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Precision Mold & Tool – Government Division

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QUALITY MANUAL

AS9100 Rev. D

Approved:	Todd Wulfe	Signature	05/31/2017 Date
Approved:	Pilar Grijalva	Signature	05/31/2017 Date

Change Record

Rev	Date	Responsible Person	Description of Change
1.0	11/14/2012	David Daniels	Approved Quality Manual
1.1	4/10/2013	David Daniels	Revised Page 34 Sec 8.2.4
2.0	6/6/2013	David Daniels	Revised title block, scope of registration to add ISO 9001:2008 and removed the N/A for 7.5.2
3.0	6/12/2013	David Daniels	Revised Interaction of QMS Flow chart to key processes by color coding activities.
4.0	7/18/2013	David Daniels	Excluded sec 7.5.1.4 Post Delivery support from scope of registration.
5.0	9/10/2013	David Daniels	Updated company Logo on all pages
6.0	2/12/2014	David Daniels	Revised Quality Objectives and corrected typographical errors.
7.0	6/30/2014	David Daniels	Revised section 7.5.1.4 to state section is excluded and removed servicing information
8.0	03/09/2015	David Daniels	Corrected the spelling of the word "Preventive"
9.0	09/09/2015	David Daniels	Revised Sec 7.5.1.4 to state only (a), (c), (d), and (e) are excluded. Revised Management process map as Management Support to be a key activity.
10.0	10/12/2015	David Daniels	Revised Interaction of QMS Processes figure 4.1A to better define the input and output interaction of the QMS processes.
11.0	02/03/2016	David Daniels	Changed MR to Pilar Grijalva
12.0	07/05/2016	Pilar Grijalva	Revised Quality Objectives to remove "To continue to reduce product defects".
13.0	03/30/2017	Brianen Martinez	Revise and reformat to align with AS9100D
14.0	05/31/2017	Brianen Martinez	Update Sections 8.1.1 and 8.4.1.1

Table of Contents

1. Scope

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 Precision Mold and Tool.
The quality management system described in this Quality Manual addresses the requirements as defined in AS9100D.

The true measure of quality at Precision Mold and Tool is customer satisfaction. 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 Precision Mold and Tool 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.

2. Normative References

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.
ISO 9000:2015, Quality Management Systems – Fundamentals and Vocabulary
ISO 9001:2015, Quality Management Systems – Requirements

3. Terms and Definitions

The terms and definitions provided below are frequently used to describe aspects of the quality management system at Precision Mold and Tool. The terms and definitions given in ISO9000:2015 and the following apply.

3.1 Counterfeit Part

An unauthorized copy, imitation, substitute, or modified part (e.g., material, part, component), which is knowingly misrepresented as a specified genuine part of an original or authorized manufacturer. *Note: Examples of a counterfeit part can include, but are not limited to, the false identification of marking or labeling, grade, serial number, date code, documentation, or performance characteristics.*

3.2 Critical Items

Those items (e.g., functions, parts, software, characteristics, processes) having significant effect on the provision and use of the products and services; including safety, performance, form, fit, function, producibility, service life, etc.; that require specific actions to ensure they are adequately managed. Examples of critical items include safety critical items, fracture critical items, mission critical items, key characteristics, etc.

3.3 Key Characteristic

An attribute or feature whose variation has a significant effect on product fit, form, function, performance, service life or producibility, that requires specific actions for the purpose of controlling variation.

3.4 Product Safety

The state in which a product is able to perform to its designed or intended purpose without causing unacceptable risk of harm to persons or damage to property.

3.5 Special Requirements

Those requirements identified by the customer, or determined by the organization, which have high risks of not being met, thus requiring their inclusion in the operational risk management process. Factors used in the determination of special requirements include product or process complexity, past experience and product or process maturity. Examples of special requirements include performance requirements imposed by the customer that are at the limit of the industry's capability, or requirements determined by the organization to be at the limit of its technical or process capabilities.

4. Context of the Organization

4.1 Understanding the Organization and Its context

Internal and External issues that are relevant to Precision Mold and Tool's purpose, strategic direction and that affect its ability to achieve the intended result(s) of its QMS have been determined. These issues are monitored and reviewed periodically during Management Review.

4.2 Understanding the Needs and Expectations of Interested Parties

Precision Mold and Tool has determined the interested parties that are relevant to the QMS are Customers, Owner, Management, and Employees. Precision Mold and Tool has also determined the requirements of said parties. Information regarding the interested parties and their requirements are monitored and reviewed periodically.

4.3 Determining the Scope of the Quality Management System

Scope of Registration

The company's scope of registration for AS9100D:2016/ISO 9001:2015 is as follows:

The scope of the Quality Management system includes the manufacturing, refurbishing, and distribution of airframe and engine components, including tooling and ground support equipment.

The following sections are Not Applicable:

8.3 Design and Development of Products and Services. Precision Mold and Tool does not perform design activities.

8.5.5 (a), (b), (c), (d), (f), (g), (h), and (i) Post-Delivery Activities. Precision Mold and Tool does not provide post-delivery activities.

Therefore, the fulfillment to the requirements of these clauses are not applicable to our QMS nor do they affect Precision Mold and Tool's ability or responsibility to ensure the conformity of products and services and the enhancement of customer satisfaction.

4.4 Quality Management System and Its Processes

4.4.1

Precision Mold and Tool's quality management system has been established, implemented, maintained and continually improves the performance of our organization, including the processes and their interactions. The quality manual describes our quality policy and general company-wide structure and procedures for maintaining the quality management system that meets the Standard, Customer and applicable statutory and regulatory quality management system requirements.

Precision Mold and Tool'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. All processes in the company are documented in our process maps.
- Determine the inputs required and the outputs expected from these processes. See process maps.

- Determine the sequence and interaction of our quality management system processes. See the Process Interaction process map.
- Determine the criteria and methods needed to ensure the effective operation and control of these processes.
- Determine the resources needed and ensure the availability of resources and information necessary to support the operation and monitoring of these processes. This is discussed at every management review meeting.
- Assign the responsibilities and authorities for these processes. See QMSD-1002 – Organization Chart
- Address the risks and opportunities as determined in accordance with the requirements of 6.1.
- Evaluate these processes and implement any changes necessary to ensure that these processes are achieving their intended results.
- Continue to improve the processes and the quality management system. This is implemented through the use of the Corrective Actions procedure.

Precision Mold and Tool manages these processes in accordance with the requirements of AS9100. 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.

4.4.2

Precision Mold and Tool maintains a documented quality management system as a means to ensure that products and services conform to the specified customer requirements and requirements imposed by applicable regulatory authorities. *Reference: QMSP-1001 Control of Documents.*

Precision Mold and Tool retains documented information to have confidence that the processes are being carried out as planned. *Reference: QMSP-1002 Quality Records Matrix.*

At Precision Mold and Tool, the quality manual is the foundation of our quality management system. The quality manual provides documented information including:

- a general description of relevant interested parties *(see 4.2)*
- the scope of the QMS, including boundaries and applicability *(see 4.3)*
- a description of the processes needed for the quality management system and their application throughout the organization *(see 4.4)*
- the sequence and interaction of these processes *(see 4.4.1)*
- assignment of the responsibilities and authorities for these processes. *(see QMSD-1002 – Organization Chart)*

5. Leadership

5.1 Leadership and Commitment

5.1.1 General

Precision Mold and Tool Management has demonstrated leadership and commitment with respect to the quality management system through:

- Taking accountability for the effectiveness of the QMS by periodical review of the QMS through Management review meetings, Quality Objectives review and providing necessary resources.
- Management has established a quality policy and quality objectives for the QMS and they are compatible with the context and strategic direction of the organization.
- Management has determined the organizational processes are integrated with the quality management system. This requirement can be verified using Interaction of QMS map.
- Management has established procedures for promoting the use of process approach and risk-based thinking.
- Resource availability will be discussed at every management review meeting.
- The company will communicate the importance of effective quality management and of conforming to the quality management system requirements with employees by posting QMS information on a Quality Bulletin Board and through meetings.
    - The company will post the quality policy on the Quality Bulletin Board.
    - The company will post the quality objectives on the Quality Bulletin Board.
- The company will conduct management reviews and post the agenda and minutes from the meeting on the Quality Bulletin Board.
- Ensuring that the quality management system achieves its intended results.
- Engaging, directing and supporting persons to contribute to the effectiveness of the quality management system by providing training, conducting awareness programs and conducting meetings.
- Promoting improvement
- Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

5.1.2 Customer Focus

Top management at Precision Mold and Tool ensures through Management Reviews and communication with employees that customer needs and expectations are determined, by following the Requirements Review procedure, and met with the aim of enhancing customer satisfaction.

Product conformity will be measured by counting Nonconformance Reports. On-time delivery will be measured by placing and shipping all orders in the FileMaker and or E2 system. On-time performance can then be displayed by running the Shipping Summary report in E2.

5.2 Policy

Precision Mold and Tool'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 Precision Mold and Tool understand and adhere to our Quality Policy.
The Quality Policy will be reviewed at every management review meeting to ensure that the policy:

- Is appropriate to the purpose of the organization.
- Includes a commitment to comply with requirements and continually improve the QMS.
- Provides a framework for establishing quality objectives.
- Is communicated and understood within the organization.
- Is reviewed for continuing suitability.

Precision Mold and Tool's Quality Policy:

Precision Mold &Tool is committed to be compliant to the AS9100 standard as well as continually improving its Quality Management System.

5.3 Organizational Roles, Responsibilities, and Authorities

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 Precision Mold and Tool.

The PRESIDENT is the leader of the quality efforts at Precision Mold and Tool and is responsible for the delegation of the various responsibilities for quality, and for the efficient operation of the company.

The Supervisor/Managers are responsible for ensuring that Precision Mold and Tool's quality policies are being carried out on a daily basis.

Quality is the responsibility of each Precision Mold and Tool EMPLOYEE. Their responsibilities for activities affecting quality are specified further in Precision Mold and Tool's Quality Manual, Procedures, and Work Instructions.

Supervisors/Managers may delegate the authority for implementation of the quality functions within their departments, but shall retain the responsibility for its function.
The responsibility and authority for the quality management system is communicated to all employees.

5.3.1 Management Representative

Pilar Grijalva is designated as the Management Representative. The Management Representative:

- Has the authority and responsibility for ensuring that the processes of the quality management system are effectively established, implemented and maintained at Precision Mold and Tool in accordance with AS9100. All process maps are in place.
- Is responsible for ensuring that the processes are delivering their intended outputs. Reviewing quality objectives during management review meetings.
- Is responsible for reporting to top management on the performance of the quality management system, including necessary improvements at the time of the Management Review. Corrective and Preventive actions will be the method used.
- Is also responsible for promoting an awareness of our customer's requirements at Precision Mold and Tool through internal communication. This will be accomplished by updating the Quality Bulletin Board.
- Is responsible for ensuring that the integrity of the QMS is maintained when changes to the quality management system are planned and implemented. This will be documented during Management Review meeting minutes.
- Has the organizational freedom and unrestricted access to top management to resolve matters pertaining to quality at Precision Mold and Tool.

6. Planning

6.1 Actions to Address Risks and Opportunities

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. Precision Mold and Tool embraces a process approach to management. For each instance of quality management system planning, the output is documented accordingly.

The integrity of the QMS is maintained when making changes to the QMS by performing internal audits.

6.2 Quality Objectives and Planning to Achieve Them

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 Precision Mold and Tool’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 every management review meeting.

Quality Objectives: To maintain on time delivery of 90-100%.
To maintain a scrap rate of less than 4%
To maintain a rework rate of less than 10%

6.3 Planning Changes

Changes to the QMS are reviewed during management review meetings. See QMSF-1026.

7. Support

7.1 Resources

It is our policy at Precision Mold and Tool to identify the resource requirements for the establishment, implementation, management, and continual improvement of our quality management system at the management review meeting. Precision Mold and Tool considers the capabilities of, and constraints on, existing internal resources and what needs to be obtained from external providers.

7.1.2 People

Precision Mold and Tool management determines and provides the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.

7.1.3 Infrastructure

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

- Buildings, workspaces and associated utilities.
- Process equipment both hardware and software.
- Supporting services such as transport, communication or information systems.

7.1.4 Environment for the Operation of Processes

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

7.1.5 Monitoring and Measuring Resources

7.1.5.1 General

The Supervisors/Managers are responsible for ensuring that measuring devices are available to assure conformity of product. Precision Mold and Tool's QMSM-1007 Calibration and related work instructions are 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.

7.1.5.2 Measurement Traceability

The Supervisor/Managers are 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. See QMSP-1011 for more information.
Where necessary to ensure valid results, the Quality Manager is responsible for ensuring that:

- The accuracy of monitoring and measuring devices used to make quality decisions in the manufacturing process, is certified at specified intervals, or prior to use, according to Precision Mold and Tool's QMSM-1007 Calibration and related work instructions. 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 via calibration stickers.
- 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.

7.1.6 Organizational Knowledge

Precision Mold and Tool has determined the knowledge necessary for operations. This knowledge is maintained through procedures, work instructions, checklists, shop routers, etc., as required. When addressing changing needs and trends, Precision Mold and Tool considers its current knowledge and determines how to acquire or access any necessary additional knowledge and required updates.

7.2 Competence

It is our policy at Precision Mold and Tool 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.
- Maintenance of appropriate training records, including education, experience, training, skills and qualifications.
- Supervisors/Managers 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 Precision Mold and Tool'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 Precision Mold and Tool's quality management system.

7.3 Awareness

Precision Mold and Tool ensures that all employees are aware of the quality policy, relevant quality objectives, and their contribution to the effectiveness of the QMS through training and posting applicable information to the Quality Boards. Employees are trained on the QMS and its importance during initial training. Employees are provided with information regarding the implications of not conforming with the quality management system requirements during initial training. Employees are provided training regarding relevant QMS documented information, and changes; their contribution to product conformity; their contribution to product safety and the importance of ethical behavior.

7.4 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. Precision Mold and Tool'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
- Staff meetings
- Company-wide meetings
- Training
- Bulletin Boards
- One-on-one coaching

7.5 Documented Information

Precision Mold and Tool maintains a documented quality management system as a means to ensure that products and services conform to the specified customer requirements and requirements imposed by applicable regulatory authorities. *Reference: QMSP-1001 Control of Documents.*

Precision Mold and Tool retains documented information to have confidence that the processes are being carried out as planned. *Reference: QMSP-1002 Quality Records Matrix.*

8.0 Operation

8.1 Operational Planning and Control

Operational Planning at Precision Mold and Tool 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. Project management is satisfied by utilizing QMSM-1011 Contract Review. All products at the company go through the Contract Review process. This provides for the proper planning, approving and verifying of the product realization process throughout the company for all products at all times. This process also works in harmony with the Risk Management procedure to determine the risks associated with the product realization process at the company. Precision Mold and Tool controls ensure all outsourced processes are controlled (see 8.4).

8.1.1 Risk Management

Risk Management is handled throughout the entire QMS. The Quality Manager, Planner and inspectors are responsible for Risk Management. See QMSM-1009, Order Entry, QMSM-1011, Contract Review and QMSM-1026, Quality Control. During Contract Review, new orders are assessed for special requirements. During Order Entry, the shop router is generated and includes all outside processes. During Quality Control, all drawings and the shop routers are reviewed to ensure accuracy. These steps will identify any risks and will be managed as appropriate by the applicable personnel. There is a documented procedure, QMSP-1008 Risk Management. The purpose of this procedure is to specify a risk management process for the company to identify the hazards associated with manufacturing devices and to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls. This procedure/process is intended to establish and document a risk management plan in accordance with the risk management process. This procedure along with the resultant records of the risk assessment will comprise the risk management file.

- Risks are clearly defined when performing the process failure mode and effects analysis.
- Any information discovered during in-house testing that could have an adverse effect on risk management will be entered into the corrective/preventive actions portion of the FileMaker and or E2 quality module.

- Any risks which exceed the acceptance criteria will be identified, implemented and managed by recording a corrective action report in the FileMaker and or E2 system.
- Acceptance of risks remaining after implementation of mitigating actions will also be clearly identified in the same corrective action report.

8.1.2 Configuration Management

There is a documented procedure, QMSP-1007 Configuration Management. The purpose of this procedure is to document the company's product's configurations. It provides identification and traceability, the status of achievement of its physical and functional requirements, and access to accurate information in all phases of the life cycle.

- Configuration management planning consists of requirements review, order entry and then the requirements are transferred to the job traveler and the router for every part.
- Configuration identification is established for all parts by the job traveler and the router.
- Change control is implemented in the contract review process. All contract changes are communicated by the customer in writing. Drawings, travelers, routers and orders are then updated.
- All of the product initial physical and functional requirements as well as the changes of any of the products are recorded in the FileMaker and or E2 system according to QMSM-1009 Order Entry and QMSM-1011 Contract Review.
- A physical configuration audit is accomplished; this is a formal examination to verify that a configuration item has achieved the physical characteristics specified in its product configuration information. This is achieved at the company by sending all products through final QC Inspection.

8.1.3 Product Safety

Precision Mold and Tool uses Risk Management and Configuration Management to ensure that any safety critical items, as identified by the customer, are manufactured to meet drawing and customer requirements.

8.1.4 Prevention of Counterfeit Parts

Precision Mold and Tool has a process to prevent counterfeit or suspect counterfeit parts from being used and their inclusion in products delivered to the customer. Thorough review of documentation, hardware and suppliers prevents counterfeit parts from being used. Any suspected counterfeit part is reported using QMSP-1005, Control of Nonconforming Product.

8.2 Requirements for Products and Services

At Precision Mold and Tool, Requirements for Products and Services, which includes Customer Communication, Determination of Requirements, Review of Requirements, and Changes to Requirements for Products and Services, 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 FileMaker and or E2 Shop System.

8.2.1 Customer Communication

The company has established processes and procedures for communicating with customers. They include at a minimum:

- Product information, this is accomplished by following the procedure for Requirements Review.
- Enquiries, contracts or order handling, including amendments. This is accomplished via the Contract Review process.
- Customer feedback, including complaints. This is accomplished by utilizing the customer survey and the Feedback feature of the FileMaker and or E2 system.
- Handling or controlling customer property. See section 8.5.3
- Establishing specific requirements for contingency actions, when relevant.

8.2.2 Determining the Requirements for Products and Services

The records are evident through the signed acknowledgement of the order, and are defined by the following procedure QMSP-1003 Requirements Review. During the requirements review process the following will be considered:

- Statutory and regulatory requirements.
- Any additional requirements necessary by the organization.
- Special requirements of the products.
- Customer requirements, including delivery and post-delivery requirements.
- Capability of Precision Mold and Tool to meet the requirements.
- Operational risks have been identified.
- Requirements not stated by the customer but necessary for the intended use.

8.2.3 Review of Requirements Related to the Product

The company reviews the product requirements with the customer according to QMSP-1003, Requirements Review procedure. If it is determined that some of the customer requirements cannot be met or can only partially be met, Precision Mold and Tool will negotiate a mutually acceptable requirement with the Customer. If the customer does not provide a documented statement of their requirements, Precision Mold and Tool will confirm customer requirements prior to acceptance. Results of the review and any new requirements for products and services based upon the review will be documented in accordance with QMSP-1003, Review Requirements. Prior to acceptance of a purchase order, the following items are ensured:

- The product requirements are defined, including delivery and post-delivery activities, if required.
- Requirements not stated by the customer, but necessary for the intended use, when known are defined.
- Requirements specified by Precision Mold and Tool are defined.

- Statutory and regulatory requirements applicable to products are defined.
- Contract or order requirements different from those previously expressed are resolved.
- Special requirements for the product are defined.
- Risks are being assessed according to the Risk Management procedure.

8.3 Design and Development of Products and Services

Not applicable to Precision Mold and Tool. All products are made per customer specifications.

8.4 Control of Externally Provided Processes, Products, and Services

8.4.1 General

Precision Mold and Tool ensures that externally provided process, products and services conform to requirements. When customer designated or approved external providers are required, Precision Mold and Tool ensures that they are used. The control of work transfers is established within the shop routers. See QMSM-1009, Order Entry and QMSM-1005, Purchasing for more details. Product requirements will be defined and recorded as well as conveyed to the vendor. All products will be inspected upon return. In the event of the product not being acceptable, a CAR (Form QMSF-1022 – Corrective Action Report) will be utilized to track and rework the product, if necessary. Risk and controls of processors and their sub-tier providers are managed through QMSP-1004, Supplier evaluation and QMSP-1010, Supplier Quality Assurance Requirements.

Note: The terms External Provider, Supplier and Vendor are used interchangeably at Precision Mold and Tool.

8.4.1.1 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 QMSM-1005 Purchasing.
All suppliers are listed in accordance with QMSP-1004, Supplier Evaluation. Conducting supplier evaluations/assessments and maintaining records of suppliers' capability, performance, and necessary follow-up actions are specified in QMSP-1004 Supplier Evaluation. The Supervisors/Managers 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.
The Purchasing Department is responsible for the following activities:

- At Precision Mold and Tool there is a register of suppliers. It is maintained in the FileMaker system under New Vendors. All suppliers in this list are designated as approved, conditional or disapproved. All suppliers are evaluated according to QMSP-1004 Supplier Evaluation. The suppliers are being rated on the following criteria, on-time delivery and the number of rejected shipments.

- In the event of unacceptable supplier performance, a Corrective Action per QMSP-1006 may be initiated. The purpose of these forms 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 Quality Department, or designee, to document, follow-up, track, and confirm supplier corrective actions taken. The Quality 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.
- If and when a customer requires a special process source/sources, the source will be documented in the purchase order by Precision Mold and Tool. It is the responsibility of the Quality Manager to ensure that only customer approved special processors are utilized to perform outside services. In addition, the Quality Manager will ensure that the outside service provider adheres to this requirement to the next sub-tier supplier, if necessary, and that the requirement always flows down to suppliers at all levels. This will be stated on the Purchase Order.
- As defined by the supplier evaluation procedure, it is the responsibility of the current members of the management team, to approve, update status and control suppliers. It is also their responsibility to maintain any and all records required when dealing with suppliers.
  See QMSP-1004 for the selection and approval process.

8.4.2 Type and Extent of Control

QMSP-1010, Supplier Quality Assurance Requirements, defines the type and extent of control placed on externally provided processes, products and services and ensures that they do not adversely affect the organizations ability to consistently deliver conforming products and services to its customers.
The Supervisors/Managers 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 and documented on the shop routers and form ST-F01, Receiving Form.
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 Precision Mold and Tool or the customer at the supplier's premises.

8.4.3 Information for External Providers

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 and QMSP-1010, Supplier Quality Assurance Requirements.
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 and the release of products and services.
- 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 and disposition 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. Requirements for the supplier to flow down to sub-tier suppliers the applicable requirements in the purchasing documents, including key characteristics where required.
- Record retention requirements.
- Right of access by the organization, their customer, and regulatory authorities to all facilities involved in the order and to all applicable records.

8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision

General manufacturing and service operations are controlled and tracked in Precision Mold and Tool's information system, the FileMaker and/or E2 Shop System.

Supervisors/Managers 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. This is accomplished by issuing job packets to production for all jobs. All job packets should contain a drawing or print of the product, if available, and a shop router.
- Availability of the necessary procedures, forms and work instructions (See QMSP- 1001 Control of Documents). Process flow charts, travelers, routers are in use.
- Availability and use of monitoring and measuring devices - described in Sections 8.5.1.1
- Implementation of monitoring and measurement activities - described in Section 8.5.1.1
- At Precision Mold and Tool the use of suitable equipment will include setup pieces, jigs, fixtures and test fixtures if necessary. Then environment for manufacturing is suitable for the products manufactured.
- Employees that are trained to the requirements based on job descriptions.
- Validation of special processing. (See 8.5.1.2)
- Human error prevention is implemented throughout production. Shop routers define all processing a part requires.

- Product release and delivery is dependent upon the successful completion of first piece, in-process and final inspection. There are no planned post-delivery activities at Precision Mold and Tool. In the event that a customer would return a product, the return would be tracked and recorded utilizing QMSP-1006, Corrective Action.
- Criteria for workmanship at Precision Mold and Tool is defined within our job descriptions.
- All product in production is accounted for by ensuring that the job traveler accompanies the product throughout production. Nonconforming product is controlled according to QMSP-1005, Control of Nonconforming Product. Should a situation occur where a job or an order is split during production, the traveler will be copied to accommodate product moving in different directions within production.
- All critical items are identified on the shop router for control and monitoring purposes.
- The method of measurement is defined on the inspection report (AS9102) and/or shop router.
- Inspection activities occur throughout production as required by process maps.
- Completed shop routers provide evidence of completed inspection operations as planned, or as otherwise documented and authorized. Records of all inspection activities at Precision Mold and Tool are being maintained by retaining all inspection reports.
- FOD/FOE (Foreign Object Detection/Foreign Object Elimination) training will be provided to all production personnel at Precision Mold and Tool in accordance with QMSP-1012.
- Due to the nature of the products produced at Precision Mold and Tool, utilities and supplies (e.g. water, compressed air, electricity, chemical products) have no effect on conformity to product requirements. Therefore, it is not necessary to monitor or carefully control these utilities and supplies
- Identification and recording of products released for subsequent production use pending completion of all required measuring and monitoring activities, to allow recall and replacement if required is documented on the shop router.

Planning at Precision Mold and Tool includes consideration for implementing processes to manage critical items like process control and identification of key characteristics. This is accomplished by performing a Process Failure Mode and Effect Analysis, as required by QMSP-1008. Special tooling and or test fixtures are designed and utilized as necessary. In-process inspection/verification points are established for all products as necessary.

8.5.1.1 Control of Equipment, Tools and Software Programs

At Precision Mold and Tool, production equipment, tools and software programs used to automate and or control/monitor product realization processes will be validated prior to use in production and will be maintained on an ongoing basis. All machines at Precision Mold and Tool undergo periodic maintenance. Records are kept on file. All tooling at Precision Mold and Tool will be stored on proper shelving and undergo periodic preservation/condition checks. Records of this activity will be maintained.

8.5.1.2 Validation and Control of Special Processes

Special processes are processes where the resulting output cannot be verified by subsequent monitoring or measurement. Special processes shall be reviewed and approved by the President and Quality Manager before production can begin. The following will be reviewed prior to approval:

- Conditions to maintain approval will be determined
- Approval of facilities and equipment
- Qualification of persons
- Use of specific methods and procedures for implementation and monitoring the processes
- Requirements for documented information to be retained.

Once a special process is approved, the Quality Manager is responsible for ensuring that all associated QMS documentation is current, including process maps, forms and documents, as required. Records of the approval are maintained in Management Review Meeting minutes. Welding is the only special process currently performed at Precision Mold and Tool. See QMSM-1036, Welding.

8.5.1.3 Production Process Verification

Precision Mold and Tool establishes and maintains documented procedures, work instructions, 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. 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. 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.

Measurement requirements for product acceptance will be documented on the router or the inspection report and will include at a minimum:

- Criteria for acceptance and/or rejection.
- Where in the sequence measurement and testing operations are to be performed.
- Required records of measurement results (at a minimum indication of acceptance or rejection).
- Any specific measurement instruments required and any specific instructions associated with their use.
- At Precision Mold and Tool, first article inspections are performed at every production process for all products. Should engineering changes, manufacturing process changes or tooling changes occur, the first article inspection will take place again. Records of inspection results are kept on file.

If critical items, including key characteristics, are identified by the company, the company will ensure that they are controlled and monitored during product inspections.

Should the company utilize sampling inspections the sampling plan will be justified based on statistical principles and appropriate use (i.e. matching the sampling plan to the criticality of the product and to the process capability).

Should any product at the company be released to production prior to determining the monitoring and measuring requirements this will be noted on the job traveler. This would enable the company to identify the product and recall and replace the product if it is subsequently found that the product does not meet the requirements.

Should the company be required to demonstrate product qualification the company will ensure that records provide evidence that the product meets the defined requirements.
Should any product at the company require documentation to be delivered with the product to the customer, this will be detailed in special packing instructions on the shipping step of the router.

8.5.2 Identification and Traceability

Precision Mold and Tool 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 Precision Mold and Tool's FileMaker and/or E2 Shop System software. Raw materials are identified with, at a minimum, the following information on at least 2 opposing ends:

- Receiver Number
- Job Number
- Date

Additional information may include Material description and Lot/Heat number. Methods for identification include labels, permanent marker, paint and tags. Materials that do not have traceability may be identified with red paint and kept for use for tooling or shop use.
Materials that have traceability must be kept separate from materials without traceability.
Stamps are controlled by the Quality Manager and records of stamp issuance are kept on file.
Precision Mold and Tool will maintain the identification of the configuration of the product to identify any differences between the actual configuration and the agreed configuration. These records will be maintained in the FileMaker and/or E2 system.
When considering traceability requirements at Precision Mold and Tool, the following criteria should always be considered:

- Should the identification be maintained throughout the entire product life?
- Does the company have the ability to trace all products from the same batch of raw material to delivery?
- For an assembly, can the company trace the assembly's components to the assembly and then to the next higher assembly?
- For a product, can the company retrieve a sequential record of its production (manufacture, assembly, inspection/verification)?

8.5.3 Property Belonging to Customers or External Providers

Precision Mold and Tool exercises care with customer and externally provided property and ensures that the property is identified, verified against specified requirements, protected, and safeguarded until required for use or incorporated into our products. If customer or external provided property is lost, damaged, or otherwise found to be unsuitable for use, Precision Mold and tool will document the findings on a Form QMSF-1022 – Corrective Action Report, and the customer will be notified. Customer and external provided property may include intellectual property, materials, components, tools and equipment premises or personal data.

8.5.4 Preservation

Employees and the Supervisors/Managers 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.
Precision Mold and Tool ensures the preservation of product in the following ways:

Identification: Specific details on the identification of product at Precision Mold and Tool are described in Section 8.5.2 (Identification and Traceability).

Handling: Precision Mold and Tool'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: Precision Mold and Tool maintains facilities, equipment, and designated areas to store material in a manner that prevents loss of product value. Methods and means appropriate for ensuring proper receipt of material, and proper dispatch to and from the pertinent areas are required and used. Supervisors/Managers 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, Precision Mold and Tool is responsible for packaging and preservation during transit, including delivery to destination.

Preservation of product shall also include where applicable:

- Provisions for cleaning
- Prevention, detection and removal of foreign objects
- Special handling and storage for sensitive products
- Marking and labeling including safety warnings and cautions

- Shelf life control and stock rotation
- Special handling and storage for hazardous materials

8.5.5 Post-Delivery Activities

Not applicable. PMT does not perform Post-Delivery Activities.

8.5.6 Control of Changes

At Precision Mold and Tool, the Quality Manager is responsible for authorizing all production process changes due to a nonconformance. The production process changes, e.g. changes affecting processes, production equipment tools or software programs, will be controlled and documented by the Quality Manager. This will be accomplished in accordance with QMSP-1005, Control of Nonconforming Product. The results of these changes will be assessed to confirm the desired effect has been achieved without adverse effects to product conformity by completing the closure step on the NCR and/or CAR.

8.6 Release of Products and Services

Product release and delivery is dependent upon the successful completion of first piece, in-process and final inspection, unless otherwise agreed upon with the customer. All shop routers include a final inspection operation and inspector's acceptance stamp. When required by the customer, detailed inspection reports are provided with the final product.

8.7 Control of Nonconforming Outputs

The Quality Manager is responsible for implementing and maintaining QMSP-1005 Control of Nonconforming Product to ensure that products that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

9.1 Performance Evaluation

9.1.1 General

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 Supervisors/Managers and is performed according to QMSM-1008 Internal Audit and QMSP-1005 Control of Nonconforming Product at regular intervals.

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.

In the event of process nonconformity, Precision Mold and Tool will:

- Take appropriate action to correct the nonconforming process by entering a Corrective Action Report in FileMaker and/or E2 and resolve the problem.

- Evaluate whether the process nonconformity has resulted in product nonconformity.
- Determine if the process nonconformity is limited to a specific case or whether it could have affected other processes or products.
- Identify and control any nonconforming product.

9.1.2 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. Information to be monitored and used to evaluate customer satisfaction should include product conformity, on-time delivery, complaints and requests for corrective actions. This information will be evaluated at management review and Corrective Action Reports issued to resolve customer issues.

9.1.3 Analysis and Evaluation

Each Supervisor/Manager 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. As necessary, Precision Mold and Tool uses statistical techniques, process capability measurements, statistical process control and failure mode and effect analysis.
Data is collected and analyzed at the Management Review Meeting accordingly to evaluate:

- Customer satisfaction.
- Conformity to product requirements.
- Effectiveness of planning
- Effectiveness of actions taken to address risks and opportunities
- Performance of external suppliers, including capability, on-time delivery, conformance to specified requirements and cost.
- Characteristics and trends of processes and products, including opportunities for preventive action.

9.2 Internal Audit

Precision Mold and Tool 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 the quality management system requirements and the requirements of AS9100.
- To determine the overall effectiveness of the quality management system as implemented and maintained.

The management representative (Lead Auditor) is responsible for overseeing all internal audit activities. The Lead auditor, 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. The Ad-Hoc audit will be based upon the importance and status of the element or process, changes affecting the organization, and the results of previous audits.

The Lead auditor, 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 event of a nonconformance or weakness, either in the quality management system and procedures, or the performance and adherence to those systems and procedures, the Lead auditor, or designee, will initiate a Corrective Action Report per QMSP-1006.

The Department Supervisor/Manager 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.

The Quality Manager, or designee, ensures that all records relating to the audit are kept in accordance with QMSP-1002 Quality Records Matrix.

The Lead auditor, or designee, reports audit results to relevant management and/or during Management Review Meetings.

9.3 Management Review

9.3.1 General

Top management conducts a review of the quality management system through "Management Review Meetings" 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 AS9100. The assessment also addresses the quality management systems alignment with the strategic direction of Precision Mold and Tool.
- 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.

9.3.2 Management Review Inputs

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

- Status of follow-up actions from previous management reviews;
- Changes that could affect the quality management system;
- Information on the performance and effectiveness of the quality management system, including trends in:
- Customer satisfaction and feedback
- Status of quality objective results
- Process performance and conformity of products
- Nonconformities and corrective actions
- Monitoring and measurement results
- Audit results
- Performance of external providers
- On-time delivery performance
- Adequacy of resources
- Effectiveness of actions taken to address risks and opportunities
- Opportunities for improvement

9.3.3 Management Review Outputs

The Management Representative creates written meeting minutes summarizing the Management Review activities, the conclusions reached and action items identified. These minutes are used to guide and improve our quality management system at Precision Mold and Tool 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.
- Risks identified

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 Precision Mold and Tool's quality management system and are maintained.

10. Improvement

10.1 General

Each Supervisor/Manager is responsible to determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction in his or her respective areas. These include:

- Improving products and services to meet requirements as well as future needs and expectations
- Correcting, preventing and/or reducing undesired effects
- Improving the performance and effectiveness of the quality management system

Correction and Corrective Actions are documented on QMSF-1013.1 – Discrepancy Log, QMSF-1021 – Nonconformance Report and/or Form QMSF-1022 – Corrective Action Report. Continual improvement, innovation and re-organization activities are discussed during meetings. Any major changes affecting the quality management system are documented during Management Review Meetings.

10.2 Nonconformity and Corrective Action

Corrective action at Precision Mold and Tool 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. When a nonconformity occurs, Precision Mold and Tool will take action to control, correct and deal with the consequences as described in QMSP-1005 – Control of Nonconforming Product and/or QMSP-1006 – Corrective Actions.

Corrective actions taken are appropriate to the effects of the nonconformities encountered and are documented on QMSF-1022 – Corrective Action Request. Corrective actions are determined by evaluation of the following:

- Reviewing and analyzing the nonconformity
- Determining the causes of the nonconformity, including, as applicable, those related to human factors
- Determining if similar nonconformities exist, or could potentially occur

The results of the evaluation determine any need for action to eliminate the cause of the nonconformity in order to prevent recurrence and to ensure it does not occur elsewhere.

The Quality Manager, or designee, is responsible for implementation of any actions required as a result of a Corrective Action.

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 the company 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.
- Flowing down corrective action requirements to a supplier when it is determined that the supplier is responsible for the nonconformity.
- For specific action where timely and/or effective actions are not achieved, see Table 1 in QMSP-1006 Corrective Actions.
- Determining if additional nonconforming product exists based on the causes of the nonconformities and ensuring that all nonconforming product is recorded in a Nonconformance Report on the company server and that the reports are maintained as records.

Customer feedback (positive comments and complaints) are recorded and reviewed through the Feedback Module within the FileMaker and or E2 Shop System. This ensures that customer complaints are documented and managed appropriately at Precision Mold and Tool, and that any resulting product or service concerns are communicated to the appropriate area(s) of the company. CAR'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 Supervisor/Manager 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 company server and are 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 Actions.

10.3 Continual Improvement

It is the overall responsibility of top management to continually improve the suitability, adequacy and effectiveness of the quality management system. Management reviews the results of analysis and evaluation and the outputs from management review to determine if there are needs or opportunities that shall be addressed as part of continual improvement. Management also monitors the implementation of improvement activities and evaluates the effectiveness of results. This is completed through various methods, including during Management review meetings.