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Quality Assurance Manual



History of Revisions

APPROVALS




ROLE	PERSON	SIGNATURE	DATE
Originator			
President/C.E.O			
Director of Operations			

REVISION HISTORY:

Revision Number	Revision Content	Date
1	Initial Release	3/10/2010
2	Added Calibration Out of Tolerance Reference	7/21/2010

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APPROVALS

ROLE	PERSON	SIGNATURE	DATE
Originator	W. Morris		7-21-10
President/C.E.O	Ken Hunter		7-21-10
Director of Operations	Tim Lamb		7-21-10

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INTRODUCTION TO HUNTER MANUFACTURING SERVICES, INC.

Hunter Manufacturing was founded in 1992 as a privately held company and since that time has supplied its ever-growing customer base with thousands of our hi-tech machined parts and products. The company has achieved the status of a reputable, capable and reliable supplier to the industry, for commercial, pharmaceutical, and military applications.

The facilities are complete for the engineering, manufacturing, and production of sophisticated Build to Print (BTP) machined parts and products from prototype to large production runs. Its concept promotes the process control approach when developing, implementing, and improving its methods and systems necessary to satisfy its customer's requirements.

1.0 PURPOSE

The purpose of this manual is to document the method in which Hunter Manufacturing implements a Quality System.

2.0 SCOPE

The scope covers all methods used by Hunter Manufacturing to implement its Quality System controlling parts and products contractually provided.

2.1 Hunter Manufacturing provides the activities of manufacturing and production of a wide variety of machined parts and products to exacting mechanical requirements using state-of-the-art equipment. The activities include the ability to Build to Print, or usage of CAD/CAM electronic data files to facilitate manufacturing. And general manufacturing PLUS custom slats and change parts for filling, packaging and tablet machines.

3.0 RESPONSIBILITIES and AUTHORITY

3.1 It is the responsibility of Executive Management to ensure issuance, distribution, maintenance, and updates to this manual. All Hunter Manufacturing Corporation employees are responsible to adhere to the requirements of this manual and are encouraged to contribute, collectively or otherwise, to maintaining and improving upon continuing success in supplying all the needs of our customers.

4.0 QUALITY SYSTEM

4.1 General Requirements

- 4.1.1 Hunter Manufacturing Corporation has established, documented, implemented and maintains a Quality System. The Quality System is continually reviewed to improve effectiveness of the system.
- 4.1.2 Management's policy is to maintain this Quality Manual as a documented guide to its quality procedures, records, and other appropriate documents and data required to product consistent quality products.
- 4.1.3 The Quality System is implemented, monitored, analyzed, and maintained through training and adherence to the Quality System in order to ensure that Hunter Manufacturing products and parts continue to conform to customer requirements and/or expectations.
- 4.1.4 The following process, when required, is outsourced to qualified suppliers:
 - a- plating
 - b- painting
 - c- coating
 - d- special processes such as *finishing* as required by contract

4.2 DOCUMENTATION REQUIREMENTS

4.2.1 General Requirements

The Hunter Manufacturing Quality System consists of the following documents:

- 1- Quality Manual
- 2- Work Process Sheets (instructions) and/or detail drawings, where applicable. (See NOTE)
- 3- Supporting records as contractually required including but not limited to Engineering Change Orders or Notices, ie ECO's or ECN's.

Note:

Hunter Manufacturing Corporation instructions and/or work sheets are dependent upon the complexity and interaction of the work, the methods used, and the skills and competency needed by our personnel to carry out the work. These instructions and/or work sheets define how an activity is performed and are utilized when the absence of such instructions may adversely affect the quality of product. The Instructions or work sheets may be hard or electronic copy, part drawings, specifications, pictorials, or other forms of media.

4.2.2 Control of Documents

Hunter Manufacturing new and/or revised media data is reviewed for adequacy by authorized personnel prior to issue for production. Obsolete data is flagged as such to prevent inadvertent release to production.

- 4.2.3.1** Engineering Change Order Control documents (i.e., drawings, prints, specifications) are reviewed, approved by manufacturing management, and controlled by revision level, purchase order mandates, and/or date.
- 4.2.3.2** External documents are identified and controlled, as needed, for the part or product manufacturing.

4.2.4 Control of Records

- 4.2.4.1** Hunter Manufacturing Corporation maintains records either in soft or hard copy media to control all data that relates to the requirements of manufacturing of product. These records are kept legible and stored in a manner to prevent damage, loss, and deterioration. Such records will be indexed, maintained, and disposed of at the discretion Hunter Manufacturing unless specifically mandated otherwise by contract to have the records sent to the customer.

5.0 MANAGEMENT RESPONSIBILITY

5.1 Management Commitment

Management provides evidence of its commitment to the development and implementation of this quality system and to continually improve its effectiveness:

- 1-** Communicating the importance of meeting customer statutory/regulatory requirements and the importance of customer satisfaction with each product produced.
- 2-** Providing resources as required.

5.2 Customer Focus

Management is responsible to ensure that customer requirements are determined and transmitted to all internal parties. All employees are responsible to ensure that customer requirements are met and are encouraged to identify and take initiative to satisfy each customer on every occasion.

5.3 Quality Policy

Hunter Manufacturing Quality Policy is stated in the acronym **CAFES**. The meaning is set forth by the words “Customer”, “Awareness”, “Focus”, “Energy” and “Satisfaction”. It means:

- 1- We exist because of our **C**ustomer.
- 2- We are **A**ware of our customer’s needs.
- 3- We **F**ocus on the needs of our customer.
- 4- We place all our **E**nergy is on our customer.
- 5- We **S**atisfy our customer.

This is accomplished by:

- a. Constant communications with the customer.
- b. A commitment by all employees to meet or exceed customer expectations.
- c. Finding opportunities for improvement in administration and manufacturing processes to meet our commitment to provide parts and product to support the customer’s needs and objectives.

5.4 Planning

5.4.1 Quality Objective

Management has established the quality objective of providing a means to meet part and product requirements at all levels of the organization.

5.5 Responsibilities, Authority, and Communication

5.5.1 Responsibility and Authority

- a. The President/C.E.O. is responsible for and has the authority over developing company policies and executive decisions made on behalf of the corporation.

5.5.2 Internal Communications

Communication is established within the company regarding the effectiveness of the Quality System using emails, management meetings, departmental memos, and bulletin boards.

The communication may include but us not limited to:

- a. customer feedback
- b. process performance and product conformity
- c. follow-up actions form previous communications
- d. changes that could affect the quality system
- e. recommendations for improvement

6.0 RESOURCE MANAGEMENT

6.1 Provision of Resources

The organization shall determine and provide the resources required to implement, maintain the quality system requirements and continually improve its effectiveness and enhancing and building customer satisfaction by continual meeting of their specifications of part and product deliveries.

6.2 Human Resources

6.2.1 General

It is the policy of the Company to assure that all employees are skilled appropriately and are fully qualified for the functions they are required to perform. Hiring practices are implemented by use of job description or position requirements. Records defining education, special training, qualification, and skills, or experience required as applicable to specific position needs. Management makes use of these in the selection and placement of personnel.

6.3 Infrastructure

Building space, selection, and the utilities available are considered to be an integral part of providing adequate resource management needs. These include processing equipment and machinery including the software and hardware required to effectively use the equipment.

6.4 Work Environment

Work environment needs are determined and managed so that product conformity and product requirements are accomplished.

7.0 PRODUCT REALIZATION

7.1 Planning of Product Realization

This is accomplished by ensuring that proper planning is established in order to ensure:

- a. Establishment of product objectives and requirements
- b. Establishment of needed processes, documents (Publications), and resources
- c. Establishment of verifications, validations, monitoring, inspection as required by contracts.

7.2 Customer Related Processes

Hunter Manufacturing Corporation clearly defines customer requirements during the Contract Review process.

7.2.1 Determination of Requirements

- a. This is to include understanding the product's intended use, delivery, and any post-delivery activities.
- b. Requirements not stated by the customer but necessary for its intended use, when known.
- c. Statutory and regulatory requirements related to the product.
- a. Any requirements needed as required by Hunter Manufacturing, prior to order confirmation.

7.2.2 Review of Requirements Related to Product

Each purchase order is reviewed prior to the organization commitment to supply product per the customer's purchase order or a purchase order change and shall ensure that:

- a. The product requirements are defined
- b. Any discrepancies between the customer's requirements and the company's capabilities to meet those requirements are formally resolved.

7.2.3 Customer Communications

The company has established an effective system for communicating with its customers in the chosen manner of e-mail, telecoms, fax's, forms, publications, and bulletins. The media chosen addresses:

- a. Product Information
- b. Enquiries, contracts or order handling, including amendments
- c. Feedback, including any customer complaint.

7.3 Purchasing

7.3.1 Hunter Manufacturing Corporation maintains control of the purchasing process to assure the ability to acquire products and services meeting specified requirements in accordance with customer requirements. Product specifications are stated on Hunter Manufacturing purchase orders by any of the following:

- a- product part number
- b- purchase order statement
- c-spec controlled drawing

d- published industry standards or specifications

7.3.2 Verification of Purchased Product

Hunter Manufacturing practices a dock-to-stock methodology for product purchased and requires written certificates of conformance from its O.E.M. suppliers

7.3.3 Identification and Traceability

It is the policy of the company to identify material and products and maintain traceability when contractually required. When inspection and/or test is required by contract, records of the inspection will be provided. The records may take the form of inspection/test sheets or by certificates of conformity issued by Hunter Manufacturing suppliers.

7.5.4 Control of Customer Property

Hunter Manufacturing Corporation maintains a policy to care for customer-owned property, materials, products or equipment. This policy seeks to identify, protect and maintain, as applicable, the customer's property while it is under control of Hunter Manufacturing.

7.5.5 Preservation of Product

Product integrity is maintained by policies and processes ensuring that personnel handle, store, package, preserve, and deliver materials and products appropriate to prevent damage and deterioration.

7.6 Control of Monitoring and Measurement Devices

The company maintains equipment for the verification of product conformance in accordance with its equipment calibration policy. The calibration addresses:

- a. Interval of Calibration traceable to recognized standards.
- b. Calibration status identification.
- c. Safeguards for tamper recognition.
- d. Protection from damage or deterioration during handling, maintenance and storage.

Electronic and/or hardcopy records of calibration is maintained per Hunter Manufacturing process CE-1, Calibration Of Equipment., which includes the equipment type, unique identification of the device, the location of the device, the pre-determined calibration interval, the method of calibration, and whether or not the equipment has been found to be acceptable. When equipment is found to be out of its tolerance of calibration action is taken to bring the equipment to within its calibrated tolerance. This action may comprise of re-adjustment and or replacement. When equipment is controlled by software to determine product conformance, the software is verified prior to release for

manufacturing and reconfirmed as necessary. Calibration of equipment records are maintained either hard copy or electronically.

8.0 MEASUREMENT, ANALYSIS, AND IMPROVEMENT

When contractually obligated and planned, the company will inspect product critical to manufacturing and to ensure conformity. This inspection when appropriate may be:

- a- upon receipt of outsourced product
- b- during the manufacturing
- c- prior to shipment to the customer
- d- when determined by Hunter Manufacturing

It is the policy of Hunter Manufacturing Corporation to maintain ongoing measures of key processes in order to assess the results on a regular basis so that product conformity may be realized, continuous, and visible. Hunter Manufacturing plans and implements the monitoring, measurement, and analysis needed. Efforts include those to ensure the ability to maintain product requirements and consist of gathering SPC data. The employees employ the 3P system (Pre-inspect – Perform – Post-inspect) throughout the manufacturing processes.

In process or final inspection is conducted in accordance with critical product requirements or by contract. Unless contractually obligated otherwise, Hunter Manufacturing uses a random sampling plan to inspect the product. A part or product rejected during this inspection is flagged, removed, and segregated from production in order to ensure nonconforming product is not inadvertently used or incorporated into deliverable product. Review of the cause of these segregated parts is performed by production management to facilitate disposition and action in prevention of production on non-conforming parts. Disposition of nonconforming material may include rework, repair, scrap, or returning purchased materials to supplier. Hunter Manufacturing DOES NOT assume the authority to disposition any contractually provided part or product as "USE AS IS".

8.2 Monitoring and measurement

8.2.1 Customer Satisfaction

Hunter Manufacturing Corporation conducts regular review and analysis of performance by monitoring part or product returns, Returned material turn-around, customer feedback, on-time delivery, and rework. These are used to drive organizational improvements and serves as a tool in assessing customer requirements and satisfaction.