

Plastics and Concepts of Connecticut Inc.

Quality Manual

Nature of Changes For This Issue:

1. Initial Release 8/14/2000
2. Reformatted and grammatical errors corrected 6/11/02
3. Minor grammatical errors corrected and current organization chart added
2/19/04

PREFACE

The policies, responsibilities and practices governing Quality and Product Integrity set forth in this Quality Manual are defined in Plastics and Concepts of Connecticut, Inc.'s procedures and work instructions. The policies and practices described in this manual conform to ISO 9001 and applicable government regulations, specifications and requirements.

The ISO 9001 Quality System encompasses the design, tool fabrication and manufacture of plastic injection molded parts and related services.

The Quality Manager is responsible to ensure the Quality System is established and effective. The Quality Manager is responsible for liaison with external parties on matters relating to the Quality system.

Executives are responsible for implementing and managing all Quality functions within their respective Areas of responsibility and for coordinating Quality interfaces one another.

Kathleen Harris
President
Plastics and Concepts

Harold S. Harris
Quality Manager

1. SCOPE

This Quality Manual provides the policy for Plastics and Concepts of Connecticut, Inc. (Plastics and Concepts) that meets the requirements of ISO 9001, contractual and regulatory requirements, to successfully design and manufacture of plastic injection molding tooling and parts.

2. PURPOSE

This Quality Manual forms the basis for subsequent Procedures, Specifications, Standards, Work Instructions, Documents and Records to form the total Plastics and Concepts Quality System to meet customer and regulatory requirements worldwide.

3. DEFINITIONS

3.1 Product: Results of activities or processes producing deliverables to customers.

A product may include service, hardware, processed materials, software, or a combination thereof.

A product can be tangible (e.g., assemblies or processed materials) or intangible (e.g., knowledge or concepts) or a combination thereof.

4. QUALITY SYSTEM REQUIREMENTS

4.1 Management Responsibility

4.1.1 Plastics and Concepts Quality Policy

Plastics and Concepts is committed to being the world class provider of plastic parts & services that delight our customers.

4.1 .1 .1 Implementation — We achieve our policy objective by careful adherence to Plastics and Concepts Policies and Procedures and the following commitments:

- (d) Use of the continuous improvement process and empowered employees, to delight our customer, fulfill and reward our employees and achieve superior business results.
- (e) As process owners, team members and individual contributors; all employees have a responsibility for Quality
- (f) Management is responsible for removing barriers to improvements and developing both teams and individuals.

4.1.2 Organization

4.1.2.1 Responsibility and Authority

The President has ultimate responsibility for establishing, implementing, and maintaining the quality system as identified in the Quality Manual.

The Executives and their responsibilities are defined in the organization chart (see appendix A).

The Executives deploy the Quality Policy. They are responsible for ensuring that the Quality Manual and the Quality Policy are understood, implemented, and maintained at all levels of the organization. The executives with the entire work force and supplier base are responsible for the quality of products and services under their control.

The Executives define and document the responsibility, authority and interrelationship of personnel who manage, perform and verify work affecting quality. Further, the Executives empower personnel with the organizational freedom and authority to:

- (a) initiate action to prevent the occurrence of any nonconformities relating to product, process and quality system;
- (b) identify and record any problems relating to the product, process and quality system;
- (c) initiate, recommend, or provide solutions;
- (d) verify the implementation of solutions;
- (e) control further processing, delivery, or installation of nonconforming product until the deficiency or unsatisfactory condition has been corrected.

4.1.2.2 Resources

The Executives identify resource requirements and provide adequate resources including the assignment of trained personnel, for management, performance of work and verification activities including internal quality audits and Executive reviews.

4.1.2.3 Management Representative

The Quality Manager also functions as the management representative with overall responsibility and authority for:

- (a) ensuring that a quality system is established, implemented, and maintained in accordance with ISO 9001, contractual and regulatory requirements, and
- (b) reporting on the performance of the quality system to management for review and as a basis for improvement of the quality system.

4.1.3 Management Review

The President and the other Executives review the quality system at least yearly to ensure its continuing suitability and effectiveness in satisfying the requirements of ISO 9001, and Plastics and Concepts' Quality Policy and objectives. Records of these reviews are maintained.

4.2 QUALITY SYSTEM

4.2.1 General

Plastics and Concepts has established, documented and maintains a quality system as a means of ensuring that product conforms to specified requirements. This Quality Manual, and subsequent procedures document the requirements of ISO 9001, contractual and regulatory requirements. The structure of the quality system documentation is shown in the list in paragraph 4.2.4.

4.2.2 Quality System Procedures

Plastics and Concepts:

(a) prepares documented procedures that are consistent with the requirements of ISO 9001 and the Plastics and Concepts quality policy, and

(b) effectively implements the quality system and its documented procedures.

The range and detail of the procedures that form the quality system are dependent on the complexity of the work, methods used, and skills and training needed by personnel involved in carrying out the activity.

4.2.3 Quality Planning

Plastics and Concepts defines, documents and conducts the following activities, as appropriate, in meeting the specified requirements for products, projects, or contracts:

(a) the preparation of quality plans;

(b) the identification and acquisition of any controls, processes, equipment (including inspection and test equipment), fixtures, resources, and skills that may be needed to achieve the required quality;

(c) the identification of suitable verification at appropriate stages in the realization of product;

(d) the identification and preparation of quality records.

This Quality Manual (QM) and subsequent flow down procedures form the quality system and the basic Plastics and Concepts quality plan. Specific quality plans are originated only in those situations where requirements vary from those covered by the

basic Plastics and Concepts quality system or as required by customer/contract.
Quality System Documentation structure:

4.2.4 Quality System Documentation:

The document hierarchy is as follows:

- 1. Quality Manual**
- 2. Procedure Manual**
- 3. Procedures, Specifications, Standards, Work Instructions, & Documents**
- 4. Records**

4.3 CONTRACT REVIEW

4.3.1 General

Satisfying our contractual requirements for commercial and government

customers is a fundamental policy of Plastics and Concepts. Contractual requirements must be thoroughly understood, properly coordinated, and approved by Plastics and Concepts prior to offer and acceptance, and fulfilled once accepted.

Documented procedures are established and maintained to ensure that customer requirements and all related support activities are reviewed, clearly understood, fully coordinated and approved for all product and service contracts.

4.3.2 Review

Before submitting a proposal, or at the acceptance of a contract or order, the proposal, contract or order is reviewed by the appropriate personnel to ensure that:

- (a) the requirements are adequately defined and documented. Where no written statement of requirement is available for an order received by verbal means, order requirements are reduced to a written document that is coordinated and approved within Plastics and Concepts prior to acceptance;
- (b) any contract or accepted order requirements differing from those in Plastics and Concepts' previous proposal, including requirements imposed by a customer as a counter offer, are coordinated within Plastics and Concepts prior to acceptance, and resolved with the customer;
- (c) Plastics and Concepts has the capability to meet contract or accepted order requirements.

4.3.3 Amendments to Contracts

Documented procedures are established and maintained to identify how an amendment to a contract is made and transferred or communicated to affected departments and individuals within Plastics and Concepts.

4.3.4 Records

Records of proposal and contract review activity will be maintained.

4.3.5 Customer Coordination

Channels for communicating and interfacing with the customer in contract related matters are established on an individual customer basis, as necessary.

4.4 DESIGN CONTROL

4.4.1 General

Plastics and Concepts maintains documented procedures to control and verify the design of the product in order to ensure that all requirements are met.

4.4.2 Design and Development Planning

The Plastics and Concepts Chief Engineer prepares plans for each design job and development activity. These plans describe the scope of the activity and define responsibility for their implementation. Design and development activities are assigned to qualified personnel equipped with adequate resources. Where internal resources are inadequate, provisions are available for contract or outsource labor and equipment. The plans are updated as the design evolves.

4.4.3 Organizational and Technical Interlaces

The Design Process involves the interaction of organizations and functional disciplines whose input is critical to the success of the design. Customer involvement in all stages of design development, review and approval, as appropriate, is an integral part of the process. Interfaces between different groups which input into the design process are defined and the necessary information is documented, transmitted, and regularly reviewed.

4.4.4 Design Input

Design input requirements relating to the product, including applicable statutory and regulatory requirements, are identified and documented, and their selection is reviewed for adequacy. Incomplete, ambiguous, or conflicting requirements are resolved with those responsible for imposing these requirements.

Design input takes into consideration the results of any contract review activities.

4.4.5 Design Output

Design output is documented and expressed in terms that can be verified against design input requirements and validated (see paragraph 4.4.8).

Design output:

- (a) meets the design input requirements;
- (b) contains or makes reference to acceptance criteria;
- (c) identifies those characteristics of the design that are crucial to the safe and proper functioning of the product (e.g., operating, storage, handling, maintenance and disposal requirements).

Design output documents are reviewed prior to release.

4.4.6 Design Review

At appropriate stages of design, formal documented reviews of the design results are planned and conducted. Participants at each design review include representatives of all functions involved in the design, as well as other specialist personnel, as required. Records of such reviews are maintained.

4.4.7 Design Verification

At appropriate stages of design, design verification is performed to ensure that the design stage output meets the design stage input requirements. The design verifications measured are recorded.

In addition to conducting design reviews, design verification may include activities such as:

- (a) performing alternative calculations;
- (b) comparing the new design with a similar proven design, if available;
- (c) undertaking tests and demonstrations, and
- (d) reviewing the design—stage documents before release.

4.4.8 Design Validation

Design validation is performed to ensure that product conforms to defined user needs and/or requirements. Validation is generally performed on the final product under defined operating conditions following successful design verification. Multiple validations may be required in earlier stages of design, or if there are multiple intended uses.

4.4.9 Design Changes

All design changes and modifications are identified, documented, reviewed, and approved by authorized personnel in accordance with the design process.

4.5 DOCUMENT AND DATA CONTROL

4.5.1 General

Plastics and Concepts maintains documented procedures to control all documents and data including to the extent practicable documents of external origin that affect the quality of products or services and relate to the requirements of ISO 9001. The procedures consider both hardcopy and electronic media.

4.5.2 Document and Data Approval and Issue

All documents and data affected by this policy are reviewed and approved by authorized personnel prior to issue. Documents and data have an owner who represents a function or an organization appropriate to the documents and data. The owner has explicit authority to approve documents. The owner may identify a designee who has the same authority as the owner.

The owner is responsible to obtain applicable approvals/concurrence from affected organizations, or groups prior to his or her approval of each issue.

A master list, or equivalent document control procedure (i.e., automated hard copy distribution systems, or electronic media controls), identifying the current revision status are established and maintained up to date to preclude the use of incorrect information.

- 4.5.2.1** Current pertinent issues of all appropriate documents are available at all locations where operations affecting the quality of products and services delivered to customers are performed.
- 4.5.2.2** Invalid and/or obsolete documents and data are promptly eliminated or otherwise assured against unintended use.
- 4.5.2.3** Any obsolete documents retained for legal and/or knowledge retention are suitably identified.

4.5.3 Document and Data Changes

Changes to documents and data shall be reviewed and approved by the current owner with applicable approval/concurrence from affected organizations, or groups. All reviewers shall have access to pertinent background information.

Where practicable, the nature of the change shall be identified in the document or the appropriate attachments.

4.6 PURCHASING

4.6.1 General

Documented Procedures are maintained to ensure that purchased product conforms to specified requirements.

4.6.2 Evaluations of Subcontractors

Subcontractors are evaluated and selected on the basis of their ability to meet contract or purchase order requirements, including the quality system and any specific quality assurance requirements.

The type and extent of control exercised by Plastics and Concepts over Subcontractors is dependent upon type of product, Plastics and Concepts Customer requirements, the impact of Subcontractor product on the quality of final product and,

where applicable, on the quality audit reports and/or quality records of the Subcontractors previously demonstrated capability and performance.

Records of acceptable Subcontractors are maintained per paragraph 4.16.

4.6.3 Purchasing Data

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

- (a) the type, class, grade, or other precise identification;
- (b) the title or other positive identification, and applicable issue of specifications, drawings, process requirements, inspection instructions, and other relevant technical data, including requirements for approval or qualification of product, procedures, process equipment and personnel;
- (c) the title or other positive identification, number, and issue of the quality system standard to be applied.

Purchasing documents are reviewed and approved by the appropriate Business Unit for adequacy of specified requirements prior to release.

4.6.4 Verification of Purchased Product

4.6.4.1 Verification of Subcontractor Premises

Where purchased product is verified by Plastics and Concepts at the Subcontractor's premises, Plastics and Concepts will specify verification arrangements and the method of product release in the purchasing documents.

4.6.4.2 Customer Verification of Subcontractor Product

Where specified in the contract, the customer or customer's representative will be afforded the right to verify at the Subcontractor's premises and at Plastics and Concepts premises that Subcontractor's product conforms to specified requirements. Such verification is not used by Plastics and Concepts as evidence of effective control of quality by the Subcontractor. Verification by the customer does not absolve Plastics and Concepts of the responsibility to provide acceptable product nor does it preclude subsequent rejection by the customer.

4.7 CONTROL OF CUSTOMER SUPPLIED PRODUCT

Plastics and Concepts maintains documented procedures for the control, verification, storage and maintenance of Customer Supplied Product intended for incorporation into products or related activities (e.g., customer owned tooling).

- 4.7.1 Customer Supplied Product is not accepted unless accompanied with proper documentation.
- 4.7.2 Customer Supplied Product is inspected upon receipt for freedom from damage in transit and for agreement with packing slips and routing documents.
- 4.7.3 Customer Supplied Product lost, unsatisfactory or unsuitable for use is documented and reported to the customer.
- 4.7.4 Customer Supplied Product is segregated from other material upon receipt. When product is found satisfactory, it is routed to Stores and remains segregated until required for use.
- 4.7.5 Periodic reviews of all Customer Supplied Product are performed to ensure that it is adequately preserved and stored to prevent damage. Any nonconformance is reported to the customer.

4.8 PRODUCT IDENTIFICATION AND TRACEABILITY

- 4.8.1 Plastics and Concepts maintains a documented system to identify product by suitable means from receipt of raw material, and during all stages of production, delivery, installation, and overhaul activities.
- 4.8.2 Production parts that require life cycle tractability as specified by Engineering Drawing are identified and tracked.
- 4.8.3 Production parts that require service life data are traceable via part numbers and permanently assigned serial numbers. These serial numbers are controlled to prevent duplication.
- 4.8.5 The system for product identification and tractability is established and maintained via documented procedures.

4.9 PROCESS CONTROL

- 4.9.1 Plastics and Concepts maintains controlled conditions for carrying out processes which directly affect the quality of products, either manufactured or serviced, to ensure they consistently meet applicable requirements and customer needs.
- 4.9.2 Production, installation, and servicing processes which directly affect quality are identified and planned to ensure that these processes are carried out under controlled conditions which include the following:
 - (a) documented procedures defining the manner of production, installation, and servicing, where the absence of such procedures could adversely affect quality;
 - (b) use of suitable production, installation, and servicing equipment; and a suitable

working environment;

- (c) compliance with reference standards/codes, quality plans, and/or documented procedures;
- (d) monitoring and control of suitable process parameters and product characteristics;
- (e) the approval of processes and equipment, as appropriate;
- (f) criteria for workmanship, is stipulated in the clearest practical manner (e.g., using written standards, representative samples, or illustrations);
- (g) suitable maintenance of equipment to ensure continuing process capability.

4.9.3 Where the results of processes cannot be fully verified by subsequent inspection and testing of the product and where, for example, processing deficiencies may become apparent only after the product is in use, the processes are carried out by qualified operators and/or require periodic monitoring and control of process parameters to ensure that the specified requirements are met.

4.9.4 The requirements for any qualification of process operations, including associated equipment and personnel are specified.

4.9.5 Records are maintained for qualified processes, equipment, and personnel, as appropriate.

4.10 INSPECTION AND TESTING

4.10.1 General

Documented procedures are maintained for inspection and test activities in order to verify specified requirements for product are met. The required inspection and testing, and the records to be established, are documented in a quality plan, when appropriate, or documented procedures.

4.10.2 Receiving Inspection and Testing

4.10.2.1 Incoming product is not used or processed (except in the circumstances described in paragraph 4.10.2.3) until it has been inspected or otherwise verified as conforming to specified requirements. Verification of specified requirements is in accordance with the quality plan and/or documented procedures.

4.10.2.2 In determining the amount and nature of receiving inspection, consideration is given to the amount of control exercised at the supplier's premises and the recorded evidence of conformance provided.

4.10.2.3 Where incoming product is released for urgent production purposes, prior to verification, it is positively identified and recorded in order to permit immediate

recall and replacement in the event of nonconformity to specified requirements.

4.10.3 In Process Inspection and Testing

Inspection and testing of product is performed per the quality plan, if applicable and/or documented procedures.

Product is held until the required inspection and test have been completed or necessary reports have been received and verified except when product is released under positive recall procedures per paragraph 4.10.2.3. Release under positive recall procedures does not preclude the activities outlined in the above paragraph.

4.10.4 Final Inspection and Testing

Final inspection and testing is carried out in accordance with the quality plan, if applicable, and/or documented procedures to complete the evidence of conformance of the finished product to the specified requirements.

The quality plan and/or documented procedures for final inspection and testing require that all specified inspection and tests, including those specified either on receipt of product or in—process, have been carried out and that the results meet specified requirements.

No product will be shipped until all the activities specified in the quality plan and/or documented procedures have been satisfactorily completed and the associated data and documentation are available and authorized.

4.10.5 Inspection and Test Records

Records are maintained which provide evidence that the product has been inspected and/or tested. These records show clearly whether the product has passed or failed the inspections and/or tests according to defined acceptance criteria. Where the product fails to pass any inspection and/or test, the procedures for control of nonconforming product apply (see paragraph 4.13). Business Unit procedures/records will identify the inspection authority responsible for the release of product.

4.11 CONTROL OF INSPECTION, MEASURING AND TEST EQUIPMENT

4.11.1 Plastics and Concepts maintains documented procedures for the control, calibration and maintenance of inspection, measuring and test equipment including any test software used in conjunction with the measurement system.

4.11.1.1 Plastics and Concepts ensures that measurement uncertainty is known and consistent with the required measurement capability.

4.11.1.2 Where test software or comparative references are used as suitable forms of inspection, they are checked to prove that they are capable of verifying the

acceptability of product. This is done prior to release for use during production, installation or servicing and shall be rechecked, if appropriate, at prescribed intervals or prior to use. The extent and frequency of such checks is established and records are maintained as evidence of control. Appropriate software controls and records of these controls are maintained.

4.11.1.3 When required by contract, data pertaining to inspection measuring and test equipment and the equipment itself is made available for on site verification.

4.11.2 Control Procedure

4.11.2.1 Inspection, measuring and test equipment is selected based on the necessary accuracy and precision required for the measurement.

4.11.2.2 All inspection, measuring and test equipment that can affect product quality is identified, calibrated and adjusted at prescribed intervals or prior to use against certified equipment having a known, valid (traceable measurement) relationship to national or internationally recognized standards. Where no such standards exist the basis for calibration is documented.

4.11.2.3 The system for calibration of inspection, measuring and test equipment including details of equipment types, unique identification controls, user and calibration location, frequency of calibration, calibration method, acceptance criteria and the action taken when results are unsatisfactory is defined.

4.11.2.4 Inspection, measuring and test equipment is identified with a suitable label or approved record to indicate the calibration status.

4.11.2.5 Calibration records are maintained and retained.

4.11.2.6 Assessment of the validity of previous inspection and test results is conducted and documented when inspection, measuring and test equipment exceed specified out—of tolerance limits.

4.11.2.7 The suitability of the environment for conducting calibration, inspection, test or other measurements is assessed in the selection process and controlled as necessary.

4.11.2.8 Inspection, measuring and test equipment is handled, preserved, transported and stored in a manner which ensures that the accuracy and fitness for use are maintained.

4.11.2.9 Inspection, measuring and test equipment, including test software and other devices, are proven capable of the required accuracy prior to production use. These devices are safeguarded from adjustments which would invalidate the calibration setting.

4.12 INSPECTION AND TEST STATUS

- 4.12.1** Plastics and Concepts maintains inspection and test status of product and customer supplied materials through all stages, from receipt of raw materials, through manufacturing, assembly, installation, servicing and release.
- 4.12.2** Status is maintained via routing tags, stamps, paperwork, and computer records. This status identifies product conformance to required specification or requirements; provides in process tractability of inspection and test status of product material; and ensures that all released parts have passed required inspections and tests.
- 4.12.3** Status of nonconforming product is maintained upon identification of nonconforming articles.

4.13 CONTROL OF NONCONFORMING PRODUCT

- 4.13.1** Systems and documented procedures are maintained to ensure that the products which do not conform to specified requirements are prevented from unauthorized use or installation.
- 4.13.3** Reviews and dispositions are recorded and are provided to affected areas for notification and/or further processing.
- 4.13.4** All accept as is or repair dispositions meet the design intent.
- 4.13.5** When required by the contract, the proposed accept as is or repair dispositions are reported for concession to the customer or customer's representative.
- 4.13.6** Description of the actual nonconformities, dispositions and, when applicable, customer concessions are recorded and maintained.
- 4.13.7** Repaired and/or reworked products are subject to reinspection or retest and acceptance by inspection
- 4.13.8** Nonconforming product is identified and/or segregated (when practical) to prevent inadvertent use and to maintain its inspection and test status.
- 4.13.9** All nonconforming material dispositioned as scrap:
 - (a) is removed from in process or storage areas; (b) is conspicuously identified as scrap; and
 - (c) is maintained under strict controls until either markings on the part are obliterated and/or it is mutilated beyond salvage and/or a combination of both actions are

completed.

4.14 CORRECTIVE AND PREVENTIVE ACTION

4.14.1 General

4.14.1.1 Plastics and Concepts maintains processes for implementing corrective and preventive action throughout the organization. Established corrective and preventive action processes are documented by procedures to ensure causes or potential causes of non conformities are identified and corrected to prevent recurrence.

4.14.1.2 Any corrective or preventive action taken to eliminate the causes of actual or potential nonconformities are appropriate for the magnitude of the problems identified and commensurate with the risks encountered.

4.14.1.3 Plastics and Concepts implements and records any changes to the documented procedures resulting from corrective or preventive action.

4.14.2 Corrective Action

Plastics and Concepts ensures procedures for corrective action include, as a minimum:

- (a) the effective handling of customer complaints and reports of product nonconformities;
- (b) investigation of the causes of nonconformities related to product, process, or quality system, and the recording of the results of the investigation;
- (c) determination of the corrective action needed to eliminate the cause of the nonconformity;
- (d) application of controls to ensure that corrective action is taken and that it is effective.

4.14.3 Preventive Action

Plastics and Concepts ensures procedures for preventive action include, as a minimum:

- (a) the use of appropriate sources of information (e.g., process information, nonconformance documents, audit results, quality records, service reports, customer complaints, etc.) to detect, analyze, determine and eliminate potential causes of nonconformities;

- (b) determination of the steps needed to deal with any problems requiring preventive action;
- (c) initiation of preventive action and application of controls to ensure that the action taken is effective;
- (d) confirmation that relevant information on actions taken is submitted for management review.

4.15 HANDLING, STORAGE, PACKAGING, PRESERVATION & DELIVERY

4.15.1 General

Plastics and Concepts maintains documented procedures for handling, storage, packaging, preservation, and delivery of product.

4.15.2 Handling

Plastics and Concepts uses methods of handling product that prevent misuse, damage, contamination, or deterioration.

4.15.3 Storage

Plastics and Concepts has designated storage areas or stock rooms to prevent damage and/or deterioration of product, pending use or delivery. Appropriate methods for authorizing receipt to, and dispatch from, such areas are controlled by Plastics and Concepts internal documentation/procedures.

In order to detect deterioration, corrosion, contamination, or damage, the condition of products in stock with shelf life or preservation requirements will be assessed at appropriate intervals in compliance with existing procedures. All items will be properly packaged and controlled in accordance with existing material specifications and internal procedures.

4.15.4 Packaging

Plastics and Concepts maintains control over packing, packaging, and marking processes (including materials used) to the extent necessary to ensure conformance to specified requirements.

4.15.5 Preservation

Plastics and Concepts uses appropriate methods for preservation and segregation of product to ensure quality.

4.15.6 Delivery

Plastics and Concepts provides appropriate protection to ensure the quality of product after final inspection and test. Product is preserved and packaged to specifications meeting industry practices, or contracted requirements as applicable. Where contractually specified, this protection extends to include delivery to destination.

4.16 CONTROL OF QUALITY RECORDS

4.16.1 Plastics and Concepts defines and documents quality system record requirements. These include:

(a) identification and definition of vital records, quality records, archival records, and other records;

Note: Records can be in the form of hard copy, electronic, or other media.

(b) required retention periods which conform with regulatory and/or contract requirements;

(c) methods to establish retention periods for new documents and revise retention periods for existing documents;

(d) requirements for legibility and acceptable methods for mark ups;

(e) specification of facilities, identification, preservation, collection, indexing, access, filing, storage, maintenance, and disposition.

4.16.2 Suppliers/Subcontractors supplying material to Plastics and Concepts are required to maintain quality records for periods which are compatible with Plastics and Concepts and/or contract requirements.

4.16.3 Plastics and Concepts retains and uses quality records, including pertinent quality records from suppliers/subcontractors:

(a) as objective evidence of product conformance to engineering, Government, quality, and contract requirements;

(b) as objective evidence of personnel/equipment approved for special purposes;

(c) as a demonstration of system effectiveness;

(d) as a means of verifying the effectiveness of required corrective action.

4.16.4 Where appropriate, composition of quality records includes:

- (a) identification of the material, part, subassembly, assembly, equipment, system, or procedure involved;
- (b) number and type of deficiencies found;
- (c) quantities accepted or rejected;
- (d) nature of corrective action taken.

4.16.5 All records are legible and are stored and retained in such a way as to be readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss.

4.16.6 Quality Assurance records are available, upon request, for examination by Government Agency representatives. When specified by contract, they are also available for examination by the customer.

4.17 INTERNAL QUALITY AUDITS

4.17.1 General

Plastics and Concepts maintains documented procedures for planning and implementing quality audits. Audits are performed to verify whether quality activities and related results comply with established requirements and to determine the effectiveness of the Quality System. The results of quality audits form an integral part of the input to management review activities.

4.17.1.1 Plastics and Concepts Procedures establish the requirements and define responsibilities for the performance of internal quality audits to be performed throughout Plastics and Concepts.

4.17.1.2 Quality Audit Procedures establish the requirements and define responsibilities for the performance of hardware audit activity for raw materials, parts, assemblies and components. These audits are conducted on P&C and Subcontractor manufactured items to ensure that the inherent design/reliability features were not compromised during manufacturing and test.

4.17.1.3 Plastics and Concepts procedures establish the requirements and define responsibilities for the performance of audits at all Plastics and Concepts subcontractors.

4.17.1.4 Quality audits are scheduled on the basis of the status and importance of the activity to be audited and are performed by individuals independent of those having direct responsibility for the activity being audited.

4.17.1.5 Audit results are collected, analyzed and reported to the Executives. These results

are then compiled and presented to the Executives for review. In addition, the results of audits are documented and brought to the attention of the Management/Supervision having direct responsibility for the activity being audited. Management/Supervision is responsible for taking timely corrective/preventive action on non conformances identified by the audit.

4.17.1.6 Follow up audits are performed to verify and document the implementation and effectiveness of the corrective/preventive actions taken.

4.18 TRAINING

Plastics and Concepts maintains documented training procedures to identify training needs and provide for the training of all employees performing activities affecting quality. Employees performing specific tasks are qualified on the basis of appropriate education, training, and/or experience, as required. Appropriate records of training are maintained per paragraph 4.16.

4.19 SERVICING

Plastics and Concepts offers a number of customer services related to the operation and maintenance of products delivered by Plastics and Concepts and its suppliers. These customer services are defined and controlled by documented procedures for performing, verifying, and reporting that all specified requirements are met. These customer services may include training, or technical publications. Servicing records are maintained per contractually identified or established retention schedules.

4.20 STATISTICAL TECHNIQUES

4.20.1 Identification of Need

4.20.1.1 Statistical techniques are required to establish, control, verify, and improve process capability and product characteristics.

4.20.1.2 Statistical techniques may be used in, but not limited to, the following areas:

- (a) product design;
- (b) product testing and development;
- (c) reliability prediction and characterization;
- (d) material characterization and improvement;
- (e) process analysis, development, control and improvement;

(f) determination/verification of quality levels;

(g) choice of inspection sampling plans and acceptance sampling plans; and

The techniques used may depend on customer and program requirements.

4.20.2 Procedures

4.20.2.1 Procedures are maintained to implement and control the application of the statistical techniques identified in the procedures.

4.20.2.2 Statistical techniques will, when required, be used to ensure conformance to contract and regulatory requirements.

4.20.2.3 The statistical techniques employed, and their applications, are assessed and improved as developments in the statistical sciences warrant, or as awareness of improved methods develop.

4.21 GOVERNMENT RELATIONS

4.21.1 General

4.21.1.1 Communication

Plastics and Concepts communicates with Government Representative in matters relating to product quality as stipulated by contract or by Regulations.

4.21.1.2 Cooperation

All personnel, working through designated lines of communication, shall extend full cooperation to the Government Representative in matters relating to product quality as stipulated by contract or by Regulations.

4.21.1.3 Access To Documents/Records

Quality personnel shall make quality documents/records available to Government Representative for on site review. Copies of individual quality documents/records, with the exception of cost data which is available via the Financial Department, shall be provided to the Government Representative when requested with notification by Quality personnel to the affected Quality Manager/Supervisor, or delegate.

4.22 ENVIRONMENT, HEALTH & SAFETY (EH&S)

EH&S is integral to all business processes that create the products, services and operations of the company. The President is responsible for developing a strategy for implementing and assessing the effectiveness of the EH&S Management System. The EH&S Manager provides functional leadership to the EH&S program and advises the President on implementation of company wide strategies, policies and standards; develops policies and practices; monitors the development and implementation of EH&S programs; and reports progress to the President and the board of directors.

5. REFERENCES

5.1 None.

Appendix

Appendix A:

Plastics and Concepts of Connecticut, Inc.

Organization Chart

February 18, 2004

President:

Kathleen Harris

Responsibilities:

- Business Operations
- Financial Control
- Communications

Corporate Secretary, Quality Manager and Chief Engineer:

Harold S. Harris P.E. (Licensed Professional Engineer)

Responsibilities:

- Corporate Records
- Product and Tool Design
- Quality Control
- Environmental Health and Safety

Treasurer and Project Engineer:

Tom O. Harris

Responsibilities:

- Financial Management
- Tax Filings and Payroll
- Manage Special Projects
- Proto-type processes

Operations Manager:

John H. Harris

Responsibilities:

Production Control
Procurement
Sales and Customer Support
Facilities and Maintenance

E- Business Manager:

Brain A. Harris

Responsibilities:

Web Page Construction
Web Page Maintenance
Electronic Communications Equipment

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