MOLDWORKS INC

Quality Policy Manual

Follows: ISO 9001:2000

Moldworks Inc.

8/31/19

Moldworks Inc.
10550 County Road 81, Suite 208
Maple Grove, Minnesota 55369

APPROVAL

Moldworks Inc. developed and implemented a quality management system to better satisfy the needs of its customers and to improve management of the company. The quality system complies with the international standard ISO 9001:2000. The purpose of this manual is to define and describe the quality system, to define the authorities and responsibilities of the management personnel affected by the system, and to provide general procedures for all activities comprising the quality system, and to present our quality system to our customers to inform them what specific controls are implemented to assure product quality.

Approved:

Patrick J. Krapfl

1.0 INTRODUCTION

Moldworks Inc. is a full function mold shop providing our customers with all the necessary resources to design, manufacture, and service custom precision plastic molds: committed to quality service, customer satisfaction and employee involvement.

To help accomplish this mission our Quality Policy is**:**

When a team of dedicated individuals makes a commitment to act as one… the sky is the limit! Above and Beyond

The adoption of this quality management system by Moldworks Inc. is a strategic decision influenced by the needs of our customers and our organization. The quality system requirements specified by the International Organization of Standards (ISO) ANSI/ISO/ASQ Q9001:2000, Quality Management Systems – Requirements is the standard to which this quality system is modeled.

1.1 PROCESS APPROACH

ISO 9001:2000 promotes the adoption of a process approach when developing, implementing, and improving the effectiveness of a quality management system. The focus on this approach is intended to enhance the ability to satisfy the customer by customer requirements.

In this Quality Manual, Moldworks Inc. has identified the key processes which interact and provide the framework for our organization. Each process uses organizational resources and are defined, implemented, and managed to enable the effective transformation of customer and organizational inputs into the products and services which provide economic satisfaction for all those involved.

As noted in the ISO 9001:2000 standard, this process driven approach emphasizes the importance of:

- Understanding and meeting requirements,
- The need to consider processes in terms of added value,
- Obtaining results of process performance and effectiveness, and
- Continual improvement of processes based on objective measurement.

1.1.1 Customer Requirements

Moldworks Inc. prides itself on customer satisfaction. Extensive quality planning has been accomplished in everything we do to ensure each requirement specified by the customer is met. Every effort is made to meet or exceed our customer's expectations.

1.1.2 Added Value

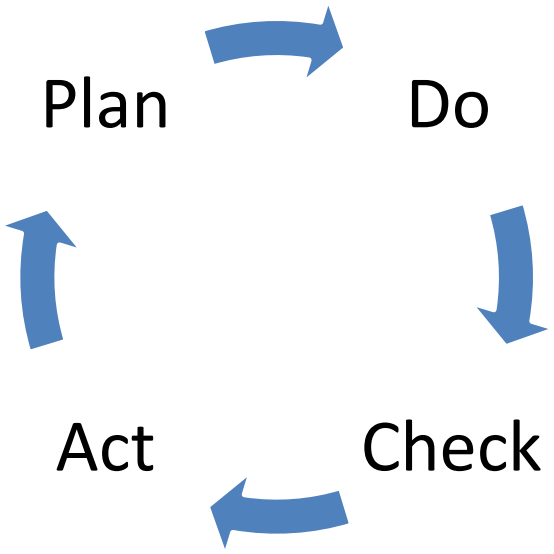
Each process is evaluated on a continual basis to ensure that value is added in the end product. If added value is not achieved, those processes are modified with the savings extended to our customers.

1.1.3 Process Measurement

Each process is measured against planned quality objectives to ensure continued effectiveness. Individual functional representatives have been empowered to define their quality measurement objectives and continually measure and monitor the overall effectiveness of their respective processes.

1.1.4 Continuous Improvement

All processes are monitored on a continual basis to ensure a continual feedback mechanism is employed to guarantee that requirements specified by the customer are achieved through product realization thereby providing customer satisfaction. The PDCA cycle described in ISO 9001:2000 is employed by Moldworks Inc. as the principal means to ensure continual improvement opportunities are explored.



2.0 MOLDWORKS, INC.

TOTAL MANUFACTURING SOLUTIONS

Moldworks Inc is a precision machining company that manufactures custom parts to the customer's specifications using a variety of materials and processes. Moldworks Inc. provides close tolerance, highly technical, precision machining and manufacturing services; to primarily medical, defense, industrial, and aerospace industries. Moldworks Inc. provides prototype and tooling capabilities with in-plant engineering and design services.

2.1 COMMITMENT TO EXCELLENCE

Moldworks Inc. has a demonstrated commitment to excellence. Moldworks Inc. provides the customer with a "Turnkey" solution to totally manage their entire precision machining and manufacturing requirements.

Moldworks Inc. highly experienced staff covers the full spectrum of manufacturing processes: R&D prototyping, precision machining, tooling, fixturing, support processes, outside< processes, (plating, heat treating), and assembly.

As a vertically integrated company, Moldworks Inc. manages the complete process from initial request for quote (RFQ) to 100% quality, on-time products delivered to the customer at a competitive price with guaranteed customer satisfaction.

Moldworks Inc. offers electronic data exchange for most design software file formats, i.e., IGES and DXF. We have extensive experience in machining stainless steel, Be Cu, tool steel, copper, brass, aluminum, graphite, plastics and more.

With regard to technology and quality, Moldworks Inc. will utilize its expertise in manufacturing methodologies and processes to manage and produce all of your precision machining requirements ensuring the highest level of quality to you the customer.

Moldworks Inc. will assure responsiveness and customer satisfaction. The owner, Pat Krapfl, will be the main contact dealing with all customer related issues: quoting, lead-time, purchase orders, scheduling, prioritization, and delivery. With over thirty-five years in manufacturing and as a business owner, he will ensure you are aware of any potential issues that could affect the finished product. Moldworks Inc. will provide its customers with an industry competitive lead time and 100% on-time delivery.

Moldworks Inc. has a very solid understanding of all cost components and will provide the customer with very competitive pricing through Continuous Process Improvement (CPI) methodology.

2.1.1 Value Proposition to the Customer

- Moldworks Inc. totally manages the entire process and thereby minimizes customer resource requirements.
- Moldworks Inc. provides a unique blend of technical expertise, materials and manufacturing management, and business savvy.
- Moldworks Inc. relationship based philosophy focuses on providing the highest level of Customer Satisfaction possible.
- Moldworks Inc. low overhead structure makes the company extremely flexible and responsive to the needs of the customer.

We would like to invite you to visit our facility. We're confident you will be favorably impressed! These commitments are further described in this quality manual and are supported using on-going measurement and analysis techniques to ensure each objective is achieved.

2.1.2 Mission

When a team dedicated individuals makes a commitment to act as one…
*the sky is the limit**!***

2.1.3 Vision

Moldworks Inc is a leader of precision machining and value-added manufacturing services; attracting and employing a team of the most technically skilled individuals in the industry, who are committed to the mission, values, and strategy of the company.

2.1.4 Core Values

- We will produce quality every time.
- We will demonstrate pride of ownership in everything we do.
- We will strive to be on the forefront of technology.
- We are committed to on-time delivery.
- We will value each other and recognize individual contributions.
- We are committed to excellence in everything we do.
- We are committed to training and development
- We will respect our environment.
- We will value the cost of quality
- We will do everything to resolve a customer complaint.

2.2 Manufacturing Operations & Capabilities

Moldworks Inc. possesses the capability to fabricate a wide variety of products. We utilize a variety of quality equipment for speed, accuracy, dependability, and advanced technology.

2.2.1 Manufacturing Equipment

1- Yasda YBM 640V Ver.111
1- Roku-Roku HC-658 II
1- Makino F5 Machining Center
1- Makino EdgeII CNC EDM (using EROWA Tooling)
1- VMX30 CNC 30” x 18” x 28” Machining Center
1- MITSUI 6 – 12 Grinder with OPTIDRESS .00005 Digital Readout
1- EROWA Tooling system
1- KENT 6 – 14 Grinder
1- 10” x 30” Lathe
2- BRIDGEPORT Mill with MILL PWR CNC
1- HARIG ULTRA GRIND
1- DECKEL Tool Cutter Grinder
1- Mold Assembly Bench with 4000 lb Capacity Traveling Hoist
All related Tooling

2.2.2 Quality Assurance/Metrology Equipment

1- S-T Industries 8700 Video Inspection System
1- MITUTOYO Tool Scope .00005 Digital Readout
3- MITUTOYO Drop Indicator .0001 Digital Readout
1- 36” x 48” Inspection Grade Surface Plate
4- 18” x 24” Inspection Grade Surface Plate
2- Gage Block Sets
1- Pin Gage Set (.011 to .750)
1- 4” x 8” Optical Comparator .0001 Digital Readout

2.2.3 Design Equipment

3- Creo Parametric
2- Cam Tool

3.0 TERMS & ABBREVIATIONS

TERM	*DEFINITION*
Deburr	An operation that requires the removal of sharp edges through the use of deburring tools
Final Inspection	A process performed by Quality Control prior to shipment
First Article Inspection	A process performed by Quality Control on the 1st part of each new method of operation
In Process Inspection	A process performed by the Quality Control Inspector and fabrication personnel to maintain quality
Quote/Estimate	The process of developing a price based on customer specified quantities and procedures
Job Folder	A set of instructions used to fabricate a part according to the customer's specifications

ABBREVIATION	DEFINITION
ANSI	American National Standards Institute
ASQ	American Society for Quality
CAD	Computer Aided Design
CAM	Computer Aided Manufacturing
CNC	Computer Numerical Control
ISO	International Organization of Standards
MRB	Material Review Board
MRP	Material Resource Planning
PDCA	Plan, Do, Check, Act
QA	Quality Assurance
RMA	Return Material Authorized
SPC	Statistical Process Control

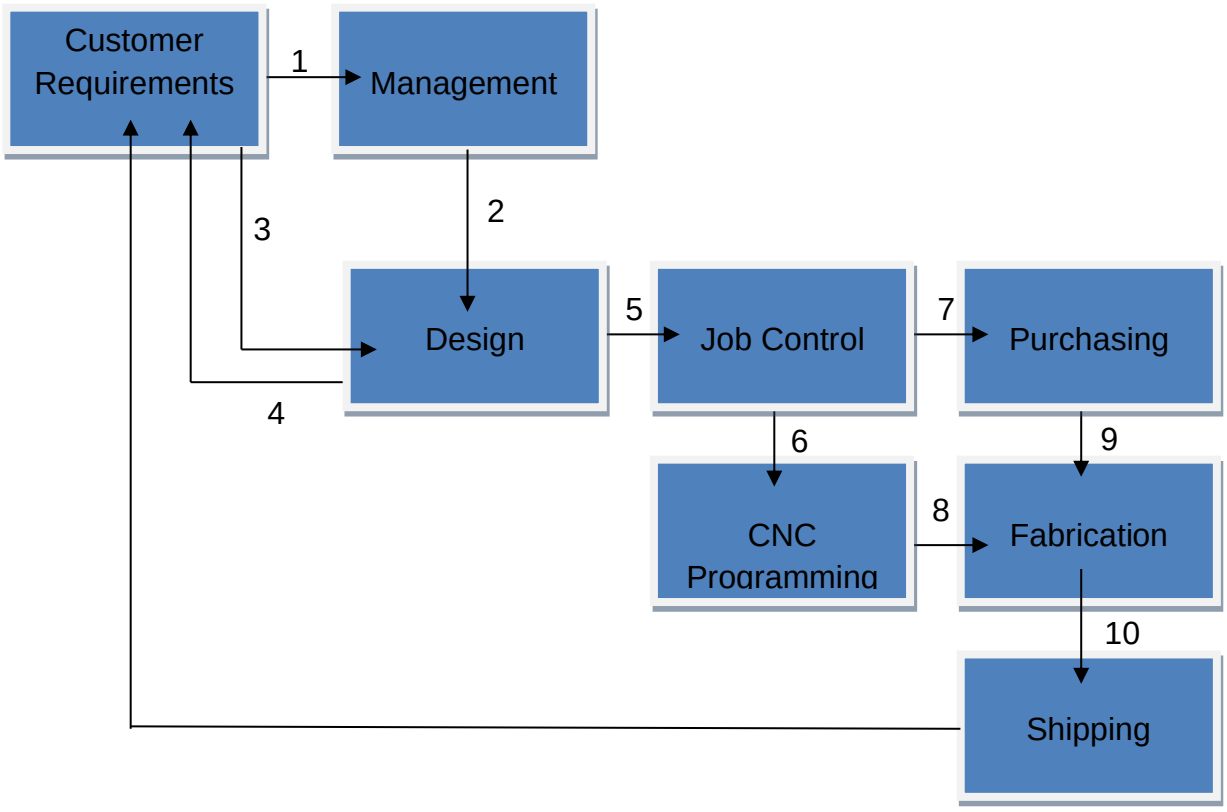
4.0 Quality Management System

With a proven track record and a state-of-the-art production facility, we're confident that Moldworks Inc. will be everything that a customer is looking for in a vendor.

The quality management system described within this document, and the processes that comprise this system, have been defined to support our goal of having a customer-oriented organization. This documented quality management system will be continually evaluated through the management review process and internal quality auditing in an effort to continually assess the overall effectiveness.

4.1 Organizational Processes

Moldworks Inc. has identified several key processes that are defined and documented by this quality management system. Those processes, and their interactions with each other are depicted in the drawing provided below



The following paragraphs explain the relationships of the major processes noted in the diagram above. The numbers in the paragraphs below correspond to the numbers noted in the diagram.

1) The customer requirements are provided to Moldworks Inc. management via a customer purchase order. The purchase order includes any applicable drawings of the final product as well as any special instructions that are needed to fabricate the part and fulfill the order.

2) Moldworks Inc. executive management evaluates the request to ensure the criteria specified by the customer can be met. If the request is for a new part, a quote is developed to ensure each manufacturing process is identified. If the request is for a part that has been previously produced by Moldworks Inc., then the cost data from the previous sale is analyzed to ensure profitability margins are still appropriate. An evaluation is made to ensure the methods utilized by Moldworks Inc. are used to ensure that both the operation and control of the processes noted below are effective.

3) When Moldworks Inc. management has completed their evaluation, the quote and purchase order is forwarded to operations for further processing. (See interface description # 6)

4) Management evaluates the customer request to ensure the availability of resources and the information necessary to complete the request are available. Production is notified of the pending job.

5) Specific customer requirements with regard to price, due date, and drawing revision numbers are negotiated by management with the customer.

6) When Moldworks Inc. management has completed the evaluation, the quote and purchase order is forwarded to operations for further processing. (See interface description # 3) Operations processes the purchase order information and forwards an acknowledgement of the final purchase order to the customer.

7) Operations notifies job control when the acknowledgement is received from the customer.

8) Production supervises CNC programming, fabrication, and shipping.

9) Job control notifies CNC programming of the status of a new purchase order. If the part is new, CNC programming develops the program script for the CNC machines. If the part has been previously fabricated by Moldworks Inc., then the part revision number is validated. If any revisions have been made, then the CNC program script is updated to reflect the changes. Job Control schedules and

releases the job for production. The CNC programmer is provided with the part requirements.

10) Job control notifies purchasing of the new job folder to perform an evaluation of the existing raw material. If needed, additional raw material is purchased to support the job

11) When CNC programming is complete, fabrication is notified. Fabrication follows the steps noted on the job folder to produce the part. Once validation has been performed, then the remaining quantities of parts for that job are authorized for completion.

12) Upon completion of fabrication, quality control is notified to perform final inspection. Upon acceptance of the final inspection, shipping is notified.

13) Upon completion of the shop order, shipping takes action as directed by the customer.

4.1.1 Out-Sourcing

Moldworks Inc. has identified functions that are out-sourced to complete the fabrication process. Those functions are:

- Heat Treating
- Plating
- Mold Bases
- Wire Cutting
- Welding

For most orders that are sent out for these functions are returned to Moldworks Inc. prior to shipment to the customer. If the customer requires direct shipment, Moldworks Inc. will make special arrangement with the outsourced vendor to ensure quality requirements are met prior to shipment.

4.1.2 Process Monitoring, Measurement, & Analysis

Moldworks Inc. maintains several pieces of measurement data which is continually analyzed to ensure the processes noted above are effective. Primary areas for measurement include, but are not limited to the following:

- Sales
- Operations
- Job Control
- CNC Programming
- Fabrication
- Shipping
- Receiving

4.1.3 Continual Improvement Initiatives

Through the use of careful planning and management oversight, several ongoing initiatives are planned and implemented to ensure Moldworks Inc. maintains a competitive and quality edge in the industry.

4.2 Documentation Requirements

4.2.1 Quality Policy

The following quality policy is reflective of the primary issues that are important to our customers and therefore are reflected in our attitude to our business.

When a team of dedicated individuals makes a commitment to act as one… the sky is the limit Above and Beyond

4.2.2 Quality Objectives

Several quality objectives are sought as a result of implementing this quality management system. Each functional area noted in paragraph 4.1.2 above is monitored, measured, and analyzed to increase the overall effectiveness of each of those functions. In an effort to ensure the quality policy is validated, Moldworks Inc. must focus on offering a quality product for a reasonable price

4.2.3 Quality Documents

The quality system described in this quality manual includes references to those procedures that are mandated by ANSI/ISO/ASQ Q9001-2000 which are:

- Internal Quality Audits
- Control on Non-Conforming Product
- Corrective & Preventive Action
- Work Instructions (as required)

4.2.4 Quality Manual

4.2.4.1 SCOPE OF THE QUALITY MANAGEMENT SYSTEM

The scope of the certification for this quality management system includes all operations for Moldworks Inc. located in a single facility at:

10550 County Road, Suite 208
Maple Grove, Minnesota 55369

Operations at this facility include management, sales, job control, operations, purchasing, fabrication, and shipping.

4.2.5 Control of Documents & Records

Moldworks takes pride in keeping your information safe. We keep your documents and records in our job folder and/or electronically filed. Unless, however a document is needed by one of our approved sub-contractors to completed a work order.

5.0 Management Responsibility

Moldworks Inc. management is actively involved in the day-to-day operations of the company and strives to implement and maintain a work environment for the benefit of all parties involved. Senior management works diligently with their customers, current and future, to explore their ever changing needs and expectations.

Company policies have been crafted to increase awareness, motivation, and involvement of the people in the organization.

5.1 Management Commitment

Moldworks Inc. has a demonstrated commitment to the organization and its customers through a wide variety of actions and initiatives. Some of these commitments discussed in this quality manual and implemented within the company include:

- Adhering to a set of core values and expressing the company vision and mission through our actions.
- Procuring newer state-of-the-art fabrication equipment to ensure quicker and more accurate production capability.
- Assessing customer satisfaction through surveys.
- Communicating the need to be socially responsible and comply with all applicable laws and regulations.
- Establishment of the quality policy with an emphasis on continuous improvement.
- Establishing quality objectives for each major process within the organization to ensure effective utilization of all resources.
- Maintaining constant vigil over organizational resources through management review.

5.2 Customer Focus

Moldworks Inc. has defined and implemented processes to enhance the customer experience when placing orders. Specifically, a streamlined quoting process has been developed to allow Moldworks Inc. the ability to develop a quote using a standardized process and ensuring the customer is involved in the validation of the quote prior to the start of any fabrication activities.

5.3 Quality Policy

As noted earlier, the quality policy focuses on continuous improvement, quality, performance, reliability, delivery, and price. By illuminating these issues through the quality policy, several key ISO 9001 requirements have been addressed.

First, the quality policy is certainly appropriate for Moldworks Inc. and provides purpose for all the activities that are done in an effort to fulfill our customer's needs. Secondly, the policy clearly addresses the organizational commitment to comply with the most crucial customer requirements. Lastly, the quality objectives that are described in this quality manual were established to support the issues within the quality policy.

All Moldworks Inc. personnel from the newest employee to the employee that has been with the organization from its inception, is aware of the quality policy and its importance to the organization. When a new employee is hired, every effort shall be made to ensure the new employee is properly indoctrinated with the quality policy.

Finally, the quality policy will be reviewed bi-annually to ensure that the policy is suitable for the organization as the values and products of Moldworks Inc. continue to transform to the customers ever changing needs.

5.4 Quality Planning

Quality objectives that are relevant to the quality policy are described in paragraph 4.2.2 of this quality manual. The measurements of those objectives that validate the quality policy are described in paragraph 4.2.1 of this quality manual.

5.5 Quality Management System Planning

Planning for the quality management system is described in the introduction of this quality manual. Any changes to this quality system shall be evaluated to ensure the integrity of the quality system is maintained and that all requirements specified by ANSI/ISO/ASQ Q9001:2000 are adequately addressed.

5.6 Responsibility, Authority, & Communication

The following paragraphs are a description of the primary responsibilities to ensure that all the employees throughout the organization are given the responsibility and authority to enable them to contribute to the achievement of the quality objectives and to establish their involvement, motivation, and commitment.

5.6.1 Executive Management

- Formulates the quality policy
- Provides resources necessary to maintain the quality system
- Conducts management reviews of the quality system
- Defines personnel qualification requirements
- Implements measures to motivate personnel

5.6.2 SALES

- Receives customer orders
- Conducts market research to anticipate customer expectations
- Collects and analyzes customer satisfaction data
- Advertises and promotes company's products
- Monitors the quality of competitors

5.6.3 OPERATIONS

- Carries out order reviews
- Administrates stockrooms
- Ships products to customers
- Provides customer liaison and service
- Handles customer complaints
- Issues returned material authorizations (RMA's) to customers
- Maintains customer complaints log

5.6.4 JOB CONTROL

- Selects qualified suppliers and subcontractors
- Prepares and approves purchasing documents
- Monitors and assesses subcontractor performance
- Receives purchased products
- Ensures compliance with environmental regulations
- Carries out contract reviews with suppliers as needed. [See Appendix H]

5.6.5 PRODUCTION

- Develops process operator instructions
- Controls and monitors processes
- Conducts in-process inspections
- Maintains production equipment
- Has responsibility and authority to stop work when quality problems are detected
- Ensures compliance with safety regulations
- Participates in product quality planning
- Plans production facilities, equipment, and processes
- Develops production processes
- Verifies process capability
- Selects methods for process performance monitoring
- Conducts production trial runs
- Develops process set-up instructions
- Coordinates design and fabrication of tooling

- Schedules production
- Marks or verifies material and product identification

5.6.6 Administrative Employees

- Conducts new hire and safety training
- Maintains training records
- Maintains job descriptions for personnel

5.6.7 Production Employees

- Has responsibility and authority to stop work when quality problems are detected
- Ensures compliance with safety regulations
- Performs work as described on the traveler
- Maintains work area

5.7 Management Representative

The management representative has been designated by executive management with the overall authority and responsibility to establish, implement, and maintain the quality management system for Moldworks Inc. Specific responsibilities include:

- Reports to top management on the performance of the quality management system and any need for improvement
- Promotes the awareness of customer requirements throughout the organization
- Participates in product quality planning
- Establishes and maintains the quality management system
- Audits implementation and effectiveness of the quality system
- Initiates requests for, and follows up, corrective actions
- Maintains and calibrates measuring and test equipment
- Carries out subcontractor quality surveys and audits
- Performs inspections and testing
- Handles non-conforming products
- Coordinates document control activities
- Conducts quality training

5.8 Internal Communication

Executive management shall routinely post information on the company bulletin board, hand out informational flyers, and make announcements to all organizational personnel regarding the effectiveness of the quality system. Types of information include

feedback from customers, alert notices regarding issues that may arise on an ad-hoc basis, and routine measurement of the quality objectives.

Employees are encouraged to communicate with executive management regarding the need to improve the quality management system to ensure Moldworks Inc. maintains a competitive edge in the market.

5.9 Management Review

The purpose of management review is to provide for a system and instructions, and to assign responsibilities for scheduling, conducting, and recording management reviews.

5.9.1 Frequency and Scheduling

Management reviews shall be conducted at least semi-annually. Executive management determines the precise date for the review, coordinating with all Moldworks Inc. managers. Responding to changing or special conditions and events, executive management may, at his or her discretion, call for unscheduled reviews.

5.9.2 Attendance

Management review meetings are chaired by executive management and are attended by the management representative and by representatives from production, operations, sales, job control, and others at the discretion of executive management. Those members who are unable to attend will receive copies of the reviewed items and the action item list, and after reviewing the information, may submit their input and comments to executive management and the management representative.

5.9.3 Agenda

The agenda for management review meetings is prepared by the Management Representative. It is then reviewed by executive management and is distributed to the participating members prior to the meeting. At a minimum, the agenda shall include the items noted in the following paragraphs.

5.9.3.1 INTERNAL QUALITY AUDIT PROGRAM

The Management Representative presents results of the internal audit program. Following the presentation, managers discuss the results, compare them with the preceding period, and identify areas where improvement is required. The internal audit system and program are defined in Internal Quality Audits Procedure.

5.9.3.2 CUSTOMER FEEDBACK

Customer survey results shall be reviewed and assessed. Improvement opportunities or modifications to the quality management system will be developed with follow-up review periods identified.

The customer complaints will be assessed. New customer complaints that were received since the previous management review will be evaluated. In addition, all customer complaints will continue to be evaluated to determine if trends are developing.

5.9.3.3 PROCESS PERFORMANCE & PRODUCT CONFORMITY

The processes within Moldworks Inc. will continually be reviewed for effectiveness in meeting the customer's requirements. Non-conforming product reports will also be evaluated to determine if any long-term preventive actions or near-term corrective actions should be accomplished. The review will also ensure that each order was fulfilled in its entirety in the event that nonconforming product was shipped to a customer.

5.9.3.4 STATUS OF PREVENTIVE & CORRECTIVE ACTIONS

The status of new preventive and corrective actions since the previous management review meeting will be reviewed. All preventive and corrective actions will be evaluated to determine potential trends.

5.9.3.5 FOLLOW-UP FROM PREVIOUS MANAGEMENT REVIEWS

All action items from previous management reviews will be reviewed to ensure actions are being taken as appropriate. Modifications to current assigned responsibilities for each action item will be evaluated in consideration of the progress being made on each action item.

5.9.3.6 QUALITY MANAGEMENT SYSTEM

Based on all information presented and discussed during the management review meeting, the managers assess the continuing suitability, adequacy, and effectiveness of the quality system. In addition, opportunities for improvement are assessed with actions defined to ensure the improvement opportunities are acted upon. Finally, the quality policy and quality objectives are evaluated to ensure their effectiveness. Changes will be made as required.

The Management Representative presents data demonstrating progress toward achieving continuous improvement goals, and reviews current and completed improvement projects. Managers discuss the data and the effectiveness of the improvement projects, and suggest new improvement targets and projects.

5.9.3.7 OTHER TOPICS

In addition to the topics covered above, the management review shall also consider such issues as the following:

- Market conditions, technology updates, and research and development opportunities
- Competitor performance

- Results from benchmarking opportunities
- Performance of suppliers
- Marketplace evaluation and strategies
- Status of strategic partnership activities
- Financial effects of quality related activities
- Company infrastructure
- Company work environment
- Social, environmental, statutory, or regulatory changes

6.0 Resource Management

Resources may be people, infrastructure, work environment, information, suppliers, partners, natural resources, financial resources, and those who we count on the most, our people resources. Moldworks Inc executive management must ensure that consideration is given to all available resources essential to the implementation, maintenance, and achievement of the quality objectives identified in this quality management system.

6.1 Provision of Resources

Moldworks Inc. executive management keep a constant awareness of current best business practices within the industry and continually evaluate their existing quality management system for improvement opportunities. Facilities are continually evaluated to ensure sufficient space is available and that the work environment is suitable. Every effort is made to keep the equipment in good working order to enhance the ability of the production staff to meet the customer's requirements. Technology improvements are continually evaluated to position Moldworks Inc. ahead of its competitors. Executive managers are encouraged to develop leadership skills in an effort to ensure Moldworks Inc. is ready for the future.

6.2 Human Resources

All personnel that are performing work affecting product quality are evaluated for their competency based on their education, training, skills, and experience. If any deficiencies exist, training and career plans are developed to meet their individual needs.

Executive management at Moldworks Inc. support open communications, encourage innovation, promote teamwork concepts, actively solicit suggestions and opinions, poll employees regarding satisfaction, and investigate trends if people leave the company.

6.3 Competence, Awareness, & Training

Each functional manager is responsible for identifying employee training needs in their areas. Once the training needs are identified, each employee must be evaluated individually to ensure they have the requisite skills to ensure quality objectives are maintained. After training is provided, the effectiveness of the training is constantly evaluated. As an on-going effort, supervisors are required to keep all personnel aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

In Fabrication, only qualified and/or trained personnel are assigned to operate key processes and equipment. Training records demonstrate who is qualified to operate specific processes and equipment.

6.3.1 Types of Training

6.3.1.1 General Orientation Training

Executive Management provides employee orientation training to all new and existing employees. The training familiarizes employees with administrative rules, and employee programs and benefits.

6.3.1.2 Product and Quality System Training

All employees are trained in the company quality system. At a minimum, the product and quality system training comprises: product orientation with emphasis on quality characteristics; presentation of the company's quality system; explanation of quality policy; discussion of continuous improvement techniques and goals; and the role of employees in maintaining the quality system and improving its efficiency.

6.3.1.3 Safety Training

All employees are trained in safe work practices, first aid, use of personal protective equipment, and emergency procedures, as applicable. Each functional area supervisor provide specific equipment operator training and instruction in equipment related safety procedures.

6.3.1.4 Job Skills Training

Employees are trained in the use of company systems, such as part and material numbering system, retrieval and creation of electronic (computer) documents and records, and any other job related systems.

6.3.1.5 External Training

Moldworks Inc. has an educational reimbursement policy for employees who participate in seminars, conferences, and other forms of external training. Prior to attending any external training, executive management approval must be obtained.

6.3.1.6 SELF-STUDY

Moldworks Inc. encourages personnel on all levels to read professional reports, magazines, and books. Requests for magazines and books are evaluated and processed by executive management. Self-study is considered an alternative form of training. Where appropriate, self-study is recorded in the training record.

6.3.2 TRAINING RECORDS

Training records are identified as a quality record. All training records for quality training shall be maintained by the Training Manager. [See Appendix A]

6.4 INFRASTRUCTURE

Moldworks Inc. executive management is responsible for continually assessing the appropriate acquisition and use of buildings, workspace, utilities, manufacturing and fabrication equipment, software support systems, and other infrastructure requirements. The management review meeting agenda described in paragraph 5.9.3.7 of this quality manual includes the requirement to evaluate the company infrastructure on a quarterly basis.

6.5 WORK ENVIRONMENT

As with the infrastructure noted above, the work environment is continually evaluated to ensure work methods are improved upon to fully realize the potential of the people in the organization, safety rules and protective equipment are utilized as required, and the ambient conditions are suitable to ensure a positive atmosphere is provided. The management review agenda described in paragraph 5.9.3.7 of this quality manual includes the requirement to evaluate the company work environment on a quarterly basis

7.0 Product Realization

Moldworks Inc. is a precision machining manufacturer that manufactures custom parts to the customer's specifications using a variety of materials and processes. The customer determines the level of quality which is captured and annotated on the customer's engineering drawings. The customer's drawings are supplied to Moldworks Inc. as a part of the sales process.

7.1 Planning of Product Realization

Moldworks Inc. has developed a general process to ensure quality requirements specified by the customer are met. This process is diagrammed in paragraph 4.1 of this quality manual. The processes and interfaces between these processes are also discussed in paragraph 4.1.

For specific products and shop orders, Moldworks Inc., in conjunction with the customer, develops the quality planning for product realization. In general, the planning process begins with a sales activity where an initial evaluation is provided to ensure that Moldworks Inc. possesses the capabilities and resources to fabricate the requested part. Moldworks Inc. receives orders directly from the customer along with an engineering drawing of the part that is requested for fabrication.

Once a positive conclusion is reached that Moldworks Inc. does possess the necessary resources for job completion, a job folder packet is created which details the steps or processes necessary to complete the fabrication process.

Prior to the commencement of the shop order, all quality planning details are communicated with the customer to ensure all quality requirements have been planned. Documentation is provided by the customer to validate all quality requirements have been included, planned, and scheduled. Upon receipt of the purchase order from the customer, the fabrication process can begin

7.2 Customer-Related Processes

7.2.1 Determination of Requirements

The customer specifies the requirements to Moldworks Inc. via database for the part to be fabricated. Moldworks Inc. creates a job folder that details the specific steps necessary build and design according to the specifications. If requirements are not specifically stated by the customer, but are required for intended or specified use, those requirements are identified and included in the job folder.

7.2.2 Review of Requirements

Prior to Moldworks Inc. making a commitment with the customer to fabricate the specified product, the Request For Quote (RFQ) is provided to the customer for review, approval, and acceptance. The customer must provide a documented record indicating acceptance of the shop order.

Any modifications or amendments identified by the customer during this review process require the development of a new quote by Moldworks Inc. The process noted above is repeated until final acceptance is obtained from the customer. Records of this review process are maintained by Moldworks Inc.

7.2.3 Customer Communication

All contacts with the customers are channeled through the Owner or Office Manager. All product information, inquiries, job folder modifications, job approval and review data, customer feedback, and customer complaints are maintained by the Owner and Office Manager.

7.3 Design and Development

7.3.1 Design and Development Planning

The design and development process flow (NPD 0-5) outlines the process for controlling the design and development process. The NPD Department ensure that the product specification requirements are clear, creates the necessary planning tools, identifies all necessary resources, oversees designs and testing activities, and coordinates all internal activities according to this procedure. The design plan includes:

- Overall Project Management.
- Design and development stages.
- Required design reviews.
- Customer reviews.
- Verification and validation methods appropriate to each design and development stage.
- Responsibilities and authorities for design and development.
- Identification of the technical interfaces required for the project.
- Updating of the design plan as the project progresses

7.3.2 Inputs

Design and/or development requirements to be met for product is defined and documented in the related job folder, these include:

- Functional and performance requirements;
- Applicable information derived from pervious similar designs: and
- Any other requirements essential for design and/or development

7.3.3 Outputs

The outputs from design and/or development process are documented in a format, which allows for verification of the design and development inputs requirements.

The design and/or development output documents are approved prior to release.

7.3.4 Design and Development Review

At suitable stages, as defined in the design plan, systematic reviews of the design and/or development activity are conducted to evaluate the capability to fulfill all input requirements, including quality, and to identify problems, if any, and develop solutions to correct the problem and/or potential problems.

Design and/or development reviews will include representatives of function concerned with the design stage being reviewed.

Design and/or development reviews are subsequent follow-up actions are documented.

7.3.5 Design and Development Verification

Design verification is planned and performed to ensure that the design and development outputs have satisfied the design and development input requirements. Initial tooling and manufacturing costs may also be reviewed at this time as well. Records of the results of the verification and any necessary actions are maintained according to the design and development process flow diagram.

7.3.6 Design and Development Validation

Design and/or development verifications are planned and conducted to ensure that the output meets the input requirements, as defined in the design plan.

7.3.7 Control of Design and Development Changes

The design and development procedure defines a process for identifying, recording, verifying, validating and approving design changes. The review of design and development changes includes an evaluation of the effect of the changes on constituent parts and delivered product (i.e. schedule cost, etc.). Records are maintained to show the results of the review and any necessary actions identified during the review.

7.4 PURCHASING

7.4.1 PURCHASING PROCESS

Quality performance of all subcontractors is continuously monitored, including their on-time delivery performance. Subcontractors showing inadequate performance are asked to implement corrective actions, and are discontinued if there is no improvement.

7.4.1.1 SUPPLIER EVALUATION

Quality and process capability of all new subcontractors is evaluated by the Management. Only qualified subcontractors may be placed on the approved subcontractor list.

A new supplier is evaluated and requested to provide one or more of the following documents and information:

- Certificate of quality system registration if certified,
- Copy of quality assurance manual if system is not certified,
- Manufacturing capabilities and capacities,
- Samples of similar products and/or workmanship, and
- References

7.4.1.2 APPROVED SUPPLIER LIST

The Management Representative maintains the Approved Supplier List. Orders may only be placed with vendors that are on the list. The supplier is formally certified and accepted for entry on the Approved Suppliers List. A rating will be issued to each supplier. The rating ranges from 1-5. The following definitions are provided:

RATING	DESCRIPTION
1.	Exceptional with no issues or problems reported.
2.	Minor issues identified with supplier.
3.	Supplier's performance has been marginal. Repeat poor performance.
4.	Supplier requested to submit corrective and preventive action information.
5.	This supplier shall not be used.

A-1 Engineering ---------- 1
American Machine & Gundriling------ 2
Buerman Machine ---------- 1
Choice Mold Components ---------- 1
DC Delivery ---------- 1
Design Phactory ---------- 1
Discount Steel ---------- 2
DME ---------- 2
EDM Sales ---------- 2
Fastenall ---------- 2
Fraisa ---------- 2
Francis Company ---------- 2
Grainger ---------- 2
H.K Thread Grinding ---------- 2
Hard Chrome ---------- 3
Incoe ---------- 2
McMasterCarr ---------- 1
Metal Supermarkets ---------- 3
Metal Treaters ---------- 2
MSC ---------- 2
Precision Punch & Plastics ---------- 2
Pro Courier ---------- 2
Productivity Inc ---------- 2
Progressive Components ---------- 2
Quality Service Machine Tool --------- 1
St. Paul Engraving ---------- 2
Bohler Uddeholm (Steel Store) ------- 2
Twin City Metal Finishing ---------- 2
UPS ---------- 2
Walter R. Hammond Company ------- 2
Bales Mold Service ---------- 3
D&D Polishing ---------- 3
Genesis Jig Grinding ---------- 1
KJS Precision Turning ---------- 1
Micro Weld ---------- 2
Mold Masters ---------- 1
North Star Coating ---------- 1
PCS ---------- 2
Precision Punch ---------- 1
Radii Form Grinding ---------- 1
Vincent Tool ---------- 1
Schmolz+Bickenback USA ---------- 1
Wire Wizards ---------- 2
Accu Prompt ---------- 2
Apex Machinery Supply ---------- 1

7.4.1.3 SUPPLIER RECORDS

A supplier quality record file is established for every supplier. All documents supporting the initial evaluation and qualification of the supplier are placed in the file. The file is also used for keeping records pertaining to the supplier's quality performance.

7.4.1.4 SUPPLIER PERFORMANCE MONITORING

All suppliers are continuously monitored for quality and delivery performance. One hundred percent (100%) on-time delivery performance is a goal. The supplier(s) shall be contacted on every late delivery. If the problem persists, the supplier is asked to implement corrective actions to improve delivery performance. When a non-conforming delivery is identified, the receiving clerk shall initiate a non-conformance report. [See appendix I] The supplier is always contacted and informed of the identified non-conformances and, if they are sufficiently serious or recurring, the supplier is requested to propose and implement a corrective action and report back on its effectiveness. Non-conformance reports, requests for corrective actions, and associated correspondence are filed in the supplier's quality record file.

7.4.1.5 SUPPLIER AUDITS

Moldworks Inc. maintains the right to assess the quality systems of suppliers of direct materials, or services incorporated into the final assembly of its products. The Management Representative is responsible for planning and scheduling subcontractor quality audits if required.

7.4.2 PURCHASING INFORMATION

Purchasing documents are prepared by the Purchasing Manager. The documents clearly and completely describe ordered products, including precise identification and quality requirements. When toxic, hazardous, or otherwise restricted substances are purchased, suppliers are required to demonstrate that the substances and their packaging comply with governmental regulations.

7.4.3 VERIFICATION OF PURCHASED PRODUCT

The Receiving Personnel, Material Handler and or/or Purchaser verify purchased items and materials for correctness.

7.5 Production & Service Provision

7.5.1 Control of Production

Moldworks, Inc. plans and carries out production and service provisions under controlled conditions. Controlled conditions include, as applicable:

- The availability of information that describes the characteristics of the product.
- The availability of work instructions.
- The use of suitable equipment.
- The availability and use of monitoring and measuring devices.
- The implementation of monitoring and measurement processes.
- The implementation of release, delivery and post-delivery activities.

Manufacturing Procedures, Routers, Inspection Control Plans, and Service Procedures define Our Company's plan for manufacturing and service. These quality control plans provide detailed planning for all phases including the methods and equipment to be used and workmanship criteria. This detailed planning will be documented for each product and/or process in the form of work instructions, drawings or specifications.

7.5.2 Validation of Processes for Production

The machine operators are provided with instructions explaining job set-ups, equipment and process operation, and may include in-process inspection. Operators of processes responsible for processes that cannot be verified by subsequent inspection (i.e. welding) are properly trained in those processes.

7.5.2.1 IN-PROCESS INSPECTIONS

In-process inspections are normally carried out for the purpose of collecting process performance data rather than detecting and segregating non-conforming product. The focus is on defect prevention rather than detection.

7.5.2.2 FINAL INSPECTION

All finished products are subjected to final inspection. First, inspectors verify that all specified receiving and in-process inspections have been carried out satisfactorily, and then they perform the remaining inspections and tests necessary to complete the evidence of product conformance. Only products that pass the final inspection can be shipped.

7.5.2.3 INSPECTION AND TEST RECORDS

All inspections are concluded with establishment of an inspection record which is maintained in the product file.

7.5.3 Identification & Traceability

7.5.3.1 PRODUCT IDENTIFICATION

All end products are identified with unique numbers, codes, or names. The identification is the same, or is cross-referenced with the product designations used in the job folder. In-house manufactured products, and in particular finished products, are identified in accordance with customer requirements.

7.5.3.2 TRACEABILITY

Traceability of materials and/or processes is maintained when required by contract. When required, materials are traceable to their purchase orders or lot numbers as received from the customer, and thereby to their inspection, testing, or process certification.

7.6 Control of Monitoring/Measuring Devices

7.6.1 Determining Monitoring & Measurement Needed

Moldworks Inc. establishes the use of monitoring and measuring devices based on the specifications and drawings provided by the customer. Inspection processes are listed on the job folder as required. Only calibration instruments and standards having known relationship to the nationally recognized standards are used for calibrating the measuring equipment.

7.6.2 Measuring Equipment

The Management is responsible for calibrating and maintaining measuring and test equipment. All active equipment is inventoried in a controlled list, indicating equipment calibration status and location. All calibrated monitoring and measuring devices are protected during handling, maintenance, and storage.

Calibration of measuring and test equipment is carried out using calibration instruments or standards certified to have a known relationship to a nationally recognized standard. This relationship is identified on the calibration record. Equipment that is sent out for calibration is required to be returned with certification that is likewise traceable to a national standard. Calibration records and certificates are maintained by the Management.

Calibrated equipment is labeled with a sticker indicating the due date for the next calibration. Equipment with a past-due calibration date or without a calibration sticker is not used and is immediately returned to the Management.
Measuring and inspection equipment is calibrated internally annually.

7.6.3 Nonconforming Equipment

When a piece of measuring or test equipment is found to be out of calibration or appears to give inaccurate readings, the piece is checked. If it is confirmed that the equipment is indeed out of calibration and the readings are outside of required accuracy, the Management Representative investigates and assesses the validity of measurements for which the measuring or test equipment was previously used.

8.0 Measurement, Analysis, & Improvement

8.1 General Policies

As part of our quality system and our commitment to continuous improvement, Moldworks Inc. has planned and implemented the monitoring, measurement, analysis and improvement processes needed to demonstrate conformity of the product, to ensure conformity of the quality management system, and to continually improve the effectiveness of the quality management system.

8.2 Monitoring & Measurement

8.2.1 Customer Satisfaction

Customers shall be surveyed on an annual basis as a method to determine if the performance of the quality management system is achieving the desired performance. Other evidence regarding customer satisfaction may be obtained through phone calls, daily contact, and general discussions with the customer. All data will be considered during the management review process.

8.2.2 Internal Audit

Identified non-conforming conditions are brought to the attention of the responsible managers and a corrective action is requested when appropriate.

The Management Representative establishes the internal audit plan and schedule in accordance with the Internal Quality Audits Procedure. Every activity and area is audited at least once a year. Selected activities may be audited more frequently, depending on their status, importance, and quality performance history.

Only personnel independent of the audited activities are assigned to conduct the internal audits. Normally, the Management Representative leads the audit team except when Quality Assurance (QA) activities are being audited. Audits of QA activities are conducted by independent approved auditors.

Auditors prepare for audits by reviewing applicable standards and procedures, analyzing quality records, and establishing questionnaires and checklists.
When conducting the audit, auditors seek objective evidence indicating whether the audited activities comply with the requirements of the documented quality system and ISO9001, and whether the quality system is effective. The evidence is collected by observing activities, interviewing personnel, and examining quality records. Audits are conducted in a way that minimizes disruption of the audited activities.

Non-conforming conditions are documented and recorded. When nonconforming conditions are identified, the manager responsible for the affected area or activity is requested to implement a corrective action. Implementation and effectiveness of the action is verified by follow-up audit activities.

8.2.3 Monitoring & Measurement of Processes

Process capability studies are conducted to verify that processes are capable of producing products that meet customer requirements. The study is conducted by the Management when required by the customer.

8.2.4 Monitoring & Measurement of Product

The organization monitors and measures the characteristics of the product to verify that product requirements are fulfilled. This is carried out at appropriate stages of the product realization process.
Evidence of conformity with the acceptance criteria is maintained. Records indicate the person authorizing release of product. Product release and service delivery does not proceed until all the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority, and where applicable by the customer.

8.2.4.1 Receiving Inspection

All received materials and products are subject to a receiving inspection. Upon unloading of deliveries, the team member performs the visual inspection and checks identification of the received goods. The team member counts the number of delivered units, checks marking and identification of packages, and inspects all packages for any signs of tampering or damage. If all these checks and inspections are satisfactory, he or she and the driver sign the delivery receipt. In the event of any shortages or damages they are noted on all copies of the delivery receipts.

The packing slips, certifications, all data, and test reports, are removed from packages. The part numbers are verified against the packing slip, and the goods are examined visually for any signs of damage. The team member also verifies that all requested material and product quality records (control charts, inspection/testing certificates, etc.) have been received from the subcontractor or supplier.

When the receiving inspection is completed with satisfactory results, the packing slip and other documents are stamped “received”, signed, and dated to create the record.

8.2.4.2 In-Process Inspections

In-process inspections that are carried out for the purpose of detecting and segregating non-conforming product are only required when processes are not capable and/or are not sufficiently stable.

In-process inspections are specified in the job folder. For complex products, and in particular when functional testing is involved, inspections are performed with the use of checklists, inspection procedures, inspection report forms, and other instructions as appropriate.

8.2.4.3 Final Inspection

Final inspection is completed by reviewing the job folder to ensure that all necessary steps in the production process were completed according to the customer requirements. Quality Control initializes the shop folder to signify completion of the final inspection. [See Appendix B- New Mold checklist][See Appendix D- Tool Certification Report]

8.2.4.4 Non-conforming Product

When a non-conforming product, sub-system, or component is identified or quality documents are incomplete, a non-conformance report is prepared. The product is segregated and identified according to Control of Non-conforming Product Procedure.

8.2.4.5 Release of Product

Only Quality Control has the authority to release product. Products that are not approved for shipment may not be shipped. When contractually imposed by the customer, a certification is generated and attached to the shipping documents.

8.3 Control of Non-Conforming Product

8.3.1 Identification and Documentation

Moldworks Inc. identifies and establishes a non-conformance report for all non-conformances that cannot be repaired or reworked within the same operating shift. Non-conformance reports are invaluable for tracking performance and trends, and for identifying areas where corrective or preventive actions should be implemented. The report describes the non-conformance, documents the disposition decision, and records closeout of follow-up activities (re-inspection, customer authorization, corrective actions, etc.). The use of the non-conformance report and its processing are explained in the Control of Non-conforming Product Procedure.
See Appendix I for Non-Conformance Report

8.3.2 Non-conformance Review and Disposition

The Management Representative or a designated appointee may make the disposition decision for a non-conforming product when it is obvious that the product must be scrapped or regarded, or if it can be repaired by a simple process without affecting its quality or appearance.

The disposition decision may be:

- Rework or repair
- Accept as-is
- Re-grade
- Scrap

Products that, with or without repair, do not fully comply with specified requirements cannot be shipped. When defects do not compromise the function and usefulness of products, customers may be asked for the authorization to ship such products.

8.3.3 Records

Records regarding control of non-conforming product are maintained by Moldworks Inc.

8.4 Analysis of Data

This quality management system is supported by the measurement and analysis of quality objectives. The data that will be collected and analyzed will demonstrate the suitability and effectiveness of the quality system. In addition, the data will be relevant to the quality objectives for this organization.

Process measurement data will be gathered and analyzed. Process data will be determined based on the results of the management review process. Consideration of the results of the quality audits will be a determining factor when identifying the process data needed for analysis.

Product data gathered during receiving inspection, in-process inspections, and final inspection will be analyzed on an as needed basis. Customer satisfaction survey data will be gathered and analyzed to determine if the quality management system is suitable and effectively supports the goals and objectives of Moldworks Inc.

Supplier data will be analyzed to ensure that the suppliers are providing services and materials that support the overall quality objectives for Moldworks Inc.

8.5 IMPROVEMENT

8.5.1 CONTINUAL IMPROVEMENT

When processes attain the required capability and/or performance, they may be further improved, especially when reduction of variation within tolerance is desired by the customer. The decision whether satisfactorily performing processes should be further improved is made on the basis of a cost-benefit analysis, i.e., comparison of the cost and effort required to further improve the process, versus the benefit the improvement will bring the customer.

8.5.2 CORRECTIVE & PREVENTIVE ACTION

Causes of product and quality system non-conformities are investigated and corrective actions are implemented to prevent their recurrence. Processes, work operations, quality records, service reports, and customer complaints are analyzed to detect any sources of potential quality problems, and preventive actions are implemented before the problems develop. Controls are applied to ensure that corrective and preventive actions are implemented and that they are effective.
[See Appendix F- Preventive Action Report, Appendix G – Corrective Action Report]

Anyone in the company may propose initiation of corrective or preventive actions. The Management Representative can authorize and request their implementation.

Corrective and preventive actions may be initiated as the result of:

- Identification of major product non-conformance or a trend of minor non-conformances of a similar character
- Problems with processes or work operations
- Non-compliances observed during audits
- Customer complaints and returned products
- Non-conforming deliveries from subcontractors
- Identification of any other condition that does not comply with the documented quality system and/or ISO9001 requirements

The Corrective and Preventive Action Procedure provides a complete list of the relevant non-complying conditions, and describes in detail the rules that apply to initiating corrective and preventive actions.