1.0 Purpose

1.1 This procedure defines the review of the quality system by the Management team.

2.0 Scope

2.1 This procedure applies to quality system documentation requirements of ISO 9002, Good Manufacturing Practices or other applicable quality standards for which elements of this system apply or qualify. The review is intended to ensure the adequacy of the quality system as well as the quality system’s effectiveness in meeting or exceeding customer requirements and expectations.

3.0 Responsibility

3.1 The Quality Manager is responsible for the implementation of this procedure and the maintenance of the documented quality system.

4.0 Definitions

4.1 Contract Review and Quality Planning
   - Document and Data Control
   - Process Control
   - Control of Quality Records
   - Internal Quality Audits
   - Contract Approval Form

5.0 Safety Requirements

6.0 Environmental Effects

7.0 Equipment & Materials

8.0 Forms

9.0 Procedure
9.1 Management Representative

The President has appointed a Quality Manager as management representative to ensure the quality system is established, implemented and maintained in accordance with ISO 9001 and Good Manufacturing Practices and other specific regulatory agency and/or customer requirements. The Quality Manager has been given the necessary authority and organizational freedom to resolve matters pertaining to quality. This person reports on status and performance of the system to Cobalt polymers management as a basis of improvements to the system.

When a change in the Quality Manager is made, the customer, and appropriate regulatory agencies will be notified in writing, when required.

9.2 Delegation of Quality Activities

The Quality Manager may delegate quality assurance activities to production or other personnel when it has been demonstrated through prior experience, training or other method that the skills necessary to perform the quality activities have been attained and documented.

A Training Certificate or List of personnel to whom quality activities have been delegated will be issued or maintained as directed by the Quality Manager.

The delegated quality activities shall be periodically audited by quality assurance to verify compliance to quality requirements. Such audits shall be used as the basis for continuation or removal of the delegation.

9.3 Continuous Review

The Management Team, will review the quality system on a continuous basis to ensure its effectiveness in meeting regulatory, customer, and quality program(s) requirements. The team will ensure that processes are in place to effectively communicate to the customer regarding product information, enquiries, processing orders and amendments and customer feedback. The review will consist of a meeting attended by the President and the Quality Manager and such other personnel as deemed necessary or a detailed report.

The following items will be included in this review: (input)

- Quality system effectiveness and suitability including all elements in the quality system and corrective/preventive action;
- Compliance to company quality policy and objectives;
- Customer surveys, where applicable
- Trends in waste and recommendations for improvement(s).
- Audit results when appropriate
- Process performance or key performance measures
- Status of preventive and corrective actions, when appropriate
- Follow up of previous actions
• Changes that may affect changes in the quality system
• Recommendations for improvement

The following output may be included during these reviews:

• Improvement of the effectiveness of the quality management system and processes,
• Improvement of product related to customer requirements;
• Required resources.

9.4 Records

The Quality Manager shall maintain records of management review. These records will include the persons attending/informed, subjects covered and a summary of the items discussed.
1.0 Purpose

1.1 This procedure defines the quality system documentation at Cobalt polymers.

2.0 Scope

2.1 This procedure applies to quality system documentation requirements of ISO 9002, Good Manufacturing Practices or other applicable quality standards for which elements of this system apply or qualify.

3.0 Responsibility

3.1 The Quality Manager is responsible for the implementation of this procedure and the maintenance of the documented quality system.

4.0 Definitions

4.1 Contract Review and Quality Planning
Document and Data Control
Process Control
Control of Quality Records
Internal Quality Audits
Contract Approval Form

5.0 Safety Requirements

6.0 Environmental Effects

7.0 Equipment & Materials

8.0 Forms

8.1 Contract Review Form
9.0 Training Required

9.1 Standard qualifications associated with management hiring practices.

10.0 Procedure

10.1 Documentation

Documentation of the quality system is maintained in English to meet customer requirements. The quality system documentation is maintained “read only,” with the exception of authorized personnel, on the computer server and is readily available to all employees, customer representatives and regulatory agencies.

The quality system documentation consists of a quality manual including appendices containing procedures, work instructions, indexes and forms covering all the Cobalt polymer systems requirements, regulatory agency, and customer requirements. There is a section in the manual corresponding to each applicable quality program standard.

10.2 Quality Manual(s)

Cobalt Polymers does not have a separate “Quality Manual” for each standard/program. Where necessary and depending on the quality program/standard, the compilation of the individual program elements listed on the matrix makes up the Manual.

The manual(s) references all applicable procedures. The document number for all manual summaries of requirements shall begin with the prefix “M”.

Procedures follow the requirements of the system standards and customer quality requirements when applicable. These are identified with a document number beginning with the prefix “P”.

Work instructions are written as needed for specific jobs, inspection operations and functions. These are identified with a document number beginning with the prefix “W”.

Forms support the above documents. These are identified with a document number beginning with the prefix “F”.

Audit check sheets form the basis of internal quality audits. Audit check sheets are written for each lowest level procedure or work instruction. The check sheets are in table format: the number, quality standard or customer quality requirement section, audit question, conforms, and comments which may include description of audit finding or for objective evidence found showing conformance. These are identified with a document number beginning with the prefix “A”.

Records are generated in the act of compliance with the quality system documentation.

10.3 Quality Planning
Quality Planning shall take place during contract review and the planning of the work order. Planning shall include all necessary receiving, in process, and final inspection operations necessary to determine that customer quality requirements are met. The acquisition of equipment, trained personnel, tooling and any necessary fixtures shall be considered. Equipment necessary for measurements of variables data when required shall be addressed.

Unless otherwise specified and/or supplemented/modified in other Cobalt polymers documentation, the quality plan assigned are those procedures applicable to the quality standard, which is agreed upon contractually.

Where changes, deviations, or customer specific requirements apply do not apply, the quality plans assigned to the orders are those requirements specified in the special Cobalt polymers Terms & Conditions.

Where appropriate, custom quality plans will be prepared and assigned. The Quality Manager is responsible for preparing, approving, and assigning these to individual sales orders, work orders, or by other means to ensure planned activities are carried out as specified.

10.4 Advanced Quality Planning (AQP)

Advanced Quality Planning (AQP) will be accomplished according to customer specific requirements. These plans are applied and are applicable as specified above.

10.5 Availability of Quality System Documentation

The Quality Manager will ensure that the quality system documentation is readily available on the computer server on a “Read Only” basis to all personnel affecting product quality.

10.6 Notification of Change in Quality System

Depending on the customer, or regulatory agency, the revision levels of the individual elements and/or matrix of the Quality Manual(s) may or may not be considered a “controlled document(s). If controlled, appropriate means to document the release & distribution of associated documents will be made by the Quality Manager or designee.

10.7 Master List or Index

The Quality Manager or designee maintains a master list or index of all quality documentation showing current revision. All documents are reviewed and approved by the Quality Manager. Approval by other departments and/or interested parties may also be done.

10.8 Revisions to Quality System Documentation

For the manual, procedures, work instructions and forms, the header of the first page of the document contains the document title, type (based on prefix), document number and revision level.
Audit checklists are considered part of the procedure or work instruction and are maintained on the server as audit check sheets. The audit check sheets have the same revision level as the procedure that is designed to audit. There is no separate approval signature or date for audit check sheet.

The quality manual, procedures and work instructions will include a revision history section describing the changes made during each revision. The revision history will be found with all controlled copies of that document. Forms and quality manual appendices do not have a revision history section.

Where specified and/or required, Cobalt polymers will ensure that changes to the individual documented elements, that are subject to approval by the customer and/or regulatory agencies, are approved by the customer/agency, prior to implementation. This will also apply to lower level documents, as applicable/required.

10.9 Configuration Management

The configuration of product is controlled by drawings and bills of materials that are associated with the work orders that contain the directions for the production of the product.

Changes to drawings and bills of materials are controlled by Engineering Change Order (ECO). ECO require the approval of Engineering, Manufacturing Engineering (Production Control) and Quality Assurance.

11.0 Process Flowchart

11.1 Organizational chart.
1.0 Purpose

1.1 The purpose of this procedure is to ensure that all contracts are reviewed prior to providing acknowledgement of the order to the customer.

2.0 Scope

2.1 This procedure applies to all customer contracts for procurement of Cobalt Polymers manufactured Products.

3.0 Responsibilities

3.1 It is the responsibility of the Quality Manager or designee to ensure that all contracts are reviewed and evidence of the contract reviews are documented.

4.0 Definitions

4.1 Contract  Customer purchase order or request for quote.
4.2 PO  Customer purchase order or contract to purchase manufactured goods from the company.
4.3 RFQ  Customer request for quotation.

6.0 Safety Requirements

7.0 Environmental Effects

8.0 Equipment & Materials

9.0 Forms

9.1 Contract Review Form
10.0 Training Required

10.1 Standard qualifications associated with management hiring practices.

11.0 Procedure

11.1 The individual responsible for receiving the customer order or request for quote will be responsible for initiating the Contract Review Form. All contracts are reviewed prior to submitting a written acceptance of the order. Acceptance of all orders will be documented in writing to the customer.

11.2 The Contract Review Form, along with the PO, or contract, will be provided to the President for review.

The contract review will be reviewed for the following:

• Customer requirements are thoroughly documented.

• Any special requirements that do not meet Cobalt Polymer’s standard procedures or lead times are confirmed to be within Cobalt Polymer’s capabilities;

• The part number and revision are verified to be current as reflected in document control.

• Exceptions to any contract will be communicated to the customer and a written amendment from the customer will be requested.
1.0 Purpose

1.1 Cobalt Polymers has established and maintains documented procedures that control and verify the process of design projects.

2.0 Scope

2.1 This procedure applies to strategic design activities.

3.0 Responsibilities

3.1 It is the responsibility of the President and Quality Manager to implement and verify this procedure.

4.0 Definitions

5.0 Safety Requirements

6.0 Environmental Effects

7.0 Equipment and Materials

8.0 Forms

9.0 Procedure

9.1 Activities

At a minimum, the following design activities will be controlled through established procedures and/or work instructions:

- Design and Development Planning
- Organizational and Technical Interfaces
- Design Input
- Design Output
- Design Review
- Design Verification
- Design Validation
- Design Changes
10.0 Design and Development Planning

Significant stages are defined and planned by the project team. These stages are defined in respect to the customer and company requirements. Significant stages generally include task sequence, mandatory steps, and method of configuration control.

Consideration will be given to the complexity of the project with relationship to structuring the design effort into significant elements. For each significant task, activity or element, analysis will be performed to define the necessary resources. This analysis will define the person responsible, design content, planning constraints, and performance conditions.

Reliability, maintainability, and safety are all important factors of the design and development planning. When defining the significant task and activities of the project, the customer and/or regulatory authority requirements will be followed.

10.1 Organizational and Technical Interfaces

Input from various groups and departments required for design or development will be defined. In such case, those groups or departments involved will have the necessary information provided to them by the design group.

10.2 Design and Development Input

All applicable statutory and regulatory requirements shall be identified, documented and reviewed by the design department. Any conflicting requirements will be documented and reviewed with those imposing the requirements. Resolution of the conflicting requirements must be resolved prior to proceeding with the design or development project.

Contract review results and functional requirements will be defined and documented. Information derived from previous designs, where applicable, shall be considered. This process is often referred to as “by similarity”. In the case of product requiring design and development planning, the input data specific to each element will be established and reviewed to ensure consistency with requirements.

Design input will be recorded and reviewed. The design requirements must be complete, unambiguous and should not conflict with each other.

10.3 Design and Development Output

Design output will consist of various documents, which include but not limited to, drawings, bill of materials, specifications, etc. The design output must be documented and expressed in terms that can be verified and validated against the design input. All pertinent data required to allow the product to be identified, manufactured, inspected, used and maintained shall be defined. The design output must:

- meet the input requirements for design and development,
- contain or make reference to acceptance criteria,
- identify those characteristics of the design that are critical to the safe and proper functioning of the product, (e.g., storage, handling, maintenance, disposal requirements),
• define material, processes, type of manufacturing and assembly of product necessary to ensure conformity to the design requirements.
• Provide appropriate information for purchasing and production,

The design output documents will be reviewed and verified prior to release.

10.4 Design and Development Review

During the planning processes, significant stages are defined. During these stages a documented review of the design results must be planned and conducted. Participants at each design review will include representatives of all functions concerned with the design stage being reviewed as well as other specialists, as required. Records of these reviews will be documented.

The intent of Design and Development Review is to accomplish the following:

• evaluate the ability of the results of design and development to meet requirements,
• identify problems or issues and propose necessary actions,
• formally authorize progression to the next stage.

10.5 Design Verification

Verification will be planned and performed to ensure that the design stage output meets the design stage input requirements. The design verification will be recorded. Verification of all associated reports, calculations, and test results, etc. demonstrate that the product definition meets the specification requirements for all identified operational conditions and the product functions correctly.

When conducting design verification, consideration may be given to alternative calculations and comparing the new design with similar proven designs. In addition, performing tests and demonstrations may prove useful as well as reviewing the design stage documents prior to release.

10.6 Design Validation

Design validation will be planned, performed and documented to ensure that the product conforms to defined user needs, requirements and meets the requirements for intended use, when known.

It is important to note that:

• design validation follows successful design verification
• validation is normally performed under defined operating conditions
• validation is normally performed on the final product, but may be necessary in earlier stages prior to product completion
• multiple validations may be necessary if there are different intended uses
10.7 Design Verification and Validation Testing

Where tests are necessary for verification and validation of the product, these tests will be planned, controlled, reviewed, and documented to ensure and prove the following:

- test procedures describe the method of operation, the performance of the test, and the recording of the results,
- The correct configuration standard of the product is submitted for the test,
- the requirements of the test plan and the test procedures are observed,
- test plans or specifications identify the product being tested and the resources being used, define test objectives and conditions, parameters to be recorded, and relevant acceptance criteria,
- the acceptance criteria are met.

10.8 Design and Development Changes

Design changes and modifications will be identified, documented, reviewed and approved by authorized personnel before their implementation. When required by contract or regulatory agencies, approval from customer and/or regulatory authority shall be acquired. Consideration will be given to the effect the changes may have on constituent parts and product already delivered.
1.0 Purpose

1.1 Cobalt Polymers has established and maintains documented procedures to ensure that current information is available at the current revision level. This applies to all documents and data that relate to the customer quality requirements. Cobalt Polymers does not make changes to customer design media, SCD or tooling designs without customer approval.

2.0 Scope

2.1 This procedure applies to all Quality Systems documents.

3.0 Responsibility

3.1 The Engineering Manager is responsible for the maintenance of the document control system. The Quality Manager is responsible for the maintenance of the quality system documentation.

4.0 Definitions

5.0 Safety Requirements

6.0 Environmental Effects

7.0 Equipment & Materials

8.0 Forms

9.0 Procedures

9.1 Documents and data including digital data used for design, production and/or inspection are controlled to ensure that product is manufactured to the current revision of the documents and data. All satellite copies of documentation are maintained at the revision level as the master files, when appropriate. The documents and data that are controlled include:

   a) quality manual, procedures, forms and work instructions;

   b) engineering drawings;

   c) process specifications;
d) external standards;

e) digital data.

The Quality Manager approves quality system documentation prior to release. The Quality Manager maintains a master list of quality system documentation. The master list shall identify the procedure or form name, the current revision level, and the appropriate document number.

Documents are available to all employees where they are needed. All quality documentation is available as “Read Only” on the server in a digital format.

9.2 Changes

Changes to documents are reviewed and approved by the Quality Manager and/or the appropriate owner of the document. The reviewer will have access to pertinent background information as necessary to determine the acceptability of the change.

The nature of the change is described on a Document Change Request form. A matrix is kept with the current document revision(s).

Invalid and obsolete documents are promptly removed from use. All copies will be destroyed, except that obsolete documents may be retained for legal or information purposes if identified as obsolete or invalid as appropriate.

The Quality Manager will forward all revisions of the quality system documentation, regulatory agencies and customers as required, except for numbering and grammatical changes.

9.3 Customer Drawings

For each new order, the sales department ensures that Cobalt Polymers has the current drawing as specified on the purchase order.

Customer drawings are maintained at the same revision level as the customer. The latest drawings supplied by the customer shall be incorporated into the appropriate Cobalt Polymers drawings used for manufacturing and inspection unless otherwise specified by the customer. The drawings may be “red lined” to reflect customer changes until the appropriate ECO has been approved. Changes that take place after purchase order has been received shall be recorded by document control on the master list and the effectivity date of the changes will be coordinated with the appropriate customer Contract Administrator.

A Master List of drawings is maintained on a database by Document Control. The list identifies the current revision level.

When drawings are received, a master list shall be updated by document control and the revised drawing is placed in the appropriate file location. The old revision shall be removed from the files and destroyed or returned to the customer if required or maintained and identified as obsolete or invalid.

Documents found to be obsolete shall be returned to the customer, if required.
Prior to final product acceptance the authorized inspection personnel shall verify the latest revision level of the drawing.

9.4 Customer Specifications and External Standards

Customer specifications are maintained at the same revision level as at customer.

Document control shall maintain a list of specifications supplied by the customer. Upon receipt of revisions, document control shall update the revised specifications. Obsolete documents shall be returned to customer for recycling or destroyed. The master list shall be revised, as appropriate, when revisions are received from customers.

External standards and/or customer source controlled drawings shall be obtained from qualified suppliers for that standard. Cobalt Polymers may subscribe to an engineering document service to ensure the current revision level of such external standards or source controlled drawings is maintained.

9.5 Identification of Controlled Documents

Quality system documents shall be available on the computer server on a “Read Only” basis at all computer terminals, except the Quality Manager or designee may access the documentation for editing. Only the quality system documentation electronically stored on the server is controlled. All other copies are for reference only. Internally controlled copies of specifications will be stamped “Controlled Copy” or identified by other means.

9.6 Drawings and Specification for Subcontractor Use

Customer supplied drawings shall be verified by Purchasing to be to the latest revision level prior to shipment to subcontractor.
1.0 Purpose

1.1 Cobalt Polymers has established and maintains documented procedures to ensure that purchased product conforms to specified requirements.

2.0 Scope

2.1 This procedure applies to all purchased items intended for production use.

3.0 Responsibility

3.1 It is the responsibility of the Purchasing Manager to ensure compliance to this procedure.

4.0 Definitions

5.0 Safety Requirements

6.0 Environmental Effects

7.0 Equipment & Materials

8.0 Forms

9.0 Procedure

9.1 Evaluation of Subcontractors

It is the responsibility of the Quality Manager, in conjunction with the purchasing representative, to evaluate the subcontractors. The Quality Manager and/or purchasing manager:

- evaluates and selects subcontractors on the basis of their ability to meet subcontract requirements including the quality system and any specific quality assurance requirements;

- defines the type and extent of control exercised over the subcontractors. This is dependent upon the type of product, the impact of subcontractors product on the quality of final product and, where applicable, on the quality audit reports or quality records of the previously demonstrated capability and performance of subcontractors;

- establishes and maintains quality records of acceptable subcontractors;

- ensures that quality assurance has the authority to disapprove the use of sources that do not have acceptable


quality systems or product history;

- periodically reviews subcontractor performance. Records of these reviews are maintained and used as a basis for establishing the level of supplier controls to be implemented;

- maintains guidelines or procedures that define the necessary corrective actions to take when dealing with subcontractors which do not meet requirements.

A list of approved subcontractors is maintained and specifies the scope of the approval.

9.2 Purchasing Data

Purchasing documents contain data clearly describing the product ordered, including where applicable:

- the type, class, grade or other precise identification;

- the title or other positive identification, and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data, including requirements for approval or qualification of a product, procedure, process equipment and personnel;

- the title, number and issue of the quality system standard to be applied, where applicable;

- design, test, examination, inspection and customer acceptance requirements and any related instructions and requirements;

- right of access by the purchaser, their customer and regulatory authorities to all facilities involved in the order and all applicable quality records;

- requirements for test specimens (production method, number, storage conditions etc.) for design approval, inspection, investigation or auditing;

- requirements relative to the notification of anomalies, changes in definition and the approval of their processing;

- requirements to flow down to sub-tier suppliers the applicable requirements in the purchasing documents, including key characteristics where required.

A company designee reviews and approves purchasing documents for adequacy of the specified requirements prior to release.

9.3 Verification of Purchased Product

Verification of purchased product may be accomplished:

- by obtaining objective evidence of the quality of product from subcontractors (e.g., accompanying documentation, certificate of conformity, test reports, statistical records, process control);
• inspection and audit at source;
• review of required documentation;
• inspection of products at delivery;
• delegation of verification to the subcontractor, or subcontractor certification.

When delegation is used, the Quality Manager defines the requirements for delegation and maintains a list of delegations.

9.4 Supplier Verification at Subcontractor’s Premises

When verification of purchased product occurs at the sub-contractor’s facility, The Quality Manager shall specify verification arrangements and the method of product release in the purchasing documents.
1.0 Purpose
   1.1 Documented procedures and controls have been established for customer supplied product or materials.

2.0 Scope
   2.1 This procedure applies to all customer supplied product or materials.

3.0 Responsibilities
   2.1 The Quality Manager or designee is responsible for maintaining this procedure and related documents.

4.0 Definitions

5.0 Safety Requirements

6.0 Environmental Effects

7.0 Equipment & Materials

8.0 Forms

9.0 Related Documents
   • Incoming Inspection Procedure

10.0 Procedure
   10.1 Customer supplied product or materials will be treated in the same manner with respect to including applicable receiving, testing and inspection practices.
   10.2 Customer supplied product or materials will be stored in a separate designated area. Customer supplied product or material will not be mixed with standard product or materials.
   10.3 Customer supplied product or materials will be identified with the customers name, description and part number where applicable.
1.0 Purpose

1.1 Where appropriate, Cobalt Polymers maintains a system of material and/or product traceability throughout all stages of receipt, incoming inspection, storage, production, final inspection and delivery.

2.0 Scope

2.1 This procedure applies to all lower level components and raw materials intended for production use. This Procedure also applies to all final product.

3.0 Responsibilities

3.1 The Quality Manager or designee is responsible for maintaining this procedure and related documents.

4.0 Definitions

5.0 Safety Requirements

6.0 Environmental Effects

7.0 Equipment & Materials

8.0 Forms

9.0 Related Documents

- Incoming Inspection Procedure
- Receiving Procedure
- Handling and Storage Procedure
- Process Control
- Inspection and Test Status

10.0 Procedure

10.1 All product or raw materials will be identified with a unique numbering system that will provide traceability to, but not limited to, the applicable purchase order, date received or manufactured, raw material used for production of the product, person(s) responsible for inspection and date shipped.

10.2 This information will be recorded on the appropriate documents during the various stages of inspection and production.
1.0 Purpose

1.1 Cobalt Polymers plans and identifies the production processes which directly affect quality of the product. Controls have been established to ensure that the processes used for production are carried out under controlled conditions and meet or exceed the customer requirements as well as the product specifications.

2.0 Scope

2.1 This procedures applies to all process necessary for production.

3.0 Responsibility

3.1 The Quality Manager or designee is responsible for maintaining this procedure and related documents.

4.0 Definitions

5.0 Safety Requirements

6.0 Environmental Effects

7.0 Equipment & Materials

8.0 Forms

9.0 Related Documents

• Work Instructions
• Inspection and Test Status Procedure
• Training

10.0 Procedure

10.1 Manufacturing operations are performed under the guidance of written work instructions.

10.1 Manufacturing will be conducted in a clean and organized environment suitable to the product.

10.3 Workmanship criteria shall be defined by the President or Quality Manager and documented when applicable.

10.4 Manufacturing processes are performed using appropriate equipment as approved by the President or Manufacturing Manager.

10.5 Where applicable, manufacturing operations will be compliant to all defined or imposed standards, codes, or quality plans.
10.6 Processing parameters and characteristics shall be controlled by the Manufacturing Manager or designee.

10.7 The Manufacturing Manager shall be responsible for establishing appropriate maintenance of equipment that will ensure continuing process capability and product quality and compliance.
1.0 Purpose
1.1 Inspection and Test (where applicable) activities are documented and maintained to ensure product compliance to the required specifications.

2.0 Scope
2.1 This procedure applies to the inspection and testing activities associated with production.

3.0 Responsibilities
3.1 The Quality Manager or designee is responsible for maintaining this procedure and related documents.

4.0 Definitions

5.0 Safety Requirements

6.0 Environmental Effects

7.0 Equipment & Materials

8.0 Forms

9.0 Related Documents
• Incoming Inspection Procedure
• Inspection and Test Status Procedure
• Receiving Inspection Instructions
• Process Control Procedures

10.0 Procedure
10.1 Inspection and testing (where applicable) will be performed at three stages; incoming inspection, in process inspection and final inspection.

10.2 Receiving inspection and testing will be performed on raw materials and lower level components that affect the quality of the finished product.

10.3 These raw materials or lower level components will be identified appropriately to ensure that they are not used or processed until they have been inspected or otherwise verified as conforming to the specified requirements. (except as defined in 5.5 of Inspection and Testing)
10.4 The amount of receiving inspection will be defined by the Quality Manager and consideration will be given to the quality system controls established and exercised at the subcontractors or suppliers premises.

10.5 In such circumstances that incoming raw materials or components are urgently needed for production purposes, they will be positively identified to allow for immediately recall in the event they are found to be nonconforming.

10.6 In-process inspection and testing is conducted in accordance with the Process Control procedures and In-process Inspection procedure and at the beginning or end of each process unless otherwise specified. This inspection activity is intended to ensure that product is compliant to the specified requirements. All product will be held until the specified inspection has been complete.

10.7 Final inspection and testing is conducted in accordance with the Process Control procedures and Final Inspection procedures.

10.8 No product will be dispatched until the above inspection activities have been completed.

10.9 All inspection activities will be documented on the appropriate documents.
1.0 Purpose

1.1 Cobalt Polymers has established and documented procedures to ensure that all inspection, measuring and test equipment, (including software when applicable), used to demonstrate the conformance of product will be controlled and calibrated.

2.0 Scope

2.1 This procedures applies to all inspection, measuring and test equipment used for production verifications.

3.0 Responsibilities

3.1 The Quality Manager or designee is responsible for maintaining this procedure and related documents.

4.0 Definitions

• NIST National Institute of Standards and Technology

5.0 Safety Requirements

6.0 Environmental Effects

7.0 Equipment & Materials

8.0 Forms

9.0 Related Documents

• Calibration procedure
• Daily validation procedure

10.0 Procedure

10.1 Inspection, measuring and test equipment (including software when applicable) will be identified and placed under a controlled plan as described in the Calibration Procedure.

10.2 The plan will define the method of recall, unique identification of all measuring and test equipment, including software, and calibration frequency.

10.3 All test and measuring equipment used to ensure the compliance of product will be adequate for the specification and tolerance required.

10.4 Adequate measuring and test equipment will adequate for the critical or control dimensions defined by the engineering department or designee.
10.5 When required by a customer contract, technical data pertaining to the inspection activities will be recorded and available to the customer for review.

10.6 Calibration records will be kept on file and will be traceable to NIST.

10.7 Most frequently used measuring or test equipment will be validated on a daily basis. This validation process will involve a measurement against a known, traceable standard defined by the Quality Manager.

10.8 If any measuring or test equipment is found to be out of calibration, a process will be followed by which product inspected with said equipment can be isolated and re-inspected for compliance.

10.9 The production and inspection environment will be adequate to ensure accuracy of measurement results.

11.0 Measuring and test equipment will be handled, stored and preserved in such a manner as to ensure that the accuracy is maintained.

12.0 Measuring and test equipment, including software, will be secured so as to prevent adjustments which would invalidate the calibration settings.
1.0 Policy
   1.1 A system has been established to ensure that the status of controlled materials and product area readily identifiable.

2.0 Scope
   2.1 This procedure applies to all inspected materials intended for production use.

3.0 Responsibilities
   The Quality Manager or designee is responsible for maintaining this procedure and related documents.

4.0 Definitions
   • MRB Material Review Board

5.0 Safety Requirements

6.0 Environmental Effects

7.0 Equipment & Materials

8.0 Related Documents
   • Quality Plan
   • Control of Nonconforming Products

9.0 Procedure
   • Incoming, in-process and final product and materials will be clearly identified as to the status of inspection.
   • The means of identification will be by quality tags and workorders or travelers.
   • Nonconforming product and materials will be segregated in a holding area. This area will ensure inadvertent use of the nonconforming product or materials prior to the MRB process.
1.0 Purpose

1.1 Non-conforming products and materials are identified, segregated (when practical), documented, evaluated and communicated in order to prevent unintentional use until an evaluation by the authorized individuals can take place.

2.0 Scope

2.1 This procedure applies to all product intended for production use.

3.0 Responsibilities

3.1 It is the responsibility of all employees to identify non-conforming material. It is the responsibility of the Quality department employees to isolate the product and complete required documentation. Products identified as non-conforming shall be dispositioned by the Quality Manager or designee.

4.0 Definitions

• Non-conforming Product or material that does not meet the specified requirements.

5.0 Safety Requirements

6.0 Environmental Effects

7.0 Equipment & Materials

8.0 Forms

9.0 Related Documents

9.1 Non-conforming Material Procedure.

10.0 Procedure

10.1 Non-conforming products or materials discovered typically during incoming inspection, in-process inspection or final inspection are segregated whenever practical. The "Hold" area will be controlled with the intent to prevent the non-conforming product or materials from unintentional use.

10.2 The non-conforming product or materials will be identified as non-conforming through the use of a readily recognized tag or sticker.

10.3 Documentation of the non-conforming product or materials will include, but may not be limited to, a description of the product, the purchase order or other identifying order number associated with the product or material and a description of the non-conformance.
10.4 Review and disposition of the non-conforming product or material is the responsibility of the President or designee and may include a group of individuals such as a Quality Department or engineering representative.

10.5 Disposition of the non-conforming product or material may include:
   - Reworking to meet the specified requirements.
   - Reviewing for an alternate application.
   - Accepting with or without repair by concession.
   - Scrapping the material.
   - Return to vendor or supplier.

10.6 Non-conforming products or material dispositioned as "rework" is controlled until the rework is complete. All reworked products or materials are subject to reinspection or retesting.

10.7 Non-conforming products or material dispositioned to be scrapped will be permanently marked so that it cannot unintentionally be reintroduced back into the system.

10.8 Records of non-conforming product or material and their dispositions are maintained within an appropriate system.

10.9 The President or designee is responsible for follow up of corrective action with both external and internal suppliers.
1.0 Purpose
   1.1 Non-conformities are documented, investigated and addressed through an extensive corrective action process to prevent recurrence. Processes, Quality records, and or reports are analyzed to detect and eliminate potential causes of failure.

2.0 Scope
   2.1 This procedure applies to internal non-conformances as well as customer rejections or complaints.

3.0 Responsibilities
   3.1 The President or designee is responsible for monitoring and implementing the procedure.

4.0 Definitions

5.0 Safety Requirements

6.0 Environmental Effects

7.0 Equipment & Materials

8.0 Forms

9.0 Related Documents
   9.1 Control of Non-Conforming Products and Material

10.0 Procedure
   10.1 The responsibility and authority for implementing corrective action is identified, and the follow up action(s) are taken and reviewed by designated personnel for effectiveness.

   10.2 Any changes resulting from corrective or preventive action affecting procedures or documents shall be recorded.

   10.3 The procedures for corrective action shall include, but not be limited to:
   • The effectiveness of handling customer related complaints and returned products.
   • The investigative process and results of the investigation.
   • Determination of corrective action required to prevent recurrence.
• Follow up of corrective action and the effectiveness of preventive action.

10.4 Preventive action shall include, but not be limited to:
• The use of appropriate sources of information to detect, analyze and prevent potential causes of non-conformities.
• Identification of actions required to prevent reoccurrence and their effectiveness.

10.5 Customer related complaints shall be made available for management review.
1.0 Purpose

1.1 It is the company policy to ensure that product is treated according to industry best practice. Documented procedures have been established for handling, storage, packaging, preservation and delivery of product.

2.0 Scope

2.1 This procedure applies to all materials, storage, packaging, preservation and delivery practices.

3.0 Responsibilities

3.1 It is the responsibility of the President or designee to monitor and maintain the documents.

4.0 Definitions

5.0 Safety Requirements

6.0 Environmental Effects

7.0 Equipment & Materials

8.0 Forms

9.0 Related Documents

• Shipping Procedure

10.0 Procedure

10.1 Product and/or materials shall be handled in such a way to prevent damage or deterioration. Additionally, product and materials shall be handled in a safe manner which maintains product quality.

10.2 Product and materials shall be stored in designated areas when received, are in process, stored for distribution, and ready for shipment. These designated areas shall be identified and suitable for the product or materials. Controls shall be implemented to maintain the products quality and prevent deterioration.

10.3 Product shall be packaged in a manner consistent with industry best practices unless otherwise stipulated by the customer.

10.4 When applicable, the product or materials shall be stored in areas that ensure preservation.

10.5 The protection of the product shall be considered a priority when selecting shipping companies.
1.0 Purpose

1.1 This procedure defines the quality records maintained at Cobalt Polymers as objective evidence of quality system implementation.

2.0 Scope

2.1 This procedure applies to all areas of the company that involve record keeping that affects quality.

3.0 Responsibility & Authority

3.1 The Quality Manager has the overall responsibility and authority to ensure this procedure, and its prescribed methods of implementing the controls associated with a records program, meet the requirements of all applicable quality programs.

3.2 All department managers, have the responsibility and authority to ensure their personnel implementing portions of this procedure are carried out, as prescribed.

3.3 The Quality Manager is responsible for the long-term storage of all quality records.

3.4 The IT department or designee personnel are responsible for the maintenance, storage, and deletion of all electronic records.

3.5 The individual/department record owners are responsible for ensuring that the records in their short-term care are legible and stored & secured in an appropriate environment so they are protected from damage, deterioration and loss.

Deviations or changes to this procedure can only be made by the Quality Manager and/or President of Cobalt polymers.

4.0 Definitions

- Quality Records:

The records listed in the Quality Record Matrix, include all material traceability, product acceptance, process completion, and any other documents required establishing conformance to customer & program quality requirements. Records from subcontractors are included in the data maintained.

5.0 Safety Requirements

6.0 Environmental Effects
7.0 Equipment & Materials

8.0 Forms

9.0 Procedure

9.1 Identification of Quality Records

Records to be kept are individually identified in the quality system documentation and are listed collectively in the Quality Record Matrix.

9.2 Collection & Filing of Quality Records

Individual employees have the responsibility to prepare, collect and file the appropriate records as they perform the work described in the quality system documentation.

Filing systems shall clearly identify the contents of individual files. They should also be identified with the year(s) in which they were created.

9.3 Retention of Quality Records

All records shown are retained for a minimum of 7 years from date of their creation, or as specified contractually, and are available for customer or customer representative review.

Depending on their use & need, quality records may periodically be moved from the individual/department holders to long-term storage. The Individual department managers are responsible for determining this need and making coordinating arrangements for moving records to long-term storage.

Cobalt Polymers has a designated area(s) for long-term storage of quality records. The Quality Manager is responsible for the long-term storage of all quality related records. This area(s) shall be:

- limited to authorized personnel only, under the responsibility of the Quality Manager.
- remain secured when not in use.
- organized in a manner to facilitate easy identification and access of records.
- In an environment that prevents damage and/or deterioration.

9.4 Disposal/Destruction of Quality Records

At the end of the specified retention time, records may be discarded. Confidential or proprietary records may be shredded as necessary.
When quality records are disposed of, a record or log of the disposal/destruction shall be used listing which type of records were discarded, who actually discarded them, and the actual date of disposal/destruction. Note: a listing of type of records can be as simple as “type and year(s)”. This record/log shall be maintained by the Quality Manager.

9.5 Approved Media

Records may be kept in hard copy or electronic media provided the electronic media is backed up or otherwise protected from loss.

The IT Manager or representative is responsible for establishing & maintaining a documented procedure(s) on how, who, & when electronic records are backed up & protected from loss. The responsibility and authority of persons performing these operations shall be incorporated within these procedures.

The IT Manager or representative has the responsibility and authority to ensure this separate procedure(s) is followed and implemented on a regular basis.

9.6 Availability of Quality Records to Customer

Quality records shall be made available to customer, customer agent or regulatory agencies upon request. The Quality Manager is responsible for coordinating this need, and making the records available.

9.7 Review of Quality Records

Quality records are reviewed for completeness, accuracy and are stored in a manner that will maintain the relationship between the data collected and the corresponding product by the document owner.
1.0 Purpose

1.1 Internal Quality Audits are planned and conducted for departments within the Quality System. Each element of the Quality System will be audited at a minimum of once a year. Internal audits are scheduled on the basis of status and importance of the activity.

2.0 Scope

2.1 This procedure applies to internal Quality Systems audits performed by Cobalt Polymers.

3.0 Responsibility

3.1 The Quality Manager is responsible for the Internal Quality Audits.

4.0 Definitions

5.0 Safety Requirements

6.0 Environmental Effects

7.0 Equipment & Materials

8.0 Forms

9.0 Related Documents

9.1 Master Internal Auditing Plan.

9.2 Internal Auditing check sheets.

10.0 Procedure

10.1 A master internal auditing plan will be developed and maintained by the Quality Manager. This plan will be scheduled in such a way as to ensure that all elements of the Quality Manual are audited within a time period not to exceed a 12 month period. More frequent auditing may be required depending on importance, or a recurring problem.

10.2 The results of the audits will be recorded and discussed with the individual being audited and the department supervisor or manager.

10.3 Any deficiencies observed during the audit will be recorded and provided to the department supervisor or manager.
10.4 A written corrective action response from the department will be required for any deficiency noted during the audit will be required from the department supervisor or manager.

10.5 Follow up audits will be performed to verify the implementation and effectiveness of the corrective action.
1.0 Purpose

1.1 This procedure defines the process employed at Cobalt Polymers to identify and provide for training of employees.

2.0 Scope

2.1 This procedure applies to all employees performing functions that affect quality.

3.0 Responsibility

3.1 The Human Resources Manager is responsible for the implementation and maintenance of this procedure.

3.2 The individual department managers are responsible for ensuring all employees within their departments are qualified and trained to perform all authorized activities for which they are assigned.

4.0 Definitions

5.0 Safety Requirements

6.0 Environmental Effects

7.0 Equipment & Materials

8.0 Forms

9.0 References

9.1 Control of Quality Records
9.2 Training Record
9.3 Certification
9.4 Inspection Personnel Qualification Summary

10.0 Procedure

10.1 Qualification of Employees
All employees performing activities affecting quality must be qualified to perform those duties. Supervisors, with the review of the Human Resources Manager, determine the qualifications of an employee. Qualification may be achieved by education, experience, or training, as appropriate.

10.2 Assessment of Qualifications

Supervisors discuss the qualification requirements for the position with each new employee so the employee understands what skills are required and when they are expected to become proficient in those skills. At each performance evaluation, supervisors and employees discuss the qualification requirements to assess qualifications, proficiency and training needs. Although the performance evaluation doesn’t have to take place according to a regular schedule, assessing qualifications and training needs is an ongoing process. An initial assessment should be done with all new employees.

Senior Management and other managers are only hired meeting specified requirements of the job duties. An assessment of their qualifications is not required, unless certain limitations or additional training is determined by their supervisor.

10.3 Master training record

The Human Resources Manager or designee, in coordination with department heads, where applicable, maintains the master training record to meet the training needs of employees. The master training record may be adjusted from time to time to meet specific production needs.

Training to maintain a level of awareness and understanding of relevant procedures and instructions shall be included in the training program.

10.4 Training Methods

Most training is on-the-job training. Employees will work under the direction of a qualified employee until the supervisor determines that the appropriate skills have been mastered. Additional training may include classroom instruction, seminars, cross training, formal enrollment in educational institutions or other means as deemed appropriate by management.

10.5 Records

The Training Record, or equivalent, shall be noted at the time of instruction by the person giving the instruction and shall document the subject covered, date, persons attending, duration and name of the instructor. The Human Resources Manager or designee maintains the training records.

Training may also be documented by sign in sheets in any format that substantially documents the information specified above.

10.6 Certification

Certain skills in production and inspection, as required by specification or otherwise, shall require certification. When sufficient on-the-job training has been completed, the candidate may also be evaluated by written and/or practical examination. The candidates shall be rated objectively and, if qualified, certified to perform such testing methods.

The certification may be documented on the master training record or other applicable form, or by an outside service, which provided such specialized training. Specific requirements for certification shall be governed by appropriate
customer specification. Certificates or other documentation of outside training shall be kept as part of the training records.

10.7 Individual Training Records

An individual employee’s training record shall be noted and initialed by the supervisor as the additional skills are mastered. Training of groups of employees will be documented within personnel files. The Human Resources Manager or designee maintains the training records.

10.8 Refresher Training

Refresher training is to be required at the discretion of the department manager or supervisor. Generally, this will be accessed at the time of performance evaluations, if there is a negative performance trend identified or if frequency of performing a specific function is seldom enough to warrant refresher training.
1.0 Purpose

1.1 This procedure defines the use of statistical techniques at Cobalt Polymers.

2.0 Scope

2.0 This procedure applies to statistical techniques used to analyze quality system data and techniques required by the customer for specific orders. The scope of this procedure does not include statistical process control.

3.0 Responsibility

3.1 The Quality Manager is responsible for the implementation and management of this procedure.

4.0 Definitions

- Control of Nonconforming Product
- Corrective and Preventive Action
- Control of Quality Records
- Internal Quality Audits

5.0 Safety Requirements

6.0 Environmental Effects

7.0 Equipment & Materials

8.0 Forms

9.0 Procedure

9.1 Statistical techniques may be used to analyze key performance measures in several areas to effectively monitor the performance of the quality system and processes within the company. The areas targeted for the use of statistical techniques are:

- supplier performance
- customer rejections
- on time delivery
- key characteristics

9.2 Basic statistical methods, such as pie graphs and Pareto charts, may be employed to analyze the above data. This enables management to review the effectiveness of the quality system and determine the need for action and additional resources.
9.3 Authorized personnel will review all internal rejection tags and determine need for corrective actions. Refer to Corrective Action procedure. Through analysis of trends and repetitive problems, Quality representatives may require a corrective action to remedy such problems. Quality representatives should, on a periodic basis, provide a report of this analysis to the Quality Manager for review and distribution to company management as part of a Continuous Improvement Program.