matrix. Records are valuable to Tri-Gon Precision, Inc. in the following ways:

- They provide evidence and assurance that the quality requirements for the product/service were satisfied.
- They show the degree of implementation and success of our quality management system.
- They provide a basis for measurement and feedback essential for continual improvement.

Records at Tri-Gon Precision, Inc. are controlled to ensure they remain legible, readily identifiable and retrievable. This procedure defines the controls needed for the proper identification, storage, protection, retrieval, retention time and disposition of records.

Tri-Gon Precision, Inc. has the following policies regarding records:

- All records are maintained in dedicated files, either by hard copy or in electronic form in accordance with in-house guidelines.
- Records shall be filed, indexed, and maintained in a manner that provides for ready access, and minimizes loss, damage, or deterioration.
- Retention times shall be defined for all records.
- Records shall be dated and initialed or signed by personnel responsible for the documented outcome or activity.
- Records shall be made available for review by the customer (or the customer's representative) when specified in the contract.

5. Management Responsibility

5.1. Management Commitment

The management of Tri-Gon Precision, Inc. is committed to development, implementation and improvement of the QMS. This commitment is reflected in the Company's quality policy and quality objectives.

Tri-Gon Precision, Inc.'s commitment to meeting customer needs and statutory and regulatory requirements is clearly embodied in our quality policy and objectives. This information is continuously reinforced by management to ensure understanding and commitment at appropriate levels within our company.

Management Reviews are conducted periodically.

Tri-Gon Precision, Inc.'s top management ensures the necessary resources are available through Planning, Management Review, and Resource Management.

5.2. Customer Focus

Top management at Tri-Gon Precision, Inc. ensures through Management Reviews and communication with employees that customer needs and expectations are determined, converted to requirements and met with the aim of enhancing customer satisfaction, according to the following policies:

- Determination of Requirements Related to the Product
- Review of Requirements Related to the Product
- Customer Satisfaction
- Monitoring and Measurement of Product

5.3. Quality Policy

Tri-Gon Precision, Inc.'s, quality policy and objectives for quality are displayed openly as a sign of our pride and commitment and as a clear reminder of our focus and direction.

Because the success of our quality management system is essential for our competitiveness, it is vital that the employees of Tri-Gon Precision, Inc. understand and adhere to our Quality Policy.

Tri-Gon Precision, Inc.'s Quality Policy and Objectives:

Quality Policy: **Tri-Gon Precision, Inc. continues to apply old school values such as integrity, honesty, dedication, commitment, and conviction to quality in our daily operation. Our organization as a whole is committed to *continual quality improvement*. This dedication shall foster and support an empowering work environment and strong business relationship(s) that *encourages continual quality improvement*. Tri-Gon Precision, Inc. was founded upon these fundamental principles and commitment to quality from the very beginning and is determined to bring these old school values into new world technologies for *continual quality success*.**

Quality Objectives: **Tri-Gon Precision, Inc.'s personnel are** committed to excellence of ***quality and continuous quality improvement*** **that start with clear and concise quality procedures. The management team at Tri-Gon is unequivocally dedicated to adhere to the quality procedures and protocol. Quality is driven into the organization from the sense of pride and ownership of each component manufactured. This is successfully accomplished by adhering to our ISO Quality Management System and Procedures.**

5.4. Planning

5.4.1 Quality Objectives

It is the responsibility of top management to ensure that quality objectives are established at the relevant functions and levels within the organization and that they are consistent with Tri-Gon Precision, Inc.'s quality policy.

All quality objectives are measurable. The measurement of quality objectives provides a consistent basis for the monitoring of continual improvement. Measurable quality objectives are determined through the Management Review Process, and are reviewed at regular intervals at production, staff, and company-wide meetings.

5.4.2 Quality Management System Planning

It is the responsibility of the Management Representative to ensure that quality management system planning is executed to meet the specified requirements.

Quality management system planning ensures that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

Quality management system planning shows our commitment to the development, correction, maintenance, and continual improvement of our quality management system.

QMSM-1001 Process Interaction and QMSM-1002 Management depict the quality management system planning process and describe the sequence and interaction of the documented processes of the quality management system. Applied together, they represent a model of a Process-Based Quality Management System. Tri-Gon Precision, Inc. embraces a process approach to management. For each instance of quality management system planning, the output is documented accordingly.

5.5. Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

The organizational structure shown in QMSD-1002 Organization Chart illustrates the responsibilities and authorities of personnel who manage, perform, and verify work affecting the quality of products and services at Tri-Gon Precision, Inc.

- The PRESIDENT is the leader of the quality efforts at Tri-Gon Precision, Inc. and is responsible for the delegation of the various responsibilities for quality, and for the efficient operation of the company.
- The MANAGERS/FOREMEN/SUPERVISORS are responsible for ensuring that Tri-Gon Precision, Inc.'s quality policies are being carried out on a daily basis. Managers/Foremen/Supervisors may delegate the authority for implementation of the quality functions within their departments, but shall retain the responsibility for its function.
- Quality is the responsibility of each Tri-Gon Precision, Inc. EMPLOYEE. Their responsibilities for activities affecting quality are specified further in Tri-Gon Precision, Inc.'s Quality Manual and Procedures.

The responsibility and authority for the quality management system is communicated to all employees.

5.5.2 Management Representative

is designated as the Management Representative who has the authority and responsibility for ensuring that the quality management system is effectively established, implemented and maintained at Tri-Gon Precision, Inc. in accordance with ISO 9001, and for reporting to top management on the performance of the quality management system, including necessary improvements at the time of the Management Review. The Management Representative is also responsible for promoting an awareness of our customer's requirements at Tri-Gon Precision, Inc. through internal communication.

5.5.3 Internal Communication

Employees have sufficient authority and the organizational freedom to identify, document, and communicate any issues related to the processes of the quality management system and their effectiveness. The organizational chart, QMSD-1002 Organization Chart, is used to communicate concerns to the appropriate parties. Tri-Gon Precision, Inc.'s top management ensures that communication regarding the effectiveness of the quality management system is facilitated throughout the organization through the use of the following:

- Weekly Production meetings
- Biweekly Staff meetings
- Company-wide meetings
- Training
- Bulletin Boards
- Tri-Gon Precision, Inc. Intranet
- One-on-one coaching

5.6. Management Review

5.6.1 General

Top management conducts a review of the quality management system through "Management Review Meetings" a minimum of every two months. At least once per year, the following will be reviewed and documented:

- Assess the suitability, adequacy, and effectiveness of the quality management system in achieving the quality policy and quality objectives, in meeting customer needs, and in satisfying the requirements of ISO 9001.

- Evaluate opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives, to improve effectiveness and to better meet the needs and expectations of our customers.
- Evaluate the Quality System processes as defined in Section 4.1 for relevance and continued accuracy.

5.6.2 Review Input

Inputs to the Management Review process include, but are not limited to, current performance data and potential improvement opportunities related to:

Audit results;

- Customer feedback (including customer satisfaction measurement data and customer complaints);
- Process performance and product conformity;
- Status of corrective and preventive actions;
- Follow-up actions from previous management reviews;
- Changes that could affect the quality management system; and recommendations for improvement.
- Review the infrastructure assessments and the work environment.

5.6.3 Review Output

Written meeting minutes summarizing the Management Review activities, the conclusions reached and action items identified will be recorded and retained as records. These minutes are used to guide and improve our quality management system at Tri-Gon Precision, Inc. by documenting:

- Actions taken to continually improve the effectiveness of the quality management system and related processes.
- Actions taken to continually improve our products to maintain a high level of customer satisfaction and consistently meet customer requirements.
- Additional resources necessary for the effective operation of the quality management system, including human resource, infrastructure and work environment needs.
- Changes to quality objectives (including those defined for product).
- Changes to any QMS Processes or Procedures.

The Quality Team initiates corrective actions and/or preventive actions, as specified during the Management Review Process.

The minutes of the Management Review serve as records for Tri-Gon Precision, Inc.'s quality management system and are maintained electronically.

6. Resource Management

6.1. Provision of Resources

It is our policy at Tri-Gon Precision, Inc. to identify the resource requirements for the implementation, management, and continual improvement of our quality management system and activities necessary to enhance customer satisfaction by meeting customer requirements.

6.2. Human Resources

6.2.1 General

Employees involved in the management, performance, and/or verification of work affecting quality are competent on the basis of education, training, skills and/or experience.

6.2.2 Competence, Awareness and Training

It is our policy at Tri-Gon Precision, Inc. to identify competence and training needs and provide for the training of personnel performing activities affecting quality. Two documents, QMSM-1003 Human Resources and QMSM-1004 Training describe our human resources processes. Specifically:

- Identification and assessment of competence needs.
- The training and/or qualification of people who perform tasks affecting quality, including mechanisms for delivery of training.
- Assessment of training effectiveness.
- Assessment of quality awareness, to ensure that employees are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.
- Maintenance of appropriate training records, including education, experience, training, skills and qualifications.

Managers/Foremen/Supervisors have the responsibility in assessing training and competence needs, providing on-the-job reinforcement of skills, and evaluating the effectiveness of training given for the personnel they directly manage.

It is Tri-Gon Precision, Inc.'s policy that any employee may request training at any time if the employee feels that training is essential to receive the knowledge and skills required to maintain the requirements of the Standard and Tri-Gon Precision, Inc.'s quality management system.

6.3. Infrastructure

To ensure that our infrastructure is suitable to create conforming product, critical infrastructure is identified and maintained. Each Manager/Foreman/Supervisor periodically assesses the infrastructure in their area(s) of responsibility to ensure that the conformity of product can be achieved. This information is reviewed biweekly at staff meetings attended by the Managers/Foremen/Supervisors and Management.

Work Environment

It is the responsibility of each Manager/Foreman/Supervisor to identify and manage both the human and physical factors of the work environment that are necessary to achieve conforming product.

6.4. Management Information System

Tri-Gon Precision, Inc. uses the intranet as its information system and the E2 Shop System.

7. Product Realization

7.1. Planning of Product Realization

Planning of Product Realization at Tri-Gon Precision, Inc. is realized through the use of all of the constituent parts of the Quality Management System. The key being process control in which all processes are clearly mapped and understood including the interactions between the processes. In addition all processes are monitored and measured and adjustments made as necessary per their specific process maps. The customer determines requirements for the product.

7.2. Customer Related Processes

At Tri-Gon Precision, Inc., Customer Related Processes, which includes Determination of Requirements, Review of Requirements, and Customer Communication, are managed at the point of customer engagement. In all cases customer requirements are clearly defined and documented on the purchase order received from the customer, which describes all necessary characteristics of the product to be produced prior to manufacturing. Records of the results of this review and actions arising from the review are maintained in the E2 Shop System. The records are evident through the signed acknowledgement of the order, and are defined by the following procedure QMSP-1003 Requirements Review.

7.3. Design and Development

Excluded. All products are made per customer specifications.

7.4. Purchasing

7.4.1 Purchasing Process

The Purchasing Department is responsible for ensuring that purchasing processes are controlled such that purchased products and subcontracted services which affect product quality conform to specified requirements utilizing the QMSM-1005 Purchasing.

The Purchasing Department is responsible for the following activities:

- Defining guidelines to govern the type and extent of control to be exercised over suppliers in ensuring that the purchasing control policy is consistently met. The level of control exerted depends on a variety of factors, including the type of purchased product or service, its impact on the quality of Tri-Gon Precision, Inc.'s final products and service provided to customers, and the availability of records demonstrating the supplier's capability.
- Establishing criteria for selection, evaluation and re-evaluation of suppliers.
- Establishing a Vendor Master List on the basis of these defined criteria related to a supplier's ability to meet Tri-Gon Precision, Inc.'s requirements for performance, quality, cost, and delivery.
- Maintaining the Vendor Master List based upon supplier performance and reviews of supplier capability versus Tri-Gon Precision, Inc.'s requirements.

All suppliers existing in our supplier database as of 7/28/2014 are considered approved. Conducting supplier evaluations/assessments and maintaining records of suppliers' capability, performance, and necessary follow-up actions are specified in Tri-Gon Precision, Inc.'s QMSM-1006 Receiving in conjunction with the form, QMSF-1001 Receiving Inspection and QMSP-1004 Supplier Evaluation (access to the Vendor Master List is explained here). The Foremen/Supervisors ensure all outsourced processes that affect product conformity with requirements and/or the quality management system are controlled. An example of these controls for outsourced services can be found in the QMSM-1005 Purchasing.

In the event of unacceptable supplier performance**,** a Corrective and/or Preventative Action Form may be initiated. The purpose of this form is to provide a method to initiate, execute, and document corrective action items in response to unacceptable supplier performance. It is the responsibility of the Purchasing Department, or designee, to document, follow-up, track, and confirm supplier corrective actions taken. The Purchasing Department also ensures that any

suppliers who have insufficiently resolved supplier corrective actions are removed from the "active" list in the Vendor Master List until the supplier corrective action is sufficiently resolved.

7.4.2 Purchasing Information

The Purchasing Department is responsible for ensuring that purchasing documents are reviewed and approved for adequacy of specified requirements prior to release by utilizing the QMSM-1005 Purchasing.

The person purchasing is responsible for ensuring that purchasing documents contain data clearly describing the product ordered, including the following, where applicable:

- Requirements for approval of product, procedures, processes, equipment, and personnel.
- Requirements for qualification of personnel.
- Quality management system requirements.
- The name or other positive identification, and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data.
- Requirements for design, test, examination, inspection and related instructions for acceptance by the organization.
- Requirements for test specimens (e.g. production method, number, storage conditions) for design approval, inspection, investigation or auditing.
- Requirements relative to, supplier notification to organization of nonconforming product and arrangements for organization approval of supplier nonconforming material.
- Requirements for the supplier to notify the organization of changes in the product and/or process definition and, where required, obtain organization approval.
- Right of access by the organization, their customer, and regulatory authorities to all facilities involved in the order and to all applicable records.
- Requirements for the supplier to flow down to sub-tier suppliers the applicable requirements in the purchasing documents, including key characteristics where required.

7.4.3 Verification of Purchased Product

The Foremen/Supervisors have the responsibility for ensuring that incoming product is not used or processed until it has been verified as conforming to specified requirements.

Verification through inspection and testing and generation of resulting records is performed according to QMSF-1001 Receiving Inspection**.**

The person purchasing is responsible for ensuring that verification arrangements and the methods for product release are clearly defined in the purchasing documents in situations where verification is to be performed by Tri-Gon Precision, Inc. or the customer at the supplier's premises.

7.5. Production and Service Provision

7.5.1 Control of Production and Service Provision

General manufacturing and service operations are controlled and tracked in Tri-Gon Precision, Inc.'s information system, the E2 Shop System.

Managers/Foremen/Supervisors involved in processes that directly affect quality of intermediate and end products are responsible for ensuring that these processes are identified, planned and executed under controlled conditions.

Controlled conditions are defined to include the following requirements:

- Availability of information describing product characteristics.
- Availability of the necessary procedures and forms (See QMSP-1001 Control of Documents). Use and maintenance of suitable equipment for production and service operations (see Sections 6.3 (Infrastructure) and 6.4 (Work Environment)).
- Availability and use of monitoring and measuring devices - described in Sections 7.6 (Control of Monitoring and Measuring Devices) and 8.2 (Monitoring and Measurement).
- Implementation of monitoring and measurement activities - described in Section 8.2 (Monitoring and Measurement).

7.5.2 Validation of Processes for Production and Service Provision

Not applicable. All processes can be verified by monitoring and measurement.

7.5.3 Identification and Traceability

Tri-Gon Precision, Inc. maintains a database for identifying, where appropriate, raw materials and supplies, component parts, subassemblies, and finished products by means of applicable drawings, specifications, and other documents from receipt and throughout the stages of production, delivery, and installation. Each product that is identified will include unique identification, the status of required monitoring and measurement activities. Where traceability is

a requirement, traceability data is controlled and recorded. Product identification and traceability are maintained and controlled through Tri-Gon Precision, Inc.'s E2 Shop System software.

7.5.4 Customer Property

Tri-Gon Precision, Inc. exercises care with customer property and ensures that the property is identified, verified against specified requirements, protected, and safeguarded until required for use or incorporated into our products. Customer property may also include intellectual property.

7.5.5 Preservation of Product

Employees and the Foremen/Supervisors are responsible for identification, handling, packaging, storage, protection, and delivery of materials and products. They are also responsible for establishing, documenting, and maintaining methods appropriate to preserve conformity of product and constituent parts during internal processing and delivery.

Tri-Gon Precision, Inc. ensures the preservation of product in the following ways:

- Identification: Specific details on the identification of product at Tri-Gon Precision, Inc. are described in Section 7.5.3 (Identification and Traceability).
- Handling: Tri-Gon Precision, Inc.'s policy is to use methods and means appropriate for the handling and transporting of product in a manner that prevents loss of product value and ensures employee safety.
- Packaging: Products are appropriately packed and identified on the packaging in a manner that allows for ready identification through the stages of processing and prevents the loss of product value.
- Storage: Tri-Gon Precision, Inc. maintains facilities, equipment, and designated areas to store material in a manner that prevents loss of product value (see Section 6.3 - Infrastructure). Methods and means appropriate for ensuring proper receipt of material, and proper dispatch to and from the pertinent areas are required and used. Foreman/Supervisor's having jurisdiction over departments where product is stored are responsible for assessing the condition of those materials at intervals sufficient to guarantee the prevention of their damage or deterioration.
- Protection: Products are protected during internal processing and delivery to maintain product quality and value when the product is under the company's control.
- Delivery: The quality of the final product is protected after final inspection. Where contractually specified, Tri-Gon Precision, Inc. is responsible for packaging and preservation during transit, including delivery to destination.

7.6. Control of Monitoring and Measuring Devices

Managers/Foreman/Supervisors are responsible for ensuring that necessary monitoring and measurement activities are identified.

The Foreman/Supervisor is responsible for ensuring that measuring devices are available to assure conformity of product. Tri-Gon Precision, Inc.'s QMSM-1007 Calibration is used to ensure that monitoring and measuring devices used for verification in any stage of production or installation are controlled, calibrated, and properly maintained to demonstrate the conformance of product to the specified requirements.

The Manager/Foreman/Supervisor is also responsible for ensuring that the required monitoring and measuring can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, the Quality Manager, or designee, is responsible for ensuring that:

- The accuracy of monitoring and measuring devices used to make quality decisions in the manufacturing process, including instruments owned by employees, is certified at specified intervals, or prior to use, according to Tri-Gon Precision, Inc.'s QMSM-1007 Calibration. Measuring devices are selected that the accuracy of the equipment exceeds the tightest tolerance of the measured product.
- Calibration activities are traceable to an international or national measurement standard. Where no such standard exists, the basis for calibration is defined and recorded.
- Monitoring and measuring devices are adjusted or re-adjusted, as necessary.
- Monitoring and measuring devices are clearly identified to enable the calibration status to be determined.
- Monitoring and measuring devices are safeguarded from adjustment to maintain the integrity of measurement activities.
- Monitoring and measuring devices are protected from damage and deterioration during handling, maintenance, and storage.
- Calibration activity that discloses the potential for discrepant material results in the initiation and recording of an ad hoc audit for the purpose of determining whether or not the potential was realized. In cases where discrepant material has already been shipped to customers, appropriate follow-up actions are performed and recorded to ensure customer satisfaction. If the material is found to be discrepant, QMSP-1005 Control of Nonconforming Product is initiated. Records are kept of the results of calibration and verification activities.

8. Measurement, Analysis and Improvement

8.1. General

The Quality Manager, or designee, is responsible for ensuring that each Manager/Foreman/Supervisor at Tri-Gon Precision, Inc. defines, plans and implements monitoring, measurement and analysis activities that are necessary to assure conformity of the product and the quality management system and to achieve improvement. Tri-Gon Precision, Inc. plans and implements monitoring, measurement, analysis and improvement according to the following.

This ensures:

- Monitoring and measurement activities on processes affecting quality are defined, planned and implemented.
- The need for statistical techniques and/or any other applicable methods is identified and the extent of their use is determined.
- Measurement, analysis, and improvement systems are reviewed during the Management Review process (see Section 5.6) to promote continual improvement.
- As necessary, Tri-Gon Precision, Inc. uses statistical techniques.

8.2. Monitoring and Measurement

8.2.1 Customer Satisfaction

The President is responsible for ensuring that customer communication is maintained and that customer satisfaction data is collected, analyzed and used at the management review meeting based on the results of the annual customer survey, QMSF-1002 Customer Survey. The following methodologies are used for monitoring and measuring customer satisfaction:

- Customer Requirements
- Customer Feedback and Complaints
- Surveys
- Customer returns
- Repeat Customers
- Direct Communication with Customers

The President is responsible for ensuring that the collected customer satisfaction data is appropriately tracked and maintained. Customer satisfaction data serves as a means to assess the overall performance and continual improvement of the quality management system.

Customer feedback (including customer satisfaction measurement data and customer complaints) is utilized in the Management Review process (see Section 5.6).

8.2.2 Internal Audit

Tri-Gon Precision, Inc. plans and conducts internal audits at planned intervals according to QMSM-1008 Internal Audit for the following purposes:

- To verify whether quality activities and related results comply with planned arrangements, ISO 9001, and quality management system requirements established by Tri-Gon Precision, Inc..
- To determine the overall effectiveness of the quality management system as implemented and maintained.

The Quality Manager, or designee, produces a long-term audit program, which identifies when each element or process of the quality management system will be audited. Every element or process of the quality management system is audited at a minimum of once per year. An individual element or process may be audited additionally, based upon the importance and status of the element or process and the results of previous audits.

The Quality Manager, or designee, is responsible for organizing and coordinating the internal audit to ensure that the audit criteria, scope, frequency and methods are defined, and that the following requirements are met:

- Definition of audit responsibilities
- Definition of requirements for planning and conducting the audit.
- Assurance of auditor independence.
- Recording of audit results
- Communication of audit results to management

The Quality Manager, or designee, is responsible for ensuring the selection of auditors and that their conduct during audits ensures objectivity and impartiality of the audit process. Auditors do not audit their own work.

Only qualified personnel may perform internal auditing activities. These qualified personnel are classified as internal auditors and have been trained. This training may be performed by a certified lead auditor or by previously trained internal auditors. Records of internal audit training are maintained according to QMSP-1002 Quality Records Matrix.

In the case of a nonconformance or weakness (in either the quality management system and procedures, or the performance and adherence to those systems and procedures), the Quality Manager, or designee, will initiate a corrective or preventative action report in the E2 Shop System.

The Department Manager/Foreman/Supervisor responsible for the area audited ensures that the corrective and/or preventive actions are resolved in a timely manner in order to eliminate detected problems and their causes. Follow-up audits are used to verify the implementation and effectiveness of the corrective and preventive actions. The verification results are recorded and reported to the appropriate personnel.

8.2.3 Monitoring and Measurement of Processes

Monitoring, and where applicable, measurement activities are performed on the quality management system processes necessary to meet customer requirements and track quality objectives, and on additional processes where the potential benefit is identified. The responsibility to identify and apply suitable methods for monitoring and measurement of processes is assumed by Department Managers/Foreman/Supervisors and is performed according to QMSM-1008 Internal Audit and QMSP-1005 Control of Nonconforming Product.

Monitoring and measurement of processes demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, action is taken to correct the immediate problem.

8.2.4 Monitoring and Measurement of Product

Tri-Gon Precision, Inc. establishes and maintains documented procedures, and/or quality plans that define the required monitoring and measurement activities and related records used to verify that product characteristics and requirements are met prior to product distribution, processing, or use (see Section 7.1). The specific monitoring and measurement activities that take place and how they are used to verify product conformance is documented in the individual manufacturing process maps.

8.2.4.1 Receiving Inspection and Testing

See Section 7.4.3 (Verification of Purchased Product)

8.2.4.2 In-Process Inspection and Testing

The Department Managers/Foreman/Supervisors are responsible for ensuring that in-process product is held and not used or processed further until it has been inspected, tested or otherwise verified as conforming to specified requirements.

If in-process product is found to be nonconforming, the Department Manager/Foreman/Supervisor is responsible for ensuring that the nonconforming product is brought into conformance before if is used or processed further, or that the nonconforming product is removed from the production process. Reference: QMSP-1005 Control of Nonconforming Product.

Inspection and testing of in-process materials are performed according to the individual process map, which addresses such issues as:

- Inspection and testing of material to documented plan.
- Reference to QMSP-1005 Control of Nonconforming Product for control of nonconforming materials.
- Documentation, use and storage of records (see QMSP-1002 Quality Records Matrix).

8.2.4.3 Final Inspection and Testing

The Final Test Manager or designee is responsible for ensuring that no product is dispatched until:

- Final inspection and testing is completed according to the appropriate documented procedures or process maps to show evidence of product conformance to specified requirements, unless otherwise approved by a relevant authority, and where applicable by the customer.
- Data and documentation covering inspections and tests (incoming, in-process, and final) specified in the quality procedures are available and authorized to show compliance and that the results meet specified requirements.

8.2.4.4 Inspection and Test Records

Inspection and test records are established and maintained at Tri-Gon Precision, Inc. to identify the persons performing inspection and test activities and the authorized personnel responsible for the release of product, and to provide evidence of conformity with the acceptance criteria. The responsibility for generating, filing and maintaining inspection and test records is defined in the quality procedures referenced above.

8.3. Control of Nonconforming Product

The Department Foreman/Supervisor is responsible for implementing and maintaining QMSP-1005 Control of Nonconforming Product (the purpose of referencing this procedure in the quality manual is to establish that the procedure itself fulfills all of the requirements of Clause 8.3 of the standard) to ensure that:

- Product not conforming to specified requirements is clearly identified and controlled to prevent unintended use or delivery until the product is reviewed and disposition is determined.
- Responsibilities and authorities for the identification, control and disposition of nonconforming product are defined, communicated and understood.

Nonconforming product is dealt with in one of the following ways:

- By taking action to eliminate the detected nonconformity (rework or repair).

- By authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer (use as-is).
- By taking action to preclude its use or application (reject or scrap).

Reworked and repaired product is re-inspected or re-verified to demonstrate conformity to the requirements.

Actions appropriate to the effects or potential effects are taken when nonconforming product is detected after delivery or use has started.

Relevant functions receive notification of nonconforming product.

8.4. Analysis of Data

Each Foreman/Supervisor is responsible for ensuring that appropriate collection and analysis of data occur in their specific department. The data collected determines, in part, the suitability and effectiveness of the quality management system and identifies areas for improvement.

Data is collected and analyzed accordingly to provide information related to:

- Customer satisfaction.
- Conformity to product requirements.
- Characteristics and trends of processes and products, including opportunities for preventive action.
- Performance of critical suppliers, including capability, on-time delivery, conformance to specified requirements and cost.

8.5. Improvement

8.5.1 Continual Improvement

It is the overall responsibility of top management to continually improve the effectiveness of the quality management system, as described throughout this manual. Each Foreman/Supervisor is responsible for the continual improvement of the quality management system in his or her respective areas. Effectiveness of continual improvement activity is assessed during the Management Review Process.

Continual improvement of the quality management system at Tri-Gon Precision, Inc. is facilitated through the use of:

- Quality Policy - Section 5.3
- Quality Objectives - Section 5.4.1
- Audit Results - Section 8.2.2
- Analysis of Data - Section 8.4

- Corrective Action- Section 8.5.2
- Preventive Action- Section 8.5.3
- Management Review - Section 5.6

8.5.2 Corrective Action

Corrective action at Tri-Gon Precision, Inc. is directed at revising the company's quality management system, policies, and procedures in order to eliminate the root cause(s) of quality problems and nonconformities and prevent their recurrence.

Corrective actions taken are appropriate to the effects of the nonconformities encountered.

The Quality Manager, or designee, is responsible for ensuring the corrective action process is managed effectively It is also the responsibility of the Quality Manager to ensure that flow down of corrective and preventative actions requirements to suppliers takes place, when it is determined that the supplier is responsible for the root cause. Where timely and/or effective actions are not achieved by suppliers the Quality Manager will address this situation in writing with the supplier and request an effective result within 30 days or the supplier will be notified again in writing that their business relationship with Esteem has concluded. Corrective actions may be used in the following situations:

- To resolve nonconformities found during internal, external (customer), or third party audits.
- To revise the quality systems, work processes, or quality procedures to eliminate the cause of a poor quality product or service, customer complaint, or internal quality failure.
- To resolve quality system problems found during the Management Review Process.
- Identifying and reviewing nonconformities (including customer complaints).
- Determining the causes of the nonconformity.
- Evaluating the need for actions to ensure that the nonconformity does not recur.
- Determining and implementing the corrective action needed.
- Recording the results of corrective action taken.
- Reviewing the implementation and effectiveness of corrective actions taken.

Customer feedback (positive comments and complaints) are recorded and reviewed through the Feedback Module within the E2 Shop System. This ensures that customer complaints are documented and managed appropriately at Tri-Gon Precision, Inc., and that any resulting product or service concerns are communicated to the appropriate area(s) of the company. CAR's and PAR's may be generated through review of the Feedback Report.

The responsibility for deciding when to utilize a CAR and undertaking the corrective action lies with the Foreman/Supervisor who is responsible for the related quality management system

element and/or process in manufacturing. Management may assign a system-related CAR to anyone.

Records of corrective actions taken are maintained within the E2 Shop System and utilized in the Management Review process (see Section 5.6). For instructions on how to enter a corrective action use the following procedure QMSP-1006 Corrective and Preventative Actions.

8.5.3 Preventive Action

Preventive action is directed at improving Tri-Gon Precision, Inc.'s quality systems, procedures, and policies.

The Quality Manager, or designee, is responsible for ensuring the preventive action process is managed effectively. Preventive actions may be in the following situations:

- To expose potential nonconformities found during either internal, external (customer), or third party audits.
- To revise the quality systems, work processes, or quality procedures to improve the quality of a process, product or service.

Preventive actions taken are appropriate to the effects of the potential problems encountered.

Tri-Gon Precision, Inc.'s E2 Shop System defines requirements for:

- Identifying potential nonconformities and their cause(s).
- Evaluating the need for action to prevent occurrence of nonconformities.
- Determining and ensuring the implementation of preventive action needed.
- Recording the results of action taken.
- Reviewing the implementation and effectiveness of preventive action taken.

The responsibility for undertaking the preventive action lies with the Manager/Foreman/Supervisor who is responsible for the related quality management system element and/or process and/or procedure.

Records of preventive actions taken are maintained within the E2 Shop System and utilized in the Management Review process (see Section 5.6). For instructions on how to enter a preventative action use the following procedure QMSP-1006 Corrective and Preventative Actions.