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PhotoMachining, Inc.

Quality Manual

QM01 Management Responsibilities

1.1 It is PhotoMachining's responsibility to manufacture product to meet or exceed the specifications and requirements of the customer's design and purchase orders. The customer retains responsibility for the integrity of the design and for the quality of the components or materials which they supply for further processing by PhotoMachining. The Quality Assurance Program within PhotoMachining is established by direction of the company President and is structured as follows:

1.2 The responsibility for the design of an integrated Quality Assurance system is delegated to the QA Manager or their designee, as is the responsibility to plan, train, monitor and perform the implementation of the system throughout the company's operations.

1.3 The managers of the company's operational departments are responsible for the performance of the QA functions within their departments.

1.4 The Quality Manager and the quality staff are independent from manufacturing and are responsible for establishing and implementing quality programs and procedures in compliance with this manual.

1.5 Responsibility for attainment of quality is that of each individual performing the work or activity throughout the company.

1.6 The verification of quality shall be the responsibility shared by quality and the individuals performing the work as follows:

a. Certified technicians must check the quality of their own work.
b. The quality organization will perform area inspections and product audits to ensure compliance with company procedures, as well as, perform product inspections on work performed by non-certified technicians.

1.7 The person verifying quality shall:

a. Identify quality problems.
b. Recommend, provide and initiate solutions.
c. Verify implementation of solutions.
d. Control any non-conforming product until properly dispositioned.

1.8 Individual employees are responsible for understanding the quality program and the specific quality requirements for their job.

1.9 The QA Manager is responsible for the evaluation of the QA Program and it's Compliance with the requirements of this manual and shall report to the Management Team as to it's effectiveness.

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References:

2004- Quality Assurance Responsibility
2009- Management Surveillance
2010- Continuous Improvement

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QUALITY MANUAL
QM02 QUALITY SYSTEM

2.0 The QA Program is a formal documented system of planned activities established to provide evidence that requirements of applicable regulations, standards, contractual specifications and company quality objectives are met as follows:

2.1 The Quality Assurance Program requirements as set forth in this manual shall apply to purchased materials, components, manufactured parts and applicable environmental conditions that may affect the quality of billable product.

2.2 The company Management Team shall ensure the following;

a. The established system of procedures and instructions are followed to assure meeting the quality goals of the company.
b. Provide appropriate controls, test equipment, tools and documented employee training to meet the desired level of quality.
c. Provide for the verification of quality through proper training of technicians, the use of product inspections and work station audits and the use of SPC whenever appropriate.
d. Generate appropriate documentation to demonstrate conformance to quality.
e. Hiring of adequate and qualified personnel.
f. Provide appropriate facilities to control quality.
g. Provide for, at a minimum, an annual independent audit of the QA System.

2.2 If specific customer requirements deviate from the requirements set forth in this manual, PhotoMachining will attempt to comply with the customer's requirements on an individual basis.

2.3 If it becomes necessary to deviate from controlled procedures, such a change must be approved and documented on the specific product documentation by Quality, Engineering and/or Manufacturing prior to initiating the change. Permanent changes will be handled through the Engineering Change Order System.

References: 1012- Quality Assurance Audit Procedures
2004- Quality Assurance Responsibility
2009- Management Surveillance Plan

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QUALITY MANUAL
QM03 CONTRACT REVIEW

3.0 The Quality, Engineering, Manufacturing and Administration Departments will be required to work closely and follow this and related procedures to ensure proper review of contracts. The quality aspects of the contract review process will be addressed as follows;

3.1 Each requisition /contract shall be reviewed by the Quality Manager or designee prior to acceptance to ensure:

a. The requirements are adequately defined and documented.
b. Any requirements that differ from those listed in an existing contract are resolved with the customer.
c. Required raw materials can be obtained from approved sources.
d. Required services can be procured from approved sources.
e. PhotoMachining has the capability to meet the contractual requirements.

3.2 Records shall be maintained of contract reviews.

3.3 The following issues must be addressed as a result of the contract review:

a. Correct translation of customer requirements into product specifications, drawings, procedures and instructions.

b. Customer approval of any changes to the customer supplied drawings / specifications if the change has any impact on the product specifications as supplied by the customer.

c. Acceptance criteria shall be established prior to release of the job to manufacturing.

d. All activities shall be documented to permit product history and traceability to be determined.

e. Revisions to product specifications and related documents shall be controlled and properly and efficiently communicated to all appropriate departments.

References: 1003- Generating Device Master Records\
1009- Operational Control of Purchase Orders, Drawings and Schedules.

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QUALITY MANUAL
QM04 DESIGN CONTROL

4.0 PhotoMachining manufactures products to customer supplied design specifications. PhotoMachining will review product design characteristics during the quoting and contract review process and may recommend design modifications to facilitate the manufacturing process. However, any design changes which will affect product specifications must be translated into modified product documentation approved by the customer.

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QUALITY MANUAL
QM05 DOCUMENT CONTROL

5.0 Control of documents is the responsibility of the Documentation Control Department. Documents will be controlled as follows:

5.1 Documentation is prepared, reviewed, approved and released for distribution to controlled locations through this system.

5.2 The document control system shall maintain documented evidence of authorized release and revision control for all company procedures and product related documentation.

5.3 Revisions to controlled documents must themselves be controlled, prepared, reviewed, approved and released through use of the Engineering Change Order (ECO) System.

5.4 This system shall provide for the following:

a. Identification of the individuals within the company responsible for issuance and maintaining of controlled documents.

b. Control of documents to ensure proper documentation is used in performing all work activities (including revision controls and the control of obsolete documents). Only current and approved procedures and product documentation are to be used for manufacturing and inspection.

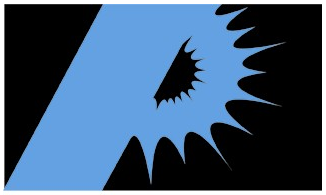
c. Ensure that only authorized and approved documents are used in verifying the quality of work performed.

5.5 Activities which affect the quality of products or system/process controls shall be performed in accordance with written procedures, instructions and/or drawings.

5.6 Instructions, procedures and drawings shall be controlled and include sufficient information for determining product acceptability.

5.7 Procedures shall ensure review, revision, and control of these documents to ensure that only authorized instructions, procedures and drawings are used.

5.8 Upon receipt of a customer drawing, it is reviewed by Engineering and Quality to ensure compliance with the latest PO requirements. Upon acceptance, two controlled copies are released, one to the contract file and one to the Quality Department.



5.9 All customer changes to product specifications are controlled through the ECO system. Any customer changes to customer supplied drawings requires updating of the drawing log and all product documentation with the removal and archiving of all obsolete drawings.

References: 1003- Generating Device Master Records
1004- Implementing Engineering Change Orders
1009- Operational Control of Purchase Orders, Drawings and Schedules.
2006- Software Quality Assurance

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QUALITY MANUAL
QM06 PURCHASING

6.0 This procedure must be followed to control purchasing activities.

6.1 The Purchasing Department shall select Suppliers based on ability to meet contract and quality requirements.

6.2 Selection of suppliers shall be dependent upon;

a. Price, delivery and historical records of supplier's previous capabilities and quality performance.

b. For new suppliers, sample approval, qualification testing and site audits may be required as part of the selection process to ensure that the supplier's quality system controls are in place and effective.

6.3 Purchasing documents shall contain data clearly describing the product ordered including:

a. Any basic technical requirements (drawings, specifications, standards, certifications).
b. Any standard or unique quality requirements agreed to by contract.

6.4 Revisions to procurement documents shall be controlled and all revisions carried through to related product documentation in a controlled manner.

6.5 The responsibility for source evaluation and supplier selection is shared by Quality Assurance, Engineering and Manufacturing.

6.6 The conduct of source audits and verification of the acceptability of materials received is the responsibility of Quality Assurance.

6.7 When specified by the customer, customer approved sources must be utilized. If in these cases, PhotoMachining selects new sources, the customer must pre-approve the source selection. Where appropriate, the Purchase Order shall include the following statements to further control materials and/or services:

a. Certification required.
b. Latest specification revision applies.
c. Significant operation, no process changes allowed.

6.8 Prior to release of product to a special process supplier, Quality Assurance will review the product and/or product documentation to verify product quality is acceptable and assure that all prior operations are complete.

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6.9 Suppliers are assessed through part inspection and/or on-site quality audits. Records of the quality status are maintained including any product deviations and issued corrective actions.

References; 2001- Requisition Responsibilities
2008- Procedure For Selecting and Qualifying Suppliers

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QM07 Purchaser Supplied Material

7.0 All customer supplied product/ material shall be subject to normal incoming material handling procedures including, quarantine and inspection prior to acceptance.

7.1 Any customer supplied material that is damaged, lost or found though inspection to be unsuitable for use shall be recorded and reported to the customer prior to performing any additional work to the product.

7.2 No further work is to be performed on material which has been determined to be out of specification without prior written customer authorization.

References:

1011- Material Traceablity and Lot Control
2007- Material Handling, Packaging and Storage

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Quality Manual
QM08 Identification and Control of Materials, Parts, Components and Products

8.0 The identification and control of materials, parts, components and products throughout receiving , manufacturing, inspection and shipping shall be controlled and documented. Control measures shall include:

8.1 At receiving, all incoming materials will be assigned a receiving report number which is then recognized and tracked as the material lot number.

8.2 Traceability of materials, parts and products shall be recorded on product documentation (traveler).

8.3 The product job and release number shall be considered the product lot number.

8.4 At any stage of the process, all materials and products must be identified and related to current product documentation.

8.5 Only materials and products meeting established customer requirements are accepted at inspection.

8.6 Records will demonstrate the acceptance of product as well as disposition of all unacceptable or rejected parts/materials.

8.7 Shipping records shall provide traceability to product lot numbers.

References:

1003- Generating Device Master Records
1012- Material Traceability and Lot Control
2007- Material Handling, Packaging and Storage

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Quality Manual

QM08 Identification and Control of Materials, Parts, Components and Products

Product Flow/ Product Documentation Block Diagram (PG 1 of 3)

A. Contract/ Purchasing Review

B. Receipt of items:

Delivery a. Items Purchased
b. Product/ materials provided by customer.

Receiving a. check for:

1. shipping damage
2. all incoming materials must have assigned part numbers
3. item verification
4. perform actual count

PROCESS:

Purchase Order 1. Match product to **P.O.** in order to receive.

STOP 2. If it does not have a **P.O.**, cannot receive without getting assistance from the appropriate product engineer.

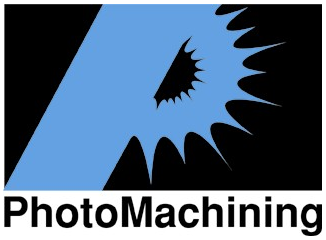
Special Handling 3. Check if Special Handling Instructions have been provided.

Product Count 4. Perform actual product count following any special handling **Instructions.**

Receiving Report 5. Complete sequentially numbered **Receiving Report**. This document identifies all incoming items with a unique lot number (the RR No.).

Label Product 6. Label product with a yellow **Quarantine Label** identifying the product by unique part and lot number, vendor, part description, received by, date received, number of parts and any related items.

Receiving Log 7. Complete **Receiving Log** for all incoming items (include



Date, Receiving Report No., P.O. No., Vendor, Part No./
Item Description, Count).

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QM08 Block Diagram (PG 2 of 3)

QC Quarantine a. If product Passes the receiving step, transfer product to QC Quarantine storage location along with RR.

PROCESS:

Inspection Criteria 1. Maintain **Inspection File** by part number with **Product Drawing/ Specification** and **Parameter Card** (specifies inspection parameters and records inspection results by lot No.).

Inspection Methods 2. Requires **Quality Assurance Procedures (QAP).**

QC Inspection Log 3. Record date, part number, lot number, vendor, Accept/ Reject (and DMR reference) in **QC Inspection Log.**

DMR 4. Parts are labeled with a red reject tag and a **Discrepant Material Report** is completed stating the disposition of the Discrepant parts;

a. Use as is.
b. Return to vendor.
c. Rework
d. Scrap

Receiving Report 5. Complete QC portion of **Receiving Report**.

Approved For Use 6. Over label quarantine label with a green **'Approved For Use' Label**.

Transfer to Stock 7. Transfer product and RR to Stock.

Stock a. Stock products

PROCESS:

Receiving Report 1. Complete **Receiving Report**.

Stock Products 2. Stock by location.

RR to Admin. 3. Notify Admin. stock ready to kit.

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QM08 Block Diagram (PG 3 of 3)

Production a. Product manufacturing.

PROCESS:

Issue Job
1. By **Finished Product Part No.** and **Job No.** (lot number).
2. Print job specific **Travelers** (Device History Record) from **Master Traveler** (Device Master Records).

Kitting
3. Stockroom to kit and record component lot numbers on Traveler.

Manufacturing
4. For all operations record operator ID, date and quantity.

QC Inspections
5. Document on Traveler.

Finish Product Quarantine/
6. Transfer product to QC quarantine. QC Inspection as per QC quarantine section but for finished product.

Inspection

Finish Product
7. Release to Labeling/ Packaging.

Release

Labeling/ Packaging- to be followed if product labeling is required by the customer

a. Product labeling and Packaging.

PROCESS:

Label Area Check
8. No other labels. Record on Traveler.

Label/ Packaging
9. Attach completed sample of product label to Traveler.

Release To Stores

Positive Lot Release
10. Final QC review and sign off of lot documentation and record on traveler.

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Shipping

Shipping Log **11. In** Shipping Log **record Date Shipped, Part No., Lot No., Quantity, Consignee Name and Address.**

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QUALITY MANUAL
QM09 PROCESS CONTROLS

9.1 All production processes which directly affect product quality shall be adequately controlled. Controlled conditions shall include the following:

9.1.1 The product manufacturing sequence is defined in the form of the Device Master Record Traveler Sheet.

9.1.2 Documented work instructions.

9.1.3 Use of appropriate production equipment.

9.1.4 Suitable working environment and adequate control of environmental conditions.

9.1.5 Compliance with referenced standards and quality plans.

9.1.6 Validation/approval of processes and equipment.

9.1.7 Monitoring and control of process and product characteristics during production.

9.2 Special Processes whose results cannot be fully verified by subsequent inspection and testing of the product, must be controlled with the following additional controls:

9.2.1 Continuous monitoring and compliance with documented procedures to ensure that the specified requirements are met.

9.2.2 Records shall be maintained for qualified processes, equipment and personnel.

References; 1003- Generating Device Master Records
1005- Numbering Fixtures, Parts and Assemblies
2012- SPC Plan
2013- Technician Control and Acceptance Plan

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Quality Manual
QM10 INSPECTION AND TESTING

10.0 The intent of the inspection program is early detection of material and product deficiencies to prevent the use or delivery of such products as well as the collection of information regarding non-conforming product for the purpose of continual improvement. Written test procedures shall be established to assure that all testing required to demonstrate that products and systems perform correctly are documented as follows:

10.1 The acceptance of all tests to verify design and manufacturing capabilities are the responsibility of the Quality Assurance Manager, or their designee.

10.2 The performance of routine manufacturing test to verify quality is the responsibility of the individual making the part.

10.3.1 The testing program shall;

a. Identify the acceptance criteria for materials and products
b. Identify appropriate equipment and instrumentation required to conduct testing to verify satisfactory performance.
c. Identify any controlled environmental conditions required.

10.3.2 Quality Control will verify that all required manufacturing tests have been performed through verification of test results, in-process audits and/or product audits.

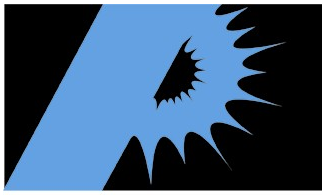
10.3.3 The inspection program will verify conformance to documented instructions, procedures and drawings for:

a. Incoming material.
b. In-process operations and materials.
c. Final product and systems.

10.3.4 Production personnel may perform in process inspections if:

a. The individual has received proper training.
b. The inspection is performed to established documented inspection criteria.
c. The inspection results are properly documented.

10.4 The inspection plan shall be designed to ensure the probability of deficiencies being detected through the identification of specified inspection test points and characteristics selected from customer drawings/product specifications. All test records shall be maintained.



10.5 Quality generates and maintains first article documentation for each new manufacturing set up. In addition, an additional first piece inspection will be required each time a new fixture, machine tool or program is used. Software controlled processes require first piece software validation by quality.

References:

2005- Inspection Responsibility

2006- Software Quality Assurance Plan

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Quality Manual
QM11 INSPECTION, MEASURING AND TEST EQUIPMENT

11.0 All inspection measuring and test equipment, whether company or customer owned, shall be properly controlled, calibrated and maintained through written procedures which comply with the requirements of this manual as follows:

11.1 Ensure that all equipment used for verification of quality are appropriate and accurate.

11.2 Identify, calibrate and adjust all inspection, measuring and test equipment at prescribed intervals and/or prior to use.

11.3 Calibration shall be traceable to a nationally recognized standard. When no recognized standard exists, the basis for calibration must be documented.

11.4 Records must include:

a. Description of the equipment.
b. Unique identification number and calibration status on test equipment label.
c. Location of equipment.
d. Frequency of checks.
e. Check method.
f. Acceptance criteria.

11.5 The procedure must include an action plan to investigate and correct the consequences of using out of specification measurement or test equipment.

11.6 Calibration equipment shall be maintained in environmentally controlled conditions.

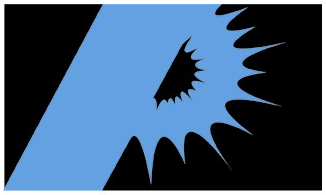
11.7 Where test hardware or software is used in inspection, they shall be included in the calibration system and be checked to prove they are capable of verifying the acceptability of the product.

11.8 Software used in inspection shall be under revision control.

11.9 Quality Assurance is responsible for ensuring verification of measuring and test equipment used in manufacturing.

11.10 Internal or outside calibration standards must be traceable to the National Institute of Standards and Technology (NIST). The calibration status of calibration standards must be included in the annual QA system audit.

11.11 Quality will maintain calibration history records for all company and customer equipment by unique identifiers.



References:

2002- Calibration Procedures

2011- Procedure for Evaluating and Investigating Calibration

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Quality Manual
QM12 INSPECTION AND TESTING STATUS

12.0 Inspection and testing shall be performed and documented to ensure that materials, products and equipment meet the specified technical and quality requirements and shall:

12.1 Identify inspections, tests and audits to be conducted.

12.2 Identify the quality status of all material and product throughout the process.

12.3 Document inspection and test status throughout production to ensure that only acceptable product is used and retain all such records of inspection, tests and audits.

12.4 Non-conforming material must be identified and segregated.

12.5 Unless otherwise specified through the customer contract, final product inspection will consist of an inspection of major and close tolerance characteristics as well as known problem areas. If such a characteristic has already been inspected and recorded through in-process inspection, it need not be re-inspected unless the dimension is subject to change due to subsequent processing.

12.6 If any part fails to meet customer specification at final inspection, it will be placed on hold for rework or MRB investigation to determine the cause of the problem and why the defect was not identified in the process. Appropriate Corrective Action will be issued, implemented and documented with prior written customer approval where appropriate.

References:

2003- Corrective Action System
2005- Inspection Responsibility

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QUALITY MANUAL
QM13 CONTROL OF NON-CONFORMING PRODUCT

13.0 The identification, segregation and disposition of non-conforming materials shall be a controlled program which shall ensure that:

13.1 The Quality Department dispositions all non-conforming product.

13.2 All non-conforming products shall be identified and segregated.

13.3 Material pending disposition shall be segregated from parts approved for use until the discrepancy is resolved. Parts dispositioned as scrap shall be removed from production access.

13.4 Records of non-conforming materials/products and their disposition records will be reviewed by management.

13.5 A disposition to use 'as is' where the non conformance may affect product quality, requires documented technical justification and prior written customer approval.

a. The internal MRB review will determine if rework to a special manufacturing process is required or if the deviation must be submitted to the customer for prior approval. All non conforming product will be segregated within a bonded area until dispositioned
b. All product requiring rework shall be dispositioned as rework on the traveler Non Conformance report and corrected on the job
c. If a repair is required, prior customer approval of the process and resultant part quality is required for any further work on the product. All further work on the product including the work instructions and job documentation, are reported on a separate traveler identifying the material as “repaired”.

13.6 A disposition decision to rework or repair requires re-inspection after the rework or repair has been completed.

13.7 When a non conformance is reported by a customer regarding delivered parts, QC will take the following actions:

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a. Request return of the material from the customer and check that additional material in-house does not exhibit the same problem.
b. Review all production and inspection records for the reported non conforming parts.
c. If the problem is verified;
    1. Determine quantity of parts affected.
    2. Identify cause and contributing factors.
    3. Develop Corrective Action Plan and report to customer.
    4. Implement Corrective Action.
    5. Report corrective action to the customer upon completion.
d. If the problem cannot be verified, QC will monitor future manufacture of the parts for the deviant characteristic.

References; 1003- Generating Device Master Records
2003- Corrective Action System
2005- Inspection Responsibility

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QUALITY MANUAL
QM14 CORRECTIVE ACTION

14.0 The company follows a documented corrective action program to ensure that conditions adverse to quality are properly identified, analyzed and corrected. The corrective action program includes the following:

14.1 Analysis of all work processes, work operations, inspection records and customer complaints to detect and eliminate potential causes of non conforming product.

14.2 Identification of any conditions adversely affecting quality as well as the root causes for such problems.

14.3 Definition of the action steps which will be implemented to correct the adverse condition.

14.4 Follow up to ensure compliance to the corrective action plan.

14.5 Management review of all quality issues and corrective actions within a timely manner.

14.6 Corrective Actions regarding non conforming materials will follow the procedures established within QM13.

References: 2003- Corrective Action System
2009- Management Surveillance Plan
2010- Continuous Improvement Plan

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QUALITY MANUAL
QM15 HANDLING, CLEANING, STORAGE, PACKAGING AND DELIVERY

15.0 Any methods required by customer contract for special product or material handling, cleaning, storage, packaging and delivery shall be specified within the product traveler and process instructions. If no special handling requirements are specified within the product documentation, handling will be in accordance with company policy to minimize product damage or loss and to maintain traceability.

15.1 Special handling requirements will be specified on the traveler.

15.2 QC approval of the 'final inspection' operation on the product traveler verifies that the product is approved and that the documentation is accurate and complete, thus releasing the product for further use or shipment to the customer.

15.3 Procedures for receipt and release of materials from secure storage areas will be followed.

15.4 Finished product shall be packed in a manner to prevent damage during transit and shall be appropriately labeled both with shipping labels complying with customer requirements if any and documentation (packing slips).

15.5 Packing Slips will identify both the product and lot number being shipped in order to provide product traceability through to the customer.

References: 1003- Generating Device Master Records
2007- Material Handling, Packaging and Storage

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QUALITY MANUAL
QM16 QUALITY RECORDS

16.0 The following procedures shall be followed for the identification, collection, storage and maintenance of quality records. These quality records must be legible and shall demonstrate the effective operation of the quality system through the following:

16.1 The Receiving Reports and inspection records provide component inspection history and traceability by assigned lot numbers as well as pertinent sub-contractor quality records.

16.2 The traveler system provides full information regarding product and inspection work history traceable to specific product lots.

16.3 Availability of records and related data regarding qualification of personnel, procedures and equipment.

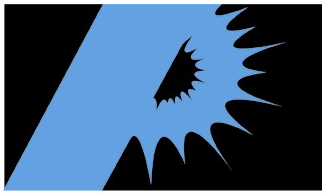
16.4 Records shall be adequate to permit analysis of conditions found to be adverse to quality.

16.5 Records are stored and maintained such that they are readily retrievable and are held for time periods meeting customer requirements. If un-specified records shall be retained for a period of at least 3 years for commercial products and follow government agency guidelines for military contracts. Medical records shall be retained in accordance with FDA requirements if not specified by contract.

16.6 Quality records shall be made readily available for evaluation by the customer and government auditors. Customer auditors shall be allowed to review records pertaining to their or their company's product.

16.7 Only quality or properly trained and certified manufacturing personnel can approve the Final Inspection operation of the traveler. Sign off of this operation entails not only product inspection release, but also review and approval of the complete product documentation. Any documentation errors or omissions must be corrected prior to release of the product for delivery to the customer.

References; 2004- Quality Assurance Responsibility
2005- Inspection Responsibility.



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2013- Technician Control and Acceptance Plan

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QUALITY MANUAL
QM17 QUALITY AUDITS

17.0 This system of planned and documented audits shall be implemented to verify compliance with all aspects of the Quality Assurance Program and this Manual. The following activities shall be addressed:

17.1 Audits shall be conducted by qualified personnel independent from the areas being audited.

17.2 Audits shall be performed to a written plan or procedure.

17.3 Objective evidence shall be reviewed for compliance with the Quality Assurance Program requirements.

17.4 The audit shall include review of process, product and testing performance and documentation.

17.5 The audit results will be reviewed by the individuals being audited prior to being submitted for management review.

17.6 Documented Corrective Actions will be required where items or activities are found to be non conforming.

17.7 Re-audits will be conducted to verify that corrective actions have been implemented and that these actions are effective.

17.8 Quality department spot audits of departmental functions and activities relative to product quality will be on a schedule to verify and assure that all customer, industry and company policies regarding product quality and compliance to custoerm requirements. Audits shall be performed, at a minimum, on a quarterly basis.

17.9 A complete comprehensive independent audit of the performance of the Quality Assurance System will be conducted annually.

17.10 All audit results will be reviewed by the management team.

References: 1014- Quality Assurance Auditing Procedure
2009- Management Surveillance Plan
2013- Technician Control and Acceptance Plan
2014- Product Audits

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QM18 Training

18.0 Employees with proper education training and experience shall be selected for activities which affect product quality, documentation and for performing the activities specified in the company procedures as specified within this manual.

18.1 Department Managers shall identify the training needs for all personnel performing activities affecting quality.

18.2 All training received or completed shall be documented and maintained by the department manager.

18.3 Temporary employees will also receive documented training for those operations they are expected to perform.

18.4 Training records shall be accessible to customers and auditors.

References 1006- Employee Training Documentation
1007- Temporary Employee Training Documentation
2012- SPC Plan
2013- Technician Control and Acceptance Plan

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QM19 SERVICE

19.0 PhotoMachining does not conduct service related activities at this time. If at a later date such activities become necessary, specific procedures shall be established to provide adequate control.

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QUALITY MANUAL
QM20 STATISTICAL TECHNIQUES

20.0 Where appropriate, procedures shall be established for identifying and establishing appropriate statistical techniques required for verifying the acceptability of product characteristics and process capabilities.

20.1 Employee training regarding the use of Statistical Process Control (SPC) techniques shall be conducted.

20.2 When used, statistical information shall be collected and analyzed to provide feed back to the technicians and to improve in process manufacturing controls.

References: 2012- SPC Plan

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PHOTOMACHINING, INC.
QUALITY MANUAL
QM21 CLEANING

21.0 All areas within the company will be maintained in a clean condition and periodic cleaning activities will be performed following an established schedule.

21.1 All manufacturing areas will be maintained such that the conditions promote proper job performance. All parts, materials, scrap, specific production and measurement equipment, and job documentation required for a specific job, will be removed from the manufacturing location upon the completion of a job and prior to initiating another job.

21.2 All eating and drinking will be restricted to non product handling areas in accordance with company policy.

21.3 All individuals involved in cleaning will be instructed as to the expectations relative to their job.

REFERENCES: 1012- PROCEDURE FOR COMPANY CLEANING

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PHOTOMACHINING, INC.
QUALITY MANUAL
QM22 SOFTWARE CONTROL

22.0 All software used in the manufacture or inspection of products shall be verified, approved and revision controlled.

22.1 All manufacturing software will be verified at first piece through inspection of the part to the product drawing.

22.2 If the operator detects any quality problems during the manufacture of the products, verification against the drawing is required.

22.3 Re-verification of a first piece is also required after any change to the set up or manufacturing equipment.

22.4 The QC Department will maintain records of first piece inspections.

Reference: 2006- Software Quality Assurance Plan

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PHOTOMACHINING, INC.
QUALITY MANUAL
QM23 COMPLAINT FILES

23.0 Product complaints involving any written or oral expression of dissatisfaction with the quality, safety, effectiveness, reliability or performance of a product shall be appropriately documented, investigated and acted upon to prevent similar problems from recurring.

23.1 The quality department is responsible for handling product complaints, generating the complaint forms and for assigning responsibilities for the various aspects of the internal complaint investigation.

23.2 The quality department also assumes responsibility for reviewing information generated in a complaint investigation and will determine if the investigation is adequate and complete.

23.3 The quality department will issue any required corrective actions and will communicate the findings of the investigation and corrective actions to the customer.

23.4 QC will determine if the reported problem (or root cause) impacts any other operations or products.

23.5 All complaint and complaint investigation records shall be reviewed by company management within the monthly management meetings and be maintained as a permanent record by the quality department.

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Quality Assurance Procedure (QAP)
Procedure No.:2003 Revision Level: A
Effective Date: 01-25-02

Author: Jim Keating Date: 01-07-02 Effectivity Date:
Approved By: Quality Manager Date:
Manufacturing Manager Date:
Engineering Manager Date:
President Date:

Title: Corrective Action System

Scope: To describe Photomachining' Corrective Action System, including Corrective Action Board Functions, Board Members Responsibilities, Board Meetings, and Corrective Actions Documentation.

1.0 Members:

1.1 PhotoMachinings' Corrective Action Board consists of the Quality Manager, Manufacturing Manager, Engineering Manager, and Company President (or designee).

2.0 Responsibilities:

2.1 Quality Manager's Responsibilities:

2.1.1 Responsible for issuing corrective action requests to manufacturing or engineering in the event of non-conforming hardware.

2.1.2 Responsible for reporting problems and trends to the members of the C.A.B.

2.1.3 Responsible for organizing and conducting C.A.B. meetings.

2.1.4 Responsible for tracking process of cause and corrective action data as well as internal and external recurrence.

2.2 Engineering Manager Responsibilities:

2.2.1 Responsible for identifying causes and initiating corrective actions for process (Engineering) problems.

2.2.2 Must attend C.A.B. meetings.

2.2.3 Must supply engineering support to Manufacturing Manager in regards to manufacturing problems.

Title: Corrective Action System

2.3 Manufacturing Manager Responsibilities:

2.3.1 Responsible for identifying causes and initiating corrective actions for manufacturing problems.

2.3.2 Must attend C.A.B. meetings.

2.3.3 Responsible for instructing and re-training operators.

2.4 Company President Responsibilities:

2.4.1 Responsible for communicating general trends and concerns to employees during company meetings.

2.4.2 Must attend C.A.B. meetings.

3.0 Corrective Action Board Meetings.

3.1 C.A.B. meets monthly, if required, as a minimum.

3.1.1 If no actions exist then meetings shall be cancelled or re-scheduled as required.

3.2 C.A.B. reviews adequacy and effectiveness of corrective actions for previous periods.

3.3 C.A.B. identifies and analyzes causes and recurrences as well as similar hardware or processes for common problems.

3.4 C.A.B. addresses any corrective action requests that have not been answered.

3.5 All items addressed during C.A.B. meetings are documented and kept on file in Quality Control.

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QUALITY ASSURANCE PROCEDURE (QAP) **Procedure No.:2004 Rev: A**

Author: Jim Keating Date: 01-07-02 Effectivity Date:
Approved By: Quality Manager Date:
Manufactuing Manager Date:
Engineering Manager Date:
President Date:

Title: Quality Assurance Responsibilities

Scope: To establish all responsibilities for the Quality Department and the Quality Manager.

1.0 Supervise and direct all quality personnel.

2.0 Administrate quality system per PMI quality manual, and Q.A.P.'s.

3.0 Plan each individual job as follows:

3.1 Review contract requirements for Quality Clauses or Quality Requirements.

3.2 Review blueprint(s) for Quality Clauses or Quality Requirements.

3.3 Fill out quality plan (outlining all quality requirements) (as required by contract).

3.3.1 Devise statistical sampling plan if required.

3.4 Write requisitions for purchase or repair of any inspection equipment.

4.0 Control Supply Chain and vendors as follows:

4.1 Conduct surveys using requirements necessary for supplier.

4.2 Conduct product audits per QAP 2014.

4.3 Evaluate reject and corrective action rates of each supplier.

4.4 Evaluate delivery performance.

5.0 Customer and supplier correspondence:

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5.1 Responsible for any necessary communication (written or verbal) with customers or suppliers regarding quality related issues.

5.2 Report nonconformance to customer on the appropriate waiver forms (when necessary).

5.3 Perform internal system audit per procedures maintained in QualityDepartment.

6.0 Disposition of company owned material per quality manual.

7.0 Issue corrective action request to in-house personnel and suppliers. Log results in non-conformance log book.

8.0 Interact with other key personnel to evaluate quality system and troubleshoot problem areas.

9.0 Assure that calibration system is maintained.

10.0 Customer audits: Act as liaison during audits.

11.0 Review and revise Quality Manual yearly or as updates occur or are necessary.

12.0 Review and sign off all master travelers.

12.1 Incorporate any additional quality requirements onto travelers.

13.0 Review and sign off requisitions for outgoing purchase orders as they relate to job order material. Use quality plan and/or customer specifications/drawings to determine requirements.

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QUALITY ASSURANCE PROCEDURE (QAP) **Procedure No.:2005 Rev Level: A**
Page 1 of 1
Author: Jim Keating Date: 01-07-02 Effectivity Date:
Approved By: Quality Manager Date:
Manufacturing Manager Date:
Engineering Manager Date:
President Date:

Title: Inspection Responsibilities

Scope: To establish responsibilities for all inspection operations.

1.0 Devise and document inspection methods for incoming, in process, and final inspection using the appropriate forms provided in the Quality Manual.

1.1 Establish frequencies for in-process dimensional inspection based on the criticality of the characteristics.

2.0 Perform and document all incoming and final inspections using the levels prescribed in the Quality Plan, see Quality Manual.

3.0 Perform and document 1st article inspections for all manufacturing operations after all operations are accepted on traveler.

4.0 Perform random (in-process floor) inspection.

5.0 If any parts are found nonconforming:

5.1 Tag with appropriate reject tag.

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5.2 Notify Q.C./Q.A. Manager for disposition.

5.3 Log in non-conformance.

5.4 Screen the rest of the lot for deviant characteristic (if applicable).

5.5 If characteristic is found in process, stop production pending corrective action.

6.0 Calibrate all inspection gauges using QAP 2002.

7.0 Using tagging procedure, maintain inspection status of all parts.

QUALITY ASSURANCE PROCEDURE (QAP) **Procedure No.:2006 Rev Level: A**
Page 1 of 3
Author: Jim Keating **Date: 01-07-02** **Effectivity Date:**
Approved By: Quality Manager **Date:**
Manufacturing Manager **Date:**
Engineering Manager **Date:**
President **Date:**

Title: Software Quality Assurance Plan

Scope: The purpose of this procedure is to control software (programs) throughout manufacturing. When a purchase order or PhotoMachining Engineer review calls for software control, all job specific software will be identified and controlled by revision levels. Commercial software used in the manufacture of products will also be identified and controlled by revision levels.

1.1 Only Engineering and Document Control departments have access to permanently change product/process software department.

1.2 All revisions are documented onto the master program listing, as well as the Program Library.

1.3 When a revision or modification is made, the program must be re-qualified by the Quality Department.

1.4 Quality Department alone is authorized to qualify programs through part quality.

1.5 Programs are qualified by 1st article inspection of all characteristics generated by that program.

1.5.1 Upon acceptance, inspection initials and dates the software acceptance log thus qualifying the program.

1.5.2 If rejected, engineering must revise the program until the part passes inspection at which time it is qualified. Any rejected parts are tagged and segregated.

1.6 Program name and revision levels are referenced on the travelers and/or job specific parameter sheet. Changes to program name and revision levels on master travelers/documentation requires an ECO.

Title: Software Quality Assurance Plan

1.7 Parts are periodically inspected for characteristics associated with the program.

1.7.1 If a non-conformance is found in process, the program is reviewed and re-qualified. All suspect parts are screened 100% for the non-conformance.

1.8 Periodic evaluations of program modifications are to be performed by engineering.

1.9 Periodic audits are to be performed by the Quality Department for adherence to the procedures listed in this document.

1.10 All systems and programs are backed up daily. It is the responsibility of the network administrator to perform all back-ups and to restore data as required or requested for use by manufacturing, engineering or quality departments or personnel.

1.11 All programs and revisions are backed up with a program listing and kept on file.

2.0 Types of Programs

2.1 There are two types of programs generated for use in the manufacturing of product.

2.1.1 Customer Controlled – those files or programs either provided by the customer or generated from information provided by the customer for the fabrication of customer deliverable products.

2.1.2 General Programs – those files that are not particular to any custoerm part number or drawing.

2.2 Customer Controlled Programs

2.2.1 All customer controlled programs are generated and/or modified by engineering or programming.

2.2.2 Customer Controlled Programs are saved to the specific customer directory on the PMI server and are named with an appropriate name to associate that file with the customer specific part number and revision.

2.2.3 Any revisions to the program will require re-inspection and re-qualification to the customer drawings and/or specifications prior to release to manufacturing.

2.2.4 Any revisions shall be recorded on the PMI process run sheet and process traveler

Title: **Software Quality Assurance Plan**

2.3 General Programs - A "General Program" is one that is not particular to any specific drawing number, but may take in a general family of parts. These programs are identified by the following mandatory information both on the program and in the program library:

2.3.1 General description of the program's capabilities.
2.3.2 Program revision.
2.3.3 Programmer's name.

NOTE:

When a purchase order or contract calls for software Quality Assurance, the customer's S.Q.A. requirements are flowed down to any subcontractors who may use software in their manufacturing process. These subcontractors flow down requirements are subject to periodic audit by PhotoMachining.

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PMI SOP INDEX

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-1001	A	Procedure for Writing Standard Operating Procedures	J. Keating	
-1002	A	Procedures for Medical Devices	J. Keating	
-1003	A	Procedure for Process Travelers	J. Keating	
-1004	A	Procedure for Implementing Engineering Change Orders (ECO's)	J. Keating	
-1005	A	Processing of Product for Commercial Applications	J. Keating	
-1006	A	Processing of Product for Military Applications		
-1007	A	Employee Training Documentation	J. Keating	
-1008	A	Temporary Employee Training Documentation	J. Keating	
-1009	A	Incoming Inspection	J. Keating	
-1010	A	Final Inspection	J. Keating	
-1011	A	Packaging and Shipping Instructions		

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-1012	A	Procedure for Company Cleaning	J. Keating
-1013	A	Corrective Action Requests/Customer Complaints	J. Keating
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Procedure No.: 1001
Standard Operating Procedure (SOP)
COVER SHEET **Effective Date: 12-14-01**

Title: Procedure For Writing Standard Operating Procedures.

Departments: Company Wide

Release Approvals:

Department	Name	Signature	Date

PhotoMachining

Pres.

Manuf.

Q.C.

Admin.

Eng.

Doc.Ctrl.

Author: Jim Keating 12-04-01

Revision History:

Revision	ECO No.	Release Date	Doc. Contrl Approval
A	original rel.		

Title: Procedure For Writing Standard Operating Procedures.

1. **Objective:** To provide a uniform method for developing company Standard Operating Procedures (SOP's).

2. **Scope:** Company Wide

3. **General:**

3.1 Standard Operating Procedures (SOP's) cover company activities which are not specific to any product, but apply to individual or multiple company departments such as Device Master Records, Engineering Change Orders (ECO's), complaint procedures, etc. SOP's will **not** replace Quality Assurance Procedures (QAP) or Process Instructions. All company SOP's will be written on standardized SOP header forms (samples attached). The same standardized header sheet format will be used for QAP's although the QAP's will be written with a different sequence of headings within the procedure.

3.2 All SOP's will be generated using this format.

3.3 All SOP's will contain the following headings:

"**Objective**"- A brief statement specifying the intent of the procedure.

"**Scope**"- A brief statement indicating the personnel or departments involved.

"**General**"- A listing of any general provisions, policies or precautions that may apply to the procedure.

"**Procedure**"- A detailed step by step set of instructions for performing the procedure.

3.4 Assignment of procedure numbers, revision levels and other changes will be controlled and coordinated by the Document Control Group.

Title: Procedure for Writing Standard Operating Procedures.

3.5 Any documentation forms used with a procedure must reference the procedure number and revision level in the upper right-hand corner of the form.

3.6 Each department is responsible for updating relevant SOP's via the company change control system (SOP# 1004).

4. **Procedure:**

4.1 The originator will develop and draft the procedure along with any associated documentation forms and identify the departments affected.

4.2 The procedure will then be submitted to the Documentation Control group which will verify the appropriate approval levels, log in the SOP and issue the next sequential SOP number, prepare a Standard Operating Cover Sheet (sample attached), ensure completion of the SOP on the approved SOP forms and present the document at the next production meeting for review, discussion and approval signatures.

4.3 After the SOP has been approved the Documentation Control group will complete the SOP log, file the original SOP Cover Sheet along with a copy of the SOP itself (and any subsequent ECO's) and distribute controlled copies to satellite filing locations.

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Procedure No.:1001
Standard Operating Procedure **Revision Level: A**
Page 4 **of** 4

Title: Procedure For Writing Standard Operating Procedures.

Procedure No.:
Standard Operating Procedure (SOP)
COVER SHEET **Effective Date:**
Page 1 of .

Title:

Departments:

Release Approvals:

Department	Name	Signature	Date
Pres.			
Manuf.			
Q.C.			
Admin.			
Eng.			
Doc.Ctrl.			
Author			

Revision History:

Revision	ECO No.	Release Date	Doc. Contrl Approval

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Procedure No.:1002
Standard Operating Procedure (SOP)
COVER SHEET **Effective Date:12-4-01**

Title: Procedures for Medical Devices.

Departments: Company Wide

Release Approvals:

Department	Name	Signature	Date
Pres.			
Manuf.			
Q.C.			
Admin.			
Eng.			
Doc.Ctrl.			

Author: Jim Keating 12-04-01

Revision History:

Revision	ECO No.	Release Date	Doc. Contrl Approval
A	original rel.		

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Title: Procedures for Medical Devices.

1. **Objective:** To provide an accurate assessment of Photomachining, Inc.'s position as a manufacturer of medical devices and medical device components.

2. **Scope:** Company wide.

3. **General:** Definitions and current policy.

3.1 A medical component is defined as "any material, substance, piece, part or assembly used during manufacture which is intended to be included in the finished product for medical use". Current FDA policy is to rely upon the **finished** device manufacturer to assure that components are acceptable for use, thus manufacturers of components sold only for further manufacturing are not scheduled for routine FDA inspection.

3.2 When finished device manufacturers produce components for devices they themselves manufacture, the production of components is considered part of the device manufacturing operation and must comply with FDA guidelines.

3.3 Accessory devices which are packaged, labeled and distributed separately (such as hemodialysis tubing) is considered a finished device.

3.4 A finished device is a device or accessory which is suitable for use whether or not packaged or labeled for commercial distribution.

3.5 Contract manufacturers are firms which manufacture a finished device under the terms of a contract with another firm. There should be a written contract. Contract manufactures of finished devices must follow FDA guidelines.

Title: Procedures for Medical Devices.

3.6 Specification developers initiate specifications for devices that are manufactured by a second party and are defined as manufacturers. The specification developer must comply with FDA guidelines for the activities they conduct.

3.7 Custom devices are considered special devices for one patient or physician which are not otherwise commercially available. Although custom devices are exempt from Performance Standards, Premarket Approvals and Premarket Notification requirements, they are not exempt from the GMP regulations. Current FDA policy is not to inspect companies which solely manufacture custom devices.

3.8 PhotoMachining, Inc. is not currently registered with the FDA as a Contract Manufacturer.

3.9 As of the current revision of this procedure, PhotoMachining, Inc. functions as a contract manufacturer and makes products to specifications supplied by customers who are responsible for the product design. Although PhotoMachining, Inc. does provide specification input to customers based or their experience with manufacturing processes, the product specifications originate with, and are supplied by, the customer.

3.10 All products made by PhotoMachining, Inc. are either shipped directly to the client company or to a subsequent vendor as specified by the customer. Photomachining, Inc. is not responsible for any finished product packaging or sterilization nor does it distribute any finished medical device products under it's own name.

3.11 The design input and manufacture of future medical device products by Photomachining, Inc. will trigger a review of the product and company obligations relative to the definitions and position stated in this procedure. If any future products change the company's regulatory obligations, this procedure will be revised and any required regulatory submissions will be filed.

Title: Procedures for Medical Devices.

4.0 Procedure

4.1 All products made by PhotoMachining, Inc. will be processed in accordance with customer specific Purchase Order requirements, customer specific drawing requirements, customer specific specification requirements, and customer specific inspection guidelines.

4.2 Any product designated for medical use will be handled accordingly to reduce any damage or possible contamination during processing. The use of protective clothing (latex gloves, clean room gowns, hair covering etc…) will be as specified in customer written requirements.

4.3 Any special handling requirements or processing requirements will be in accordance with customer written specifications and these requirements will be transferred to PMI internal documentation (travelers, process guidelines, inspection procedures)

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Procedure No.:1003
Standard Operating Procedure (SOP)
COVER SHEET **Effective Date:12-14-01**

Title: Procedure For Process Travelers.

Departments: Company Wide

Release Approvals For Revision A:

Department	Name	Signature	Date
Pres.			
Manuf.			
QC.			
Eng.			
Doc.Ctrl.			

Author: Jim Keating 12-04-01

Revision History:

Revision	ECO No.	Release Date	Doc. Contrl Approval
A	original rel.		

PhotoMachining

Title: Procedure For Process Travelers.

1. **Objective:** To provide a controlled system for the development, approval and release of Process Travelers for the processing of finished products.

2. **Scope:** Company Wide

3. **General:**

3.1. All **Process Travelers** will be developed by authorized persons using the format and description provided in this procedure. Sample **Process Traveler** is shown in **Attachment 1**

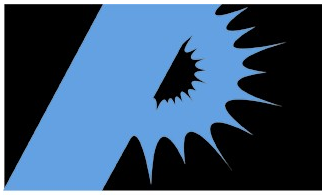
3.2. All Process Travelers will be generated, approved and maintained in hard copy form using the **Process Traveler** approved template (PMI Form 1 Rev A) as shown in **Attachment 1** to this procedure.

3.3. All work being completed within the facility will be accompanied by a **Process Traveler**. The **Process Traveler** will, at a minimum supply the Job #, Customer Name, Drawing # and current Revision, and P.O. #. Other information that may be included consists of a scheduled start date and scheduled finish date.

3.4. The **Process Traveler** document will accompany the work to be processed throughout the manufacturing facility and the appropriate information will be filled out by those individuals completed the tasks. Completed **Process Travelers** will be kept on file within the Documentation Control Area and will include a copy of the **Process Run Sheet** (PMI Form 2 Rev A) as shown in **Attachment 2.**

3.4.1 If multiple technicians are involved or likely to be involved in an operation each technician must sign the process traveler for the tasks that they perform.

3.4.2 A Process Run Sheet (Attachment 2) will be referenced on the traveler as required.


PhotoMachining

Title: Procedure For Process Travelers.

3.4.34 All travelers released to production will also include a Non-conformance Record (Attachment 3) which must be completed for all unplanned repair work and discrepant parts (rejects) accumulated on the job.

3.4.5 When planned product repairs are considered a normal part of the production job, repair must be listed on the non-conformance record (attachment 3) as repair. The Technician will note on the form the number of units repaired and the balance quantity listed for the repair operation will be the number of units successfully repaired plus the quantity of good. Unsuccessful repairs must be listed on the non-conformance report as units scrapped.

4. **Procedure:**

4.1. Development of Process Traveler

4.1.1. Travelers will be initiated when a Purchase Order is received for deliverable product or when material is received for processing. Requests for processed samples may or may not require a traveler. Originator will fill out the top of the Process Traveler (attachment 1) with all of the information required.

4.1.2. Receiving Inspection

4.1.2.1. The person receiving the raw un-processed material shall visually inspect the material and note any unusual characteristics or damage and record any customer identifier (i.e. Lot # etc…). Number of parts received should be recorded if feasible.

Title: Procedure For Process Travelers.

4.1.3. Incoming Inspection

4.1.3.1. Technician shall inspect all product to customer supplied documentation or specifications and denote any non-conforming material or damage incurred during shipment. Damaged material should be brought to the attention of supervisor or lead person for dispensation.

4.1.3.2. Any material that is deemed to be defective at in-coming inspection shall be recorded on the Product Non-Conformance Report (PMI Form 3 – attachment 3)and customer is to be notified.

4.1.4. Laser Processing

4.1.4.1. Technician performing manufacturing tasks is required to document all information in this section. If technician has any questions as to the requirements of the job they are to consult the customer supplied documentation (prints, specifications, letters, e-mail messages etc…) to clearly understand the customers desired result prior to processing parts.

4.1.4.2. Technician is responsible for all set-up, first piece inspection, and in-process inspection of processed parts.

4.1.4.3. If multiple technicians are processing parts each individual is responsible to inspect the product that they process. Each individual will be required to sign off the Process Traveler.

4.1.4.4. All processed material, including scrapped or defective material is to be forwarded to Final Inspection.

Title: Procedure For Process Travelers.

The following items are to highlight and emphasize the need to watch for required conditions or precautions. The actual instructions will be presented fully in other process documentation.

1. Notice whether or not special handling is required.
2. Notice if customer must approve first piece prior to production.
3. Notice if test coupons are required before, during or following production.
4. Notice if special packaging instructions are specified.
5. Notice if scrap material is to be returned to the customer.
6. Notice if this is a first-time job and likely to require added vigilance.
7. Look for special notes amplifying upon or in addition to the Process Traveler items to further ensure that all proper procedures and conditions are recognized and observed.

4.1.5. Final Inspection

4.1.5.1. Technician or quality representative performing final inspection shall record the information in the appropriate section of the traveler.

4.1.5.2. All final inspection is to be performed using the customers supplied documentation as a guideline.

4.1.5.3. All rejected material shall be recorded on the Product Non-Conformance Report. (PMI Form 3 – attachment 3)

4.1.5.4. All processed material, both accepted material and rejected material is to be forwarded to shipping department

4.1.5.5. For additional information and instruction on Final Inspection see SOP # 1010.

4.1.6. Shipping

4.1.6.1. Person responsible for shipping shall record all the correct information in the appropriate locations on the traveler prior to shipping product.

4.1.6.2. For additional information on packaging and shipping see SOP # 1011

Title: Procedure For Process Travelers.

Attachment #1
Photomachining Process Traveler (PMI Form 1)

Title: Procedure For Process Travelers.

Attachment #2
Process Run Sheet (PMI Form 2)

Attachment 3
Product Non-Conformance Form (PMI Form 3)

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Procedure No.:1004
Standard Operating Procedure (SOP)
COVER SHEET **Effective Date:12-14-01**

Title: Procedure For Implementing Engineering Change Orders(ECOs) or Engineering Change Requests (ECRs)

Departments: Company Wide

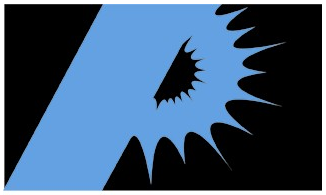
Release Approvals:

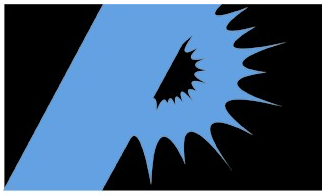
Department	Name	Signature	Date
Pres.			
Manuf.			
Q.C.			
Admin.			
Eng.			
Contr.Manuf.			
Doc.Ctrl.			

Author Jim Keating

Revision History:

Revision	ECO No.	Release Date	Doc. Contrl Approval
A	original rel		


PhotoMachining



Title: Procedure For Implementing Engineering Change Orders(ECOs) or Engineering Change Requests (ECRs)

1. **Objective**: To provide a uniform, standardized system for assessing and implementing modifications to controlled documents and changes to components, finished products and manufacturing processes.

2. **Scope**: This procedure applies Engineering Change Order (ECO) and Engineering Change Request (ECR) controls to all components, products, processes and documentation.

3. **General**:

3.1. Changes to company products, parts and documents must be controlled through an Engineering Change Order system to ensure that the changes are properly reviewed and approved.

3.2 Documentation Control is responsible for issuing ECR and ECO numbers and controlling and maintaining all ECR/ECO's.

3.3 An Engineering Change Request (ECR) is a suggestion or request for a proposed change. The ECR along with marked up documents and supporting data, if required, becomes part of the ECO documentation package. If all the information within the ECR remains correct, the ECR can be used to temporarily implement an ECO. The ECR information shall be transcribed onto an ECO form for review and approval.

3.3.1. Anyone in the company can submit an ECR suggesting a change. The ECR provides a mechanism for the preliminary assessment of a potential change prior to complete review. For an ECR form to be considered a proposed ECO however, all required information must be present and Manufacturing and QC, as well as the Project Engineer or alternate must approve the form.

Title: Procedure For Implementing Engineering Change Orders(ECOs) or Engineering Change Requests (ECRs)

3.3.2. An initial ECR is not required for the submission of an ECO.

3.4. An ECO is only required for a change in a controlled company activity or document which affects the FORM, FIT or FUNCTION of the part or document. Changes in layout, spelling or simple clarification of wording do not require an ECO.

4.0 **Procedure**:

4.1. The **ECO** form and explanation for completion are provided as **Attachment 1**.

4.2 The **ECR** form and explanation for completion are provided as **Attachment 2**.

4.3. Each section of the ECO or ECR form must be completed. If a section does not apply, a "N/A" must be entered.

4.4. All involved drawings, part numbers and documents must be individually listed, the changes clearly specified and a copy of the current revision of any documents with the marked up changes supplied with the ECR/ECO review package.

4.4.1. Careful attention must be paid by the originator to assess the potential impact of the proposed changes on secondary documents and/or products. Engineering or their designee prior to assigning an ECO number will also review this as a second check.

4.5. Document Control will assign a sequential ECO number from the ECO log for any properly completed ECO form intended to be subsequently circulated for approval signatures. The ECO log will also record the originator, the product/primary document involved and the current revision level, the proposed effective date and the final release date. If an ECO does not ultimately get approved and is withdrawn, "void" will be recorded in the final release date column and the ECO package will be stored within a folder for withdrawn ECOs in case it may later be needed for reference.

4.6. In the event that all individuals required to approve an ECO are not available and implementation of the change is essential, a completed ECO package can be approved and released for use if a majority of those required for approval sign and approve release. Faxed signatures are acceptable if required to reach a majority. Documentation Control will collect the approval signatures of all remaining individuals as they become available. In addition, the company president and/or the General Manager can sign for any other company manager if necessary.

4.7. Approval of ECOs can be addressed either by circulating them or during production meetings to ensure timely review and approval. It is incumbent on all appropriate individuals to obtain copies of necessary documents at the most recent revision and to come to Document Control to review and approve any outstanding ECOs.

4.7.1 If retrospective review for approval of an ECO by those individuals not present in the original approval process reveals problems such that approval by a required individual is not possible without changes, a subsequent Engineering Change Order (ECO) with a full description of the situation will be necessary to implement any such change.

PhotoMachining

Procedure No.:1005
Standard Operating Procedure (SOP)
COVER SHEET **Effective Date:12-14-01**

Title: Processing of Product for Commercial Applications.

Departments: Company Wide

Release Approvals:

Department	Name	Signature	Date
Pres.			
Manuf.			
QC.			
Eng.			
Doc.Ctrl.			

Author: Jim Keating 12-04-01

Revision History:

Revision	ECO No.	Release Date	Doc. Contrl Approval
A	original rel.		

PhotoMachining

Title: Processing of Product for Commercial Applications.

1. **Objective:** To define the requirements for the laser processing of parts for commercial applications.

2. **Scope:** Company Wide

3. **General:**

3.1. Commercial Applications by definition are products that are designated for use in non-military or non-medical fields. Included are products for the electronics industry, telecommunications, industrial applications, automotive industry, or other applications. Also included in this definition would be product designated for military or medical uses in which the customer has designated that “best commercial practices” be used in the processign of their product.

3.2. Product processed by Photomachining, Inc. will be in compliance to all written customer requirements. The order of precedence, unless otherwise stated in writing by the customer is: Customer Purchase Order Requirements, Customer Drawing Requirements, Customer Specifications, Industry Requirements, PMI Internal Requirements.

3.3. All work being completed within the facility will be accompanied by a Process Traveler. The Process Traveler will, at a minimum supply the Job #, Customer Name, Drawing # and current Revision, and P.O. #. Other information that may be included consists of a scheduled start date and scheduled finish date.

3.4. The Process Traveler document will accompany the work to be processed throughout the manufacturing facility and the appropriate information will be filled out by those individuals completed the tasks. Completed Process Travelers will be kept on file within the Documentation Control Area and will include a copy of the Process Run Sheet (PMI Form 2 Rev A).

3.5. All material shall be handled at all times in a manner to prevent any damage to the product during processing or

transport both while at Photomachining, Inc. or during transit to any outside service processing or final shipment to the end user.

Title: Processing of Product for Commercial Applications.

3.6 Operators and personnel involved in the processing of product shall at all times wear protective eyewear and when necessary protective earwear to prevent any injury when in the processing lab or operating any laser equipment.

3.7 The use of clean room garments and gloves and/or finger cots may be necessary as outlined in customer or traveler requirements.

4. **Procedure:**

4.2. Processing Material

4.2.1. Technicians shall fully understand the operation and safety requirments of the laser equipment prior to processing any product.

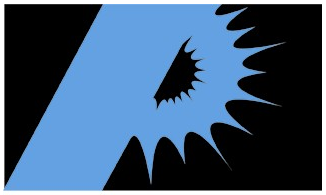
4.2.2. Laser must have all safety devices fully operational prior to the processing of materials.

4.2.3. Laser shall be inspected to assure that it is in good working order and that all preventative maintenance has been completed prior to the processing of product.

4.2.4. Technician shall review all customer requirements prior to the processing of material.

4.2.5. Operator/Technician shall verify that the quantity of parts matches the process traveler and that the material is not damaged prior to processing any material.

4.2.6. Start Up Of Laser



4.2.6.1. Laser to be turned and any warm-up shall be per laser manufacturers or PMI procedural requirements.

4.2.6.2. Verify that the camera and any other peripheral equipment is operating correctly.

4.1.7 Tooling or Fixturing

4.1.7.1 Technician to set-up any tooling or fixturing as required to meet customer requirements. The use of any tooling should be noted on the Process Run Sheet.

4.1.7.2 Verify that the tooling will not interfere with the movement or operation of the laser and that it is positioned in such a way to prevent anyone from coming in contact with the laser beam.

4.1.8 Operation of Laser

4.1.8.1 Technician to operate laser in accordance with manufacturers guidelines and in such a way to prevent any damage to product or other equipment.

4.1.8.2 Lasers emmit high energy light. Operator safety must be strictly adherred to during the operation of any laser. Always wear protective eyewear when in the processing lab or in an area where a laser is in operation. Always take the necessary steps to assure that others will not be affected by the laser beam either during operation or when in the general area where the laser is being operated.

Title: Processing of Product for Commercial Applications

4.1.9 Inspection of Product

4.1.9.1 First piece inspection

4.1.9.1.1 Technicians are required to perform first piece inspection using customer requirements as a guideline. First piece inspection is to be performed until such time as the laser and set-up is capable of producing product that is in compliance with **ALL** customer written requirements.

4.1.9.2 In-Process Inspection

4.1.9.2.1 In-process inspection shall be performed by operator or technicians processign parts at periodic intervals to assure that the product being produced meets all customer requirements.

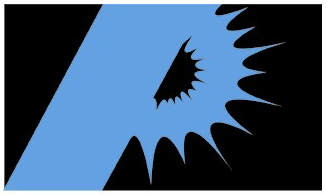
4.1.9.2.2 Product shall be inspected for any visual defects caused by the laser such as burning of charring as it is being processed.

4.1.9.3 Cleaning of Product

4.1.9.3.1 It is Photomachinings' policy to not clean parts either before, during or after processing unless specifically instructed to by either the customer or PMI management.

4.1.9.3.2 When required all cleaning shall be performed to customer requirements using approved materials and processes.

4.1.9.3.3 Technician shall ensure that the method of cleaning does not cause any damage to the part or material.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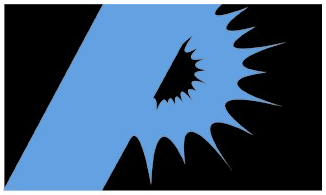


Title: Processing of Product for Commercial Applications

PhotoMachining

Procedure No.:1007
Standard Operating Procedure (SOP)
COVER SHEET **Effective Date:12-14-01**

Title: COMPANY EMPLOYEE TRAINING DOCUMENTATION.

Departments: Company Wide

Release Approvals:

Department	Name	Signature	Date
Pres.			
Manuf.			
Q.C.			
Admin.			
Eng.			
Contr.Manuf.			
Doc.Ctrl.			

Author. Jim Keating

Revision History:

Revision	ECO No.	Release Date	Doc. Contrl Approval
A	Original rel		

PhotoMachining

Title: COMPANY EMPLOYEE TRAINING DOCUMENTATION.

1. **Objective:** To provide a consistent and permanent record for documenting the training received by all company employees.

2. **Scope:** Company Wide

3. **General:**

3.1 Employees with proper education, training, background and experience will be selected with respect to the requirements of the position to be filled.

3.2 Employees shall be adequately trained to properly perform their assigned functions and will be encouraged to pursue additional job related courses and training..

4. **Procedure:**

4.1 Department Managers or Supervisors shall be responsible to ensure that all employees are adequately instructed and trained to perform the assigned tasks and are capable of performing the work assigned to them.

4.2 All new hires, inexperienced or untrained employees shall receive adequate training to perform the assigned job including closely monitored on-the-job training and/or technician qualification programs. All training shall be documented either as specific successfully completed programs or as the completion of training periods (i.e., 3, 6, 9 and 12 month employee reviews).

4.3 All employees working in the applications lab or performing work on customer deliverable product shall be instructed in the proper way to handle parts, perform manufacturing operations or part inspections and properly complete documentation relative to the medical device and electronics industry regulations. They must also receive adequate on-the-job training and monitoring to ensure continuing compliance with job requirements.

Title: COMPANY EMPLOYEE TRAINING DOCUMENTATION.

4.3 Safety procedures and discussion of the potential impact from improper performance of the job shall be included in the training.

4.4 All employees will be trained regarding the quality requirements of their job, as well as, the need to fully comply with any supplied process instructions, procedures drawings and documents.

4.4.1 Within the first quarter of their employment with Photomachining, Inc., all new company employees will attend a basic laser operation and safety course and a QA course.

4.4.2 All employees processing product for delivery to customers will be required to receive adequate laser operation and safety training prior to working un-supervised in the applications lab.

4.4.3 All employees working in the applications lab on customer deliverable product shall receive adequate training on the use and operation of precision inspection equipment within the first quarter of employment with Photomachining, Inc.

4.5 All employees will also be trained regarding the quality, regulatory/GMP and documentation requirements of their job, as well as, the need for ECO system changes to alter any existing products, procedures and documents.

4.6 The completion of all training shall be documented on the attached Employee Training Record form and shall be signed by the Employee and the Supervisor or Department Manager. Copies of course certifications must also be kept.

4.7 A separate form will be kept for each company employee and shall be maintained within departmental and/or centrally maintained employee personnel files.

Title: EMPLOYEE TRAINING DOCUMENTATION.

Employee Training Record

Employee Name:_____ Date of Hire:_____

TYPE OF TRAINING			PRESENT EMPLOYEE	SUPERVISOR/MANAGER
Date	Training	Hours	Job Title	Signature	Signature

PhotoMachining

Standard Operating Procedure (SOP)
COVER SHEET **Effective Date:12-14-01**

Title: TEMPORARY EMPLOYEE TRAINING DOCUMENTATION.

Departments: Quality, Manufacturing and Administration

Release Approvals:

Department	Name	Signature	Date
Pres.			
Manuf.			
Q.C.			
Admin.			
Eng.			
Contr.Manuf.			
Doc.Ctrl.			

Author Jim Keating

Revision History:

Revision	ECO No.	Release Date	Doc. Contrl Approval
A	Original Rel.		

PhotoMachining

Title: TEMPORARY EMPLOYEE TRAINING DOCUMENTATION.

1. **Objective**: To provide a consistent and permanent record for documenting the training received by all temporary employees involved in the manufacture, inspection or handling of products or controlled documents.

2. **Scope**: Quality, Manufacturing and Administration

3. **General**:

3.1 Temporary employees with proper abilities, training, background and experience will be selected with respect to the requirements of the position to be filled.

3.2 Temporary employees shall be adequately instructed and trained to properly perform their assigned functions and shall be monitored closely.

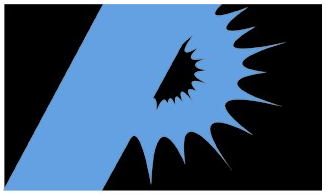
4. **Procedure**:

4.1 Department Managers or Supervisors shall be responsible to ensure that all temporary employees are adequately instructed and trained to perform the assigned tasks and are capable of performing the work assigned to them.

4.2 All temporary employees shall be instructed in the proper way to handle parts, perform manufacturing operations or part inspections and properly complete documentation relative to the medical device and electronics industry regulations. They must also receive adequate on-the-job training and monitoring to ensure continuing compliance with job requirements.

4.3 Safety procedures and discussion of the potential impact from improper performance of the job shall be included in the training.

4.4 All temporary employees will also be trained regarding the quality requirements of their job, as well as, the need to fully comply with any supplied process instructions, procedures, drawings and documents.


PhotoMachining

Title: TEMPORARY EMPLOYEE TRAINING DOCUMENTATION.

4.5 All temporary employees shall be required to complete the attached Temporary Employee Certification Record and sign and date it along with the Department Manager.

4.6 The temporary employee on-the-job assessments shall be documented on the attached Temporary Employee Certification Record and shall be initialed and dated by the Department Manager or Supervisor or their designee (reviewer). The time and work assessment will also be recorded along with any corrective action (C/A) if required.

4.7 These forms will be retained and filed for each temporary employee and shall be maintained by the Department Manager within departmental files.

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Title: TEMPORARY EMPLOYEE TRAINING DOCUMENTATION.

Temporary Employee Certification Record

Temporary Employee Name:_____
Customer Name:_____
Part Description or Number:_____
Operation Name/Number:_____

I understand that I am working on parts that are used either in medical products or for military or commercial electronics. As such, I understand that the work I do is extremely important and that complete and accurate records of the work I do are essential. I agree to perform and document my work accurately and completely following the instructions I am given as follows:

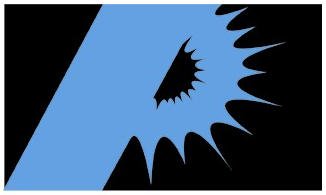
1. The work I have been asked to perform has been explained and demonstrated to me and I understand how to perform the work in accordance with the instructions I have received.

2. I understand how to check that the work I do is acceptable or not and I agree to segregate any nonconforming or questionable parts I identify for review by the Department Manager, Supervisor, or Quality Control.

3. I agree not to deviate from the process instructions or parts drawings I have been instructed to follow.

4. I have been instructed how to complete the documentation for the work I perform and I agree to complete the records with the appropriate quantities and date and sign in full (as below) for each operation I perform.

5. If I have any questions regarding the parts I am working on or the documentation I am to complete I will request assistance immediately.



Signature:_____ Date:_____

Dept. Mgr.or Designee:_____ Date:_____

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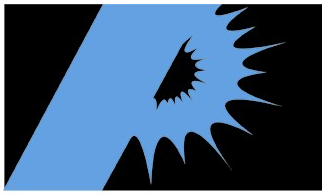
Title: TEMPORARY EMPLOYEE TRAINING DOCUMENTATION.

Temporary Employee On-The-Job Review:

Employee Name: **DATE OF HIRE:**

Reviewer	Date	Acceptable	Unacceptable	C/A

Reviewer Sig. **Date:**
Employee Sig. **Date:**



Procedure No.: 1009
Standard Operating Procedure (SOP)
COVER SHEET **Effective Date: 12-14-01**

PhotoMachining

Title: Procedure for Performing Incoming Inspection.

Departments: Quality, Manufacturing and Administration

Release Approvals:

Department	Name	Signature	Date
Pres.			
Manuf.			
Q.C.			
Admin.			
Eng.			
Doc.Ctrl.			

Author: Jim Keating 12-11-01

Revision History:

Revision	ECO No.	Release Date	Doc. Contrl Approval
A	original rel.		

PhotoMachining

Title: Procedure For Performing Incoming Inspection.

1. **Objective:** To provide a uniform method for inspecting received materials, parts, or product for subsequent processing.

2. **Scope:** Quality, Manufacturing and Administration

4. **General:**

3.1 All material or parts received for subsequent processing shall be inspected prior to being accepted or processed.

3.2 Any damage to either the shipping container or the contents shall be recorded on the **Product Non-Conformance Report** (PMI Form 3) **(attachment 1)**.

3.3 Customer or vendor shall be contacted regarding any damaged product prior to order acceptance or processing.

3.4 Inspection shall be per customer or vendors prints, specifications, purchase order requirements or other written information.

3.5 The total quantity of parts, material or product received shall be recorded.

Title: Procedure For Performing Incoming Inspection.

4. **Procedure:**

4.1 The person performing the inspection shall visually inspect the shipping container as well as the contents and record any damage or abnormalities in the Incoming Inspection section of the **Product Non-Conformance Report (attachment 1)**.

4.2 The quantity of product received as well as the number inspected, rejected and accepted shall be recorded. If it is not feasible to count or measure the quantity then the customers or suppliers shipping information shall be used as the quantity received.

4.3 The method of measurement used shall be appropriate for the product being inspected. Units of measurement shall match the customers or vendors units of measurement (e.g. inches or mm, feet, lbs., total units etc…).

Attachment 1

PMI Product Non-Conformance Report

PhotoMachining

COVER SHEET **Effective Date: 12-14-01**

Title: Procedure for Performing Final Inspection.

Departments: Quality, Manufacturing and Administration

Release Approvals:

Department	Name	Signature	Date
Pres.			
Manuf.			
Q.C.			
Admin.			
Eng.			
Doc.Ctrl.			

Author: Jim Keating 12-11-01

Revision History:

Revision	ECO No.	Release Date	Doc. Contrl Approval
A	original rel.		

PhotoMachining

Title: Procedure For Performing Final Inspection.

1. **Objective:** To provide a uniform method for inspecting materials, parts, or product prior to shipment.

2. **Scope:** Quality, Manufacturing and Administration

5. **General:**

3.1 All material or parts processed by Photomachining, Inc. shall be inspected prior to shipment to the customer or end user.

3.2 Quality or manufacturing personnel may perform final inspection.

3.3 Employees performing final inspection shall be trained in the use of precision measurement devices and optical inspection equipment.

3.4 Inspection shall be per customer prints, specifications, purchase order requirements or other written information.

3.5 The total quantity of parts, material or product received, inspected and accepted shall be recorded.

3.6 All material shall be handled at all times in a manner to prevent any damage to the product during handling or transport both while at Photomachining, Inc. or during transit to any outside service processing or final shipment to the end user.

Title: Procedure For Performing Final Inspection.

4. **Procedure:**

4.1 Technician performing the inspection shall record the results of any dimensional inspection on the **Final Inspection Report** (PMI Form 4) **(attachment 1)**. This document shall be submitted along with the Process Traveler to Doc. Control for retention.

4.2 The person performing the inspection shall record any damaged, scrapped or rejected product in the Final Inspection section of the **Product Non-Conformance Report** (PMI Form 3) **(attachment 2)** along with a description of the discrepancy or cause for rejection. This document shall be submitted along with the Process Traveler to Doc. Control for retention.

4.3 The quantity of product received as well as the number inspected, rejected and accepted shall be recorded.

4.4 The method of measurement used shall be appropriate for the product being inspected. Units of measurement shall match the customers or vendors units of measurement (e.g. inches or mm, feet, lbs., total units etc…).

4.5 Technician performing the inspection shall record the quantity of parts or units received, inspected, rejected and accepted in the appropriate section of the PMI Traveler.

4.6 Any rejected material shall be identified and kept separate from accepted material and forwarded to Q.A. Manager or Materials Manager for disposition.

Attachment 1

PMI Final Inspection Report

Attachment 2

PMI Product Non-Conformance Report

PhotoMachining

COVER SHEET **Effective Date:12-14-01**

Title: Procedure For Company Cleaning.

Departments: Company Wide

Release Approvals :

Department	Name	Signature	Date
Pres.			
Manuf.			
Q.C.			
Admin.			
Eng.			
Contr.Manuf.			
Doc.Ctrl.			

Author Jim Keating

Revision History:

Revision	ECO No.	Release Date	Doc. Contrl Approval
A	original rel.		

PhotoMachining

Title: Procedure For Company Cleaning.

1. **Objective**: To establish the company's systems for creating and maintaining a clean work environment.

2. **Scope**: Company Wide

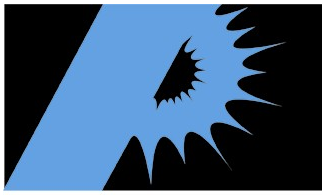
3. **General**:

3.1 This procedure applies to cleaning of all company departments and areas.

4. **Procedure**:

4.1 In order to minimize the risk of product mix-ups and to maintain an audit ready appearance, a company policy statement has been issued which directs all employees to maintain clean workstations. In the production area, this requires that all technicians clean up any manufacturing debris at the end of every job and to put away tooling, fixturing and any other materials when no longer needed. The intent is to prevent an excess accumulation of materials within all work areas thus maintaining a standard of a clean, well organized, and professional work environment.

4.2 The company will use either it's own employees or the services of a contract cleaning firm to perform company cleaning. This cleaning will be performed on a weekly basis and will include: cleaning of restrooms; washing the tile floors within the lunch room, the corridors, and the QC area; sweeping all production/shipping area hallways; production area trash collection; and trash collection and vacuuming of the front offices. Other cleaning activities will be assigned as required to keep all areas of the company suitably clean.



4.2.1 The company will supply all cleaning materials and equipment for use by employees. If an outside service company is employed they shall be responsible to supply all cleaning materials and equipment.

Title: Procedure For Company Cleaning.

4.3 Employees working in the clean room will be responsible to maintain the integrity of this area by not bringing into the area any cardboard, wood, or other type of product that readily sheds fibers unless that material is being processed to fill a customer order.

4.4 Weekly Cleaning Schedule

4.4.1 The following tasks are to be performed on a weekly basis:

4.4.1.1 Cleaning of the cafeteria, rest rooms, conference rooms, hallways and other general work areas.

4.4.1.2 Cleaning shall include vacuuming all carpeted areas, sweep and mop all tiled areas, wipe down all counters and tables, wipe all glass.

4.4.1.3 Clean microwave, coffee maker, refrigerator, and sinks in cafeteria.

4.4.1.4 Cleaning and mopping of all fixtures and floors in rest rooms.

4.5 Monthly Cleaning Schedule

4.5.1 The following tasks are to be performed on a monthly basis (**Clean Room and Vestibule Only**):

4.5.1.1 Damp cloth dust or duster cloth wipe of all equipment and work surfaces.

4.5.1.2 Vacuum all machine and computer fan grills.

4.5.1.3 Vacuum and wipe all air intake and return grills.

4.5.1.4 Vacuum and duster cloth mop of floor surfaces including under all equipment and work benches.

4.5.1.5 Damp mop floor.

Title: Procedure For Company Cleaning.

4.6 Quarterly Cleaning Schedule

4.6.1 In addition to the monthly tasks above the following tasks are to be performed on a quarterly basis (**Clean Room and Vestibule Only**).

4.6.1.1 Duster cloth wipe of all walls and ceilings.

4.6.1.2 Change air filters on heater return above clean room.

4.7 Annual Cleaning Schedule

4.7.1 In addition to the tasks outlined in sections 4.5 and section 4.6 the following shall be performed annually:

4.7.1.1 Change HEPA filter inlet filter.

4.7.1.2 All work areas shall be purged of all unnecessary materials and clutter including magazines, old catalogs, unidentifiable materials, scrap materials, etc…

4.7.1.3 All tool benches shall be cleaned and organized. Broken tools and tool bits are to be discarded and replaced with new if available.

4.7.1.4 All offices shall be cleaned and organized including filing cabinets and work surfaces. All clutter is to be removed or filed neatly away.

4.7.1.5 Additional cleaning or maintenance as warranted or as necessary shall be performed per supervisor or management direction.

PhotoMachining

Procedure No.:1013
Standard Operating Procedure (SOP
COVER SHEET **Effective Date:01-03-02**

PhotoMachining

Title: CORRECTIVE ACTION REQUEST / CUSTOMER COMPLAINTS.

Departments: Company Wide.

Release Approvals:

Department	Name	Signature	Date
Pres.			
Manuf.			
Q.C.			
Admin.			
Eng.			
Doc.Ctrl.			

Author Jim Keating 01-03-02

Revision History:

Revision	ECO No.	Release Date	Doc. Contrl Approval
A	original rel.		

PhotoMachining

Title: CORRECTIVE ACTION REQUEST/ CUSTOMER COMPLAINTS.

1. **Objective:** To evaluate and investigate all corrective action requests or product complaints in a consistent and timely manner.

2. **Scope:** Company Wide.

3. **General:**

3.1 A request for corrective action or product complaint is defined as any written or oral expression of dissatisfaction with the quality, safety, effectiveness, reliability or performance of a product, or component thereof, which was manufactured or processed by Photomachining, Inc. It should be noted that because Photomachining, Inc. is a contract manufacturer any responsibility for product defects should be limited to those aspects of the product which Photomachining, Inc. performed.

3.2 A complaint is initiated through an expression of dissatisfaction, either in writing (preferred) or orally coming from a customer or a government/regulatory agency.

3.3 All product complaints shall be investigated and the results of the investigation shall be documented within the company's corrective action system. If no investigation is conducted, the reason not to investigate shall be expressly stated and signed by the Quality Assurance Manager, Materials Manager or company representative.

3.3.1 All new, outstanding and recently closed corrective action requests or customer complaints will be reviewed by management on a routine basis.

3.4 The Corrective Action file shall be maintained by and located within the Quality Assurance Department. All complaints will be assigned a sequential number and will be listed within a Corrective Action log.

Title: CORRECTIVE ACTION REQUEST/ CUSTOMER COMPLAINTS.

3.5 Requests for Corrective Action or Product Complaints are considered confidential documents for internal use only. Only the company president or department managers may authorize review of the complaint file by government inspectors, auditors, or any other outside company or service bureau. Customer company auditors are only entitled to review those complaints originating from their own products or company.

4. **Procedure:**

4.1 All Corrective Action Requests or Product Complaints shall be directed to the Quality Assurance Manager, Materials Manager, Project Engineer or Company President. Copies of any customer documentation or complaint shall be distributed and retained in the Document Control Department.

4.2 Upon receipt of a Request for Corrective Action or product complaint, the Quality Manager, or their designee, shall complete the Request for Corrective Action Form **(attachment 1)** and assign a corrective action number. The customer name, part number and lot/serial number shall be recorded along with any customer ref. Number (complaint number). The customer contact and a phone number, FAX number or e-mail address must also be recorded. Details on the complaint form must be as complete as possible and all Corrective Action Request forms shall be logged sequentially.

4.3 The Quality Manager, or their designee, shall determine if the referenced product lot (or a sample) is being returned to Photomachining, Inc. for evaluation. If so, any corrective action investigation may be delayed until that time. However, if no product is being returned, or if there is sufficient information to initiate an investigation or determine a corrective action, the Quality Manager, or their designee, may initiate immediate corrective action with other involved departments.

Title: CORRECTIVE ACTION REQUEST/ CUSTOMER COMPLAINTS.

4.4 All requests for corrective action and/or returned product evaluation will be documented on the Supplier Corrective Action Report form **(attachment 1)** and may involve collaboration between Quality, Manufacturing and the Project Engineer.

4.5 The Supplier Correction Action Report shall be completed by either the Quality Manager of the person taking the complaint. The form shall be completed in its entirety prior to being submitted and must contain the following information:

4.5.1 Description of Non-Conformance. A brief description of the customer non-conformance or complaint.

4.5.2 Root Cause of Non-Conformance. A brief description of what caused the defect or customer dissatisfaction. Operator error may be used as the root cause only if followed up by sufficient training of the operator (see SOP #1007).

4.5.3 Action Taken to Prevent Recurrence. A brief description of what changes will be incorporated by Photomachining, Inc. to prevent the defect from happening again. This could entail employee training, machine or fixture maintenance or calibration, or better definition of inspection practices to prevent defective product from being produced (i.e. first piece or in-process inspections)

4.6 The final disposition of the corrective action will be established by the Quality Manager, or their designee, who will verify that the proper corrective action steps have been incorporated into the procedures to prevent any recurrence of the defect. The form is then signed and dated by the person that verified that the changes have been incorporated along with an effectively date. The Supplier Corrective Action Report form will also reference any correspondence with the customer and final conclusions regarding the corrective action / product complaint.

Title: CORRECTIVE ACTION REQUEST/ CUSTOMER COMPLAINTS.

4.7 The completed and signed Supplier Corrective Action Report will be filed in the closed complaint records within the Document Control Department.

4.8 Quality Assurance Department will provide one copy of the Complaint form and any Complaint Investigation report to Administration for placement within the contract file.

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PHOTOMACHINING, INC. CUSTOMER COMPLAINT FORM

Customer Name:_____ Complaint No.:_____
Part No.:_____ Complaint Date:_____
Lot Number:_____ Serial No.:_____

Reported By:_____
(name, title, telephone)

Reported To:_____

1. Explain the specifics of the complaint in detail
_____
_____
_____

2. Is the product:
a) Acceptable to the customer ____
b) Scrap ____
c) Require rework; or _____
d) other/explain:_____
_____

3. Does the customer have any information or suggestions as to what may have caused the problem?_____
_____
_____

4. Will the product **lot** or a **sample** (circle one), be returned to PhotoMachining, Inc. for evaluation? If so, when? If not, why not?
_____
_____
_____

5. If PhotoMachining, Inc. requires additional information whom should we call? _____
_____

PRODUCT COMPLAINT ASSESSMENT:

____ The information within this complaint is complete and requires no further follow up or investigation (C/A No ____)

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____ This is an open complaint requiring a returned product evaluation or further investigation (see attached report).

Quality Assurance Mgr:_____ Date:_____

PRODUCT COMPLAINT EVALUATION/INVESTIGATION FORM

Customer Name:_____ Complaint No.:_____
Part No.:_____ Lot Number:_____

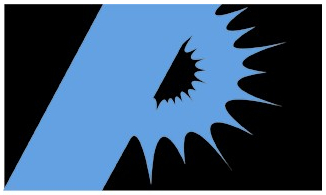
1. Returned Product Evaluation Report (attach any supporting documentation):_____
_____
_____
_____
_____
_____
_____
_____
_____

Report By:_____ Date:_____

2. Complaint Investigation Report:_____
_____
_____
_____
_____
_____
_____
_____

REVIEW AND DISPOSITION (reference any corrective action reports):
_____
_____
__
_____
_____
_____
___

Quality Assurance Mgr:_____ Date:_____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