
CARROLL MACHINE WORKS
QUALITY ASSURANCE MANUAL

SECTION 1.0

GENERAL

1.1 Purpose

To provide the requirements for Quality Assurance Manual control, indoctrination and training and organizational responsibilities.

1.2 Scope

The Quality Assurance manual requirements shall apply to products manufactured, modified and/or repaired by Carroll Machine Works. The Quality Program meets the applicable requirements of API Q1, ISO 9002, MIL-I-45208A, and ASME/ANSI. The Quality Assurance Manual is the property of CARROLL MACHINE WORKS and shall be returned upon request. Copies of the Quality Assurance Manual or any part thereof shall not be made without the prior written permission of the President.

1.3 Responsibilities

1.3.1 The President has the authority, responsibility and organizational freedom to:

- a.** identify problems affecting quality
- b.** initiate or recommend corrective action
- c.** verify corrective action, and
- d.** control non conforming materials and products

1.3.2 Delegation of tasks is allowed, but the assigned function maintains responsibility for acceptable completion of the task.

1.4 Quality Assurance Manual Control

1.4.1 The Quality Assurance Manual and revisions shall be approved by the President, as indicated by his signature and date on the Statement of Authority.

1.4.2 The Office Manager is responsible for the issuance and revision of the Quality Assurance Manual. Each controlled copy is assigned a copy number. A log of all issued controlled is maintained.

1.4.3 A controlled copy of the Quality Assurance Manual and revisions shall be submitted to a customer upon request.

- a.** Uncontrolled copies of the Manual may be issued outside of CARROLL MACHINE WORKS, and issuance is not documented.
- b.** Each designated employee shall be issued a controlled copy of the Manual.
- c.** Recipient of a controlled copy of the Quality Assurance Manual will destroy obsolete pages upon receipt of revisions.

1.4.4 Each recipient of a controlled copy of the Manual shall sign and date the transmittal letter, which is returned within 10 days internally and within 20 days externally. If an external transmittal letter is not received:

- a.** The Quality Assurance Manual will no longer be controlled and revisions will not be issued.

1.4.5 The revision number of the manual is indicated on the Table of Contents page and reflects the latest section revision. The revision number of each section is noted in the Table of Contents. An asterisk next to the paragraph number, except when a section(s) of the Manual is extensively revised, identifies revised text.

1.5 Indocctrination and Training

1.5.1 Indocctrination and/or training of personnel performing quality-related functions is provided and documented, when required, to assure conformance to the Quality Program.

1.5.2 The President is responsible for Manual indocctrination of personnel performing quality-related functions. The indocctrination is documented and includes the name and position of the employee; the scope, date and duration of the indocctrination; and the instructor's name.

1.5.3 Quality Assurance Manual retraining of personnel is required whenever significant changes are made to the Quality Assurance Manual, or when personnel are reassigned to a different area of responsibility which includes a quality-related task.

1.5.4 On-the-job training by supervisory personnel is used to train employees in job-related functions and does not require documentation.

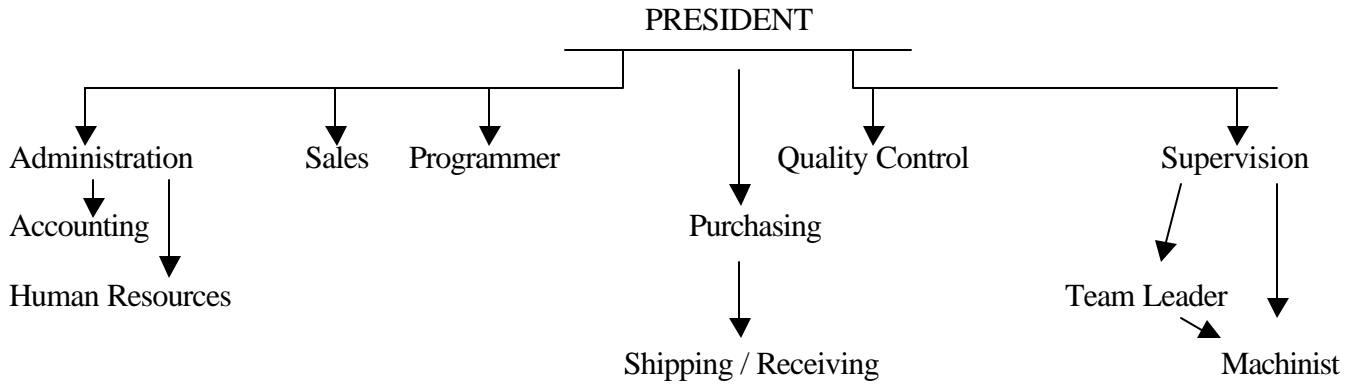
1.5.5 Qualification requirements for personnel identified as performing functions described within the Quality Assurance Manual shall be documented. These requirements shall be based on education, training, experience, and/or examination. Qualifications of each individual shall be documented. Records shall be maintained on each individual.

1.5.6 Qualification requirements for employees performing special processes are documented by the President, and shall meet the criteria of the customer's specification or applicable codes and

standards. Subcontract personnel performing special processes shall meet the same personnel qualification criteria, when required.

1.6 Organization Chart

The following organization chart identifies key personnel and reflects the reporting relationships:



SECTION 2.0

DOCUMENT CONTROL

2.0 **Purpose**

To provide requirements for the control of customer furnished documents and documents originating at CARROLL MACHINE WORKS.

2.1 **Scope**

This section is applicable to documents furnished by Customers and documents which originate at Carroll Machine Works.

2.2 **Customer Furnished Documents**

2.2.1 The Office Manager is responsible for the control of drawings, bills of material and specifications received from the customer.

2.2.2 An addendum or revision to customer documents may require changes to the applicable travelers or purchase orders.

2.2.3 Customer-furnished documents are returned to the customer upon completion of a purchase order, when requested.

2.2.4 All documents are considered confidential and viewed only as required for completion of the customer order.

2.3 **Availability of Drawings, Bills of Material and Specifications**

2.3.1 Specifications are available to personnel for the preparation and revision of purchase orders, and receipt of purchased materials or parts.

2.3.2 Drawings and bills of material are available to personnel at the location where the activities are being performed.

2.3.3 Upon completion of the customer order: all Drawings, Bills of Material and Specifications are packaged by work order and secured.

2.4 **Instructions**

Special instructions may be given on any order; these instructions will be in written form. These may be included in travelers and purchase orders.

2.5 Procedures

Quality Procedures may be established as necessary to document and/or implement the Quality Program. Quality procedures are approved by the President and distributed to the personnel responsible for performing the prescribed activities. These procedures are revision controlled.

SECTION 3.0

PROCUREMENT

3.1 Purpose

Provide requirements for procurement and receiving inspections.

3.2 Scope

This section applies to the purchasing requirements, approval of vendors and receiving inspection.

3.3 Purchasing

3.3.1 Materials, parts and services are procured for a specific sales order, except for calibration services. Purchase orders are issued to customer-approved vendors when required by the customer for SPPE-1 orders.

3.3.2 A purchase order is prepared using the information furnished by the customer for purchasing materials, parts and services.

3.3.3 Purchase orders for subcontract work on traceable items will identify the heat number(s) of the applicable material or parts. Subcontract vendors are furnished a purchase order with the applicable drawing, specifications and/or procedure with the material or part.

3.3.4 Raw material certifications and heat tractability are required for raw material. When required by contract, personnel and procedure qualification records are to be furnished by special process vendors.

3.3.5 Purchase orders are reviewed for accuracy, quality, requirements, and compliance to customer requirements and a copy is filed with the sales order package.

3.3.6 The Purchasing Department Supervisor/Buyer is required to notify applicable vendors of any purchase order changes and to forward revised documents to the appropriate vendors.

3.4 Approved Vendors List

3.4.1 Vendors approved by the President are listed on the Approved Vendors List. Vendor approval is based on one or more of the following:

- a. vendor's name and address
- b. applicable ISO or API certification
- c. vendor site evaluation
- d. customer designated vendor

3.4.2 The Approved Vendors List shall include, as applicable:

- a.** vendor's name and address
- b.** approval scope
- c.** any constraints or limitations
- d.** date of approval
- e.** method of approval
- f.** QA Manual revision or applicable certification number when required

3.5 Vendor Evaluation

3.5.1 When a vendor evaluation is required, a qualified auditor shall evaluate the vendor to determine the vendor's ability to provide materials, products, and/or services, which conform to purchase, order requirements. The qualified auditor will be out sourced, Quality personnel at CMW, or the President of CMW

3.5.2 If the President determines the vendor is acceptable, the vendor is added to the Approved Vendors List. If the vendor is unacceptable, the President shall notify the vendor. The vendor is required to respond with acceptable corrective action before a purchase order can be issued.

3.6 Receiving Inspection

3.6.1 Purchased raw material and parts are inspected upon receipt to determine compliance to the purchase order requirements. Material certifications, when required, are verified. The heat number on the material or parts is verified. Acceptable items are sent to storage and/or released to manufacturing.

- a.** The work order number and heat number are written or marked on the material or parts upon acceptance.
- b.** The CMW inventory number if applicable – material for inventory
- c.** The vendor and heat number is recorded on the Receiving Log.
- d.** The certification and/or heat number is recorded on the data sheet included in each work order.

3.6.2 If certifications do not accompany the order, the Purchasing Agent contacts the vendor. The material or parts are held in Receiving until the certifications are available.

3.6.3 Unacceptable material or parts are written up on a Non Compliance Report (NCR). The unacceptable materials or parts are segregated from the acceptable items, and a tag, which identifies the NCR number, is attached.

3.6.4 Customer-furnished material or parts are inspected upon receipt to verify compliance with the customer's purchase order and packing list.

SECTION 4.0

MANUFACTURING

4.1 Purpose

Provide the requirements for control of the Manufacturing area.

4.2 Scope

This section applies to the Manufacturing area for machining and repair of customer material and/or parts.

4.3 Process Control Documents

4.3.1 A Traveler Package is prepared by the Office Manager, and consists of a Traveler and a machine drawing for each part to be machined, modified or repaired. A work order number is automatically generated when the traveler is printed. The Traveler consist of:

- a.** work order number,
- b.** part number and revision,
- c.** Customers name and purchase order
- d.** material to be issued, including the heat number (Pick Ticket)
- e.** A list of machining operations, first piece inspection, marking instructions and final inspection as the last operation.

4.3.2 Upon completion of the Traveler Package, the Office Manager issues the Traveler to manufacturing.

4.3.3 The material is pulled, issued, and documented on the picket ticket. Production Control will be responsible for this procedure.

4.3.4 The machine operator maintains heat tractability when required. If the heat number is machined off, the operator shall re-stamp or re-mark the number before the part leaves his/her station. As the work is completed, the Traveler package and the parts are sent to Final Inspection for inspection and marking. The inspector shall complete a QC Data Sheet (Exhibit 4), to include the as-built dimensions of each item inspected.

4.3.5 The Traveler is initialed and dated by the Inspector upon completion of final inspection. The package is sent to shipping.

4.3.6 The traveler package is returned to the Office Manager.

4.3.7 Acceptable parts are properly packaged and shipped to the customer along with the customer-furnished documents and nay documentation required by the purchase order.

4.4 Revision Control

4.4.1 If customer drawings for parts being machined are revised, the Office Manager is responsible for delivering the revised document to the machine, revising the traveler (if required), and retrieving the obsolete documents. The Quality Control shall determine if the parts are still acceptable at the operation based on the document revision.

4.4.2 Unacceptable parts are segregated. Written up on a Rejection Report, and disposed in accordance with Quality Assurance Manual Requirements.

4.5 Hold Points

The Quality Assurance Department shall notify the customer when a hold point is reached which requires a customer witness. Further processing of the part is delayed until approved by the customer or his authorized representative.

4.6 Records

The Office Manager is responsible for maintaining closed Traveler Packages.

SECTION 5.0

MATERIAL / PRODUCT IDENTIFICATION AND TRACTABILITY**5.1 Purpose**

Provide the requirements for material and product identification and tractability.

5.2 Scope

This section shall apply to the identification of all material and parts, and to the tractability of heat traceable material and parts.

5.3 Material Identification and Tractability

5.3.1 The vendor or the customer is required to identify raw material. The receiving inspector shall identify acceptable raw material with the sales order number. Heat traceable material shall be identified with the heat number prior to receipt.

5.3.2 Traceable parts in the manufacturing area, as required, will be identified with the heat number, which is also recorded on the traveler when issued. A traveler is issued for each part number on an order.

5.4 Product Identification and Tractability

5.4.1 Purchased finished items are identified as required by the customer, which may include marking and / or tagging.

5.4.2 Acceptable machined or repaired parts are low-stress steel stenciled or marked by the Inspector as required by the customer, including the heat number for traceable parts.

SECTION 6.0

SPECIAL PROCESSES

6.1 Purpose

To provide the requirements for the control of special processes

6.2 Scope

This section shall apply to special processes required during the manufacture or repair of material or parts.

6.3 Identification of Special Processes

Special processes, which may be required during the manufacture, modification, or repair of products, include welding, weld repair and heat-treating.

6.4 Control of Special Processes

6.4.1 When approved by the customer, authorized personnel using qualified procedures may perform special processes. The personnel qualifications shall be in compliance with the customer's specification or applicable codes and standards. The procedures used for special processes shall meet the customer's specification or applicable codes and standards.

6.4.2 If special processes require subcontracting, the purchase order shall include in the requirements: Qualified personnel and procedures shall be in compliance with the customer's specification or applicable codes and standards. When required, the subcontract personnel and procedure qualifications records shall be reviewed and approved by the customer prior to issuance of the purchase order.

6.5 Records

6.5.1 The Office Manager shall maintain personnel qualification records, for employees performing special processes. In-house procedure/process qualification records for special processes shall be maintained by the Office Manager

6.5.2 The subcontractor shall maintain special processes personnel and procedure/process qualification records for his/her personnel, unless otherwise required by the contract.

SECTION 7.0

INSPECTION

7.1 Purpose

Provide the requirements for inspection of material and/or products.

7.2 Scope

This section applies to the receiving, in-process and final inspection of material and /or parts.

7.3 Inspection Qualifications

Qualified personnel other than those who performed or directly supervised the manufacture, modification or repair of the products being inspected shall perform inspection for compliance and acceptance.

7.4 Inspection Areas

7.4.1 Receiving Inspection - is required for incoming materials and parts in compliance with the Quality Assurance manual, and is documented in the Inspection Log by the inspector

7.4.2 In-Process Inspection - are performed when required by the customer as noted on the traveler. These inspections are documented in the Inspection area on the travelers by the inspector or supervisor.

7.4.3 Final Inspection - is required for parts machined, modified or repaired in-house, to verify drawing and purchase order compliance. Final inspection results are documented in the Inspection data sheet by the inspector. Personal gages are not allowed for final acceptance inspection. Customer gages are used to inspect parts when permissible.

7.5 Nondestructive Examination

When required by the customer, NDE technicians who are qualified in accordance with ASNT-TC-1A shall perform nondestructive examination

SECTION 8.0

CALIBRATION CONTROL

8.1 Purpose

Provide the requirements for calibration of measuring and inspection equipment.

8.2 Scope

This section applies to measuring and inspection equipment used for final product compliance and acceptance.

8.3 Measuring and Inspection Equipment

Measuring and inspection equipment used for product acceptance shall be identified, controlled, calibrated and adjusted at specific intervals, or prior to use, in order to maintain accuracy. Measuring and inspection equipment shall be calibrated against certified measuring standards traceable to National Standards, where such standards exist.

8.4 Calibration Control Procedure

8.4.1 Each gage is identified with a serial number, which corresponds to the calibration record. Also each item has a calibration sticker attached to it or to its container, which identifies the calibration date (m/d/y), next calibration due date, equipment serial number and calibrator.

8.4.2 Measuring and inspection equipment suspected of being inaccurate shall be brought to the President. An item found to be out of calibration shall be tagged immediately. The tag may only be removed when the gage has been re-calibrated. If it cannot be re-calibrated, the gage will be repaired, then re-calibrated or scrapped.

8.4.3 Calibration methods will be documented and controlled thru the automated software. The gage type will determine the exact procedure. The exception will be gages sent to and approved Calibration Vendor.

8.5 Records

Calibration records shall be maintained which identify:

- a.** serial number of the gage,
- b.** manufacturer,
- c.** calibration frequency,
- d.** standards used
- e.** as-found condition,
- f.** calibrator
- g.** Action taken.

Note: Quality Control is responsible for maintaining the calibration records and a recall system. The review will be by the President and/or an independent source.

SECTION 9.0

HANDLING, CLEANING, STORAGE AND SHIPPING

9.1 Purpose

Provide the requirements for control of handling, cleaning, storage and shipping

9.2 Scope

This section applies to customer material, purchased material and finished parts.

9.3 Handling and Cleaning

Handling and cleaning procedures are included in on-the-job training of employees in order to prevent damage to products and to protect machined surfaces.

9.4 Storage

9.4.1 Items are shipped upon completion, unless otherwise requested by the customer.

9.4.2 Items requested for later shipment are labeled and placed in storage.

9.5 Shipping

9.5.1 Parts shall be prepared for shipment in accordance with customer requirements. If not specified, standard commercial methods are used to prevent damage during shipping. Required documentation is put in the shipping container, unless otherwise specified by the customer. The shipping containers are marked in accordance with customer requirements.

9.5.2 Blind shipments shall be prepared in accordance with customer instructions. Special attention is given to shipping labels and packing slips as specified by the customer.

SECTION 10.0

ACCEPTANCE STATUS

10.1 Purpose

Provide the requirements for control identification of the acceptance status of material and parts.

10.2 Scope

This section applies to the acceptance status of material and parts.

10.3 Status of Materials / Products

10.3.1 The inspector, upon receipt, identifies acceptable materials and parts with the work order number. The inspector also circles the heat number on the raw material with a paint marker.

10.3.2 The traveler for parts accepted at final inspection is initialed and dated by the inspector to indicate completion. The traveler is traceable to the heat traceable parts.

10.3.3 Rejected material and parts are documented on a Rejection Report, and a Rejection tag is placed on the segregated items. Upon disposition, the President may remove the Rejection tag to allow further processing.

10.4 Status Indicators

Status indicators include stenciling, stickers, paint marking, tags, and Rejection Reports.

- a.** Paint marking is used on acceptable raw material
- b.** Stenciling or marking is used on acceptable finished components.
- c.** Stickers are used to identify gages.
- d.** Tags are used to identify gages overdue or out of calibration and rejected materials and products.

SECTION 11.0

NON - CONFORMANCES

11.1 Purpose

Provide the requirements for control and disposition of nonconforming items.

11.2 Scope

This section applies to non-conforming materials, parts and assemblies.

11.3 Control of Non-Conformances

11.3.1 Non-conforming materials, parts and assemblies are rejected and documented on a Non-Conformance Report. The Non-Conformance Report is sequentially numbered and logged.

11.3.2 The rejected items are segregated from acceptable items and tagged to await disposition.

11.4 Disposition of Non-Conformances

11.4.1 Disposition of Non-Conformances items may be:

- a. rework
- b. scrape
- c. return to vendor
- d. acceptable for use

11.4.2 The Quality Control department is responsible for the disposition of a Non-Conforming item, recording the corrective action on the NCR and if approving, by initialing and dating the NCR.

11.4.3 When required, the customer shall also approve the disposition and direct the corrective action. The customer or authorized representatives, name and date of disposition, will be included on the NCR

11.4.4 Final inspection is required for rework items upon completion of the corrective action.

11.5 Corrective Action

11.5.1 The Inspector shall verify that rework corrective action has been completed as required by the NCR. This inspection is documented on the NCR. The Inspector may release acceptable items for further processing.

11.6 Records

The Office Manager is responsible for retaining closed NCR and the NCR records. QC will keep a log or binder with a copy of the NCR. This will be handled the same way with external NCR's.

SECTION 12.0

MANAGEMENT REVIEW AND AUDITS

12.1 Purpose

Provide the requirements for management reviews, internal auditing procedures, and vendor evaluation.

12.2 Scope

This section applies to the annual management review, internal quality audit of the Quality Assurance Manual and evaluation of vendors.

12.3 Management Review

The President shall review the Quality Program annually to determine if updates and/or revisions are needed. Changes may require revision of the Quality Assurance Manual. Revisions shall be documented. This review includes but is not limited to:

- a. identifying changes to API Q1
- b. ISO-9002
- c. MIL-

12.4 Internal Audit

12.4.1 An internal audit shall be conducted annually to determine compliance to, and implementation of, the Quality Assurance manual. The President is responsible for appointing a qualified auditor to audit the applicable areas of the company.

12.4.2 The audit shall be conducted using a written checklist. An audit report is prepared by the auditor and sent to the President for review, a signature and date.

12.4.3 Personnel responsible for any non-compliance shall be sent a Corrective Action Request by the Supervisor and requested to respond with the corrective action to be taken and the date corrective action expects to be completed. A copy will be retained in the personnel training records.

12.4.4 The auditor shall verify that corrective action has been completed and prepare a final report for review by the President.

12.5 Vendor Evaluation

12.5.1 When required, a vendor evaluation is conducted at the vendor's facility to determine if the vendor is capable of complying with applicable requirements.

12.5.2 A qualified auditor shall evaluate the vendor's facility. A vendor evaluation report is written, and the President shall determine if the vendor is acceptable or unacceptable. If acceptable, the vendor is added to the Approved Vendors List.

12.5.3 If unacceptable, the vendor is notified. The vendor has an opportunity to come into compliance and respond in writing as to the corrective action taken. After the corrective action has been approved and verified, the vendor may be added to the Approved Vendors List.

12.6 Records

The office Manager is responsible for maintaining management review and internal quality audit records.

SECTION 13.0

CORRECTIVE ACTION

13.1 Purpose

Provide the requirements for identification and analysis of repetitive non-conformance and quality trends.

13.2 Scope

This section applies to non-conformances identified and documented

13.3 Identification

13.3.1 A review of Rejection Reports, Corrective Action Request, Inspection Log, Internal Audit Reports and Vendor Evaluations shall be conducted quarterly by the President to identify the cause(s) of repetitive non-conformance. This review will be documented.

13.4 Corrective Action

13.4.1 Corrective action will be taken and documented to minimize recurrence.

SECTION 14.0

QUALITY RECORDS

14.1 Purpose

Provide the requirements for identification and retention of records, and customer documentation.

14.2 Scope

This section applies to those records generated as a result of the Quality Program, which are listed, and the documentation furnished to the customer or provided for review.

14.3 Record Requirements

14.3.1 The Records List in this section identifies the applicable records, the originator, and the function responsible for maintaining the record

14.3.2 The records identified in this section are clear, identifiable, retrievable, protected from possible damage and legible. These records are maintained for a minimum of five years from the date of origination, unless otherwise specified by the customer.

14.4 Documentation

14.4.1 Documentation is Quality Records required by the sales order to be furnished to the customer or to be available for review by the customer. Documentation may include:

- a. Material certifications
- b. Certificate of Conformance
- c. Heat treat reports / charts
- d. Weld repair reports/sketch
- e. NDE reports
- f. Personnel / Procedure qualification records
- g. QC Data Sheet

RECORDS LIST

NAME OF RECORD	ORIG. BY	MAINTAINED BY
QA Manual plus revisions	President	Office Manager
QA Manual Log	Office Manager	Office Manager
QA Manual Transmittal Letters	President	Office Manager
Indoctrination/Training Records	President	Office Manager
Personnel Qualifications	President	Office Manager
Customer-Furnished Documents	Customer	Office Manager
Quality Procedures	President	Office Manager
Purchase Orders	President	Office Manager
Material Certifications	Vendor	QC
Approved Vendors List	Office Manager	Office Manager
Inspection Log	QC Inspector	President
Traveler Number Log	Office Manager	Office Manager
Completed Travelers	Office Manager	Office Manager
Procedure Qualifications	Vendor	Vendor
Personnel Qualifications for	Vendor	Vendor

SPECIAL PROCESSES

NAME OF RECORD	ORIG. BY	MAINTAINED BY
Calibration Records	Vendor	President
Rejection Reports	President	President
Management Review Reports	President	President
Internal Audit Reports	Auditor	Office Manager
Vendor Evaluation Reports	Auditor	Office Manager
Repetitive Non-Conformance Report	President	President
Material Test Reports	Vendor	QC
NDE Reports	Vendor	Office Manager
NDE Personnel Qualifications	Vendor	Office Manager
Heat Treat Reports/ Charts	Vendor	Office Manager
Corrective Action Reports	President	Office Manager
Field Non-Conformance Reports	Customer	Office Manager

SECTION 15.0

FIELD NON-CONFORMANCES

15.1 Purpose

Provide controls to ascertain field non-conformance reports are resolved in a timely manner.

15.2 Scope

This section applies to non-conforming items returned by the customer.

15.3 Identification of Field Non-Conformance

15.3.1 The President is responsible for handling field non-conformances and ensuring timely and effective actions.

15.3.2 Products in the field which are determined to be non conforming shall be returned to Carroll Machine Works with a written report describing the non-conformance.

15.4 Resolutions

15.4.1 The President shall review the Field Non-Conformance report and conduct an analysis of the returned item.

15.4.2 The results of the analysis shall be documented, and a copy of the report sent to the customer.

15.5 Corrective Action

15.5.1 The President shall determine the corrective action to be taken. A report is written and forwarded to the customer as to the corrective action required. When required, customer approval of the corrective action shall be in writing.

15.5.2 Corrective action shall be implemented and verified by the President

SECTION 16.0

FORMS

Approved Vendor List

Inspection Data Sheet

Quality Assurance Manual Log

Non Conformance Report (Internal)

Non Conformance Report (Customer)

DMR Report

Job Package

NOTES

TABLE OF CONTENTS

SECTION 1.0.....	1
GENERAL.....	1
SECTION 2.0.....	4
DOCUMENT CONTROL.....	4
SECTION 3.0.....	6
PROCUREMENT.....	6
SECTION 4.0.....	8
MANUFACTURING.....	8
SECTION 5.0.....	10
MATERIAL / PRODUCT IDENTIFICATION AND TRACTABILITY.....	10
SECTION 6.0.....	11
SPECIAL PROCESSES.....	11
SECTION 7.0.....	13
INSPECTION.....	13
SECTION 8.0.....	14
CALIBRATION CONTROL.....	14
SECTION 9.0.....	16
HANDLING, CLEANING, STORAGE AND SHIPPING.....	16
SECTION 10.0.....	17
ACCEPTANCE STATUS.....	17
SECTION 11.0.....	18
NON - CONFORMANCES.....	18
SECTION 12.0.....	20
MANAGEMENT REVIEW AND AUDITS.....	20
SECTION 13.0.....	22
CORRECTIVE ACTION.....	22
SECTION 14.0.....	23
QUALITY RECORDS.....	23
SECTION 15.0.....	26
FIELD NON-CONFORMANCES.....	26
SECTION 16.0.....	27
FORMS.....	27