

## **SIEMENS MANUFACTURING CO., INC. QUALITY POLICY**

Siemens Mfg. Co., Inc. is a contract electronics assembler dedicated to the manufacturing of products which will meet or exceed our customer's requirements and expectations.

### **Objectives:**

Siemens Mfg. Co., Inc. will accomplish this by installing a system of policies and procedures which will minimize defects by continuously monitoring and improving processes, training of personnel, and working with our customers to establish a partnership for success in today's business environment.

# QUALITY SYSTEM MANUAL

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	<b>Revision</b>
QC 20 Customer Satisfaction Questionnaire	Original
QC 22 Shipping Information	A
QC 23 Material Hold	Original
QC 25 Approved Supplier list	Original
QC 26 Static Strap Control Sheet	Original
QC 29 Quality System Survey (Not included with the Manual)	A
QC 32 Packaging Log	Original
QC 33 Contract Review Problem Form	E
QC 35 Certificate of Conformance	Original
QC 36 Shelf Life Sticker	Original
QC 37 Requisition/Shortage Card	Original
QC 40 Purchase Requisition	Original
QC 41 BOM verification control sheet (Customer specific)	Original
Table B Rev change routing flowchart	Original
Table C General process Flow	Original

### SECTION 1

## QUALITY SYSTEM POLICIES AND MANAGEMENT RESPONSIBILITIES

1.1. Organizational relationships for Siemens Mfg. Co., Inc. are defined and documented in the organizational chart Form QC 2.

1.2. Responsibility and authority are defined and documented in each procedure.

1.3. Quality System Manager is given authority and responsibility by Siemens Mfg. Co., Inc. executive management to plan, review, implement and maintain quality system policies and procedures as outlined in this manual and which comply with the customers contract requirements to assure conformity to product requirements and services.

1.4. Quality System Manager is responsible for maintaining current outlined policies and procedures in this manual and for making them available as needed.

1.5. Quality System Manager is responsible for determining and providing resources (including information, equipment, and the assigning of competent personnel) (see Section 18) for the performance of verification activities (other than testing of Siemens assembled product) including internal quality audits. The Quality System Manager is responsible for determining and providing resources needed to enhance customer satisfaction by meeting customer requirements.

1.6. The SIEMENS Mfg. Co. President shall appoint the Quality System Manager as the ISO management representative who shall have the authorities and responsibilities to establish, implement, maintain, and continually improve the Quality System to ISO 9001: 2008 (excluding design) version requirements. The Quality System Manager will, furthermore, report on the performance of the Quality System for management review.

1.7. The Quality System Manager is responsible for determining opportunities for improvement (preventive/corrective action) using Pareto analysis of defect data gathered (inspection & test results, customer complaints, returned material, etc) to determine conformity to product requirements (to determine what to work on) in conjunction with trend analysis (to determine if progress is being made) and for presenting these opportunities to a management review meeting to determining objectives with measurable goals. Any additional analysis will be determined at the management review meeting. The Quality System Manager is also responsible for determining an index of customer satisfaction and for presenting this index at the management meeting (ref. also customer satisfaction questionnaire, Form QC 20).

1.8 The Quality System Manager is responsible for determining opportunities for improvement (preventive/corrective action) using Trend analysis of information related to customer satisfaction (Form QC 20).

1.9. Every 12 months, as a minimum, Siemens Mfg. Co., Inc. performs a management review to review the suitability and effectiveness of the quality system, quality policy, as well as quality objectives and quality management system changes set at the management review meeting. The results of the review shall be recorded.

**RECORDS:** Management Review

Form QC 20 Customer Satisfaction Questionnaire

## SECTION 2

## QUALITY SYSTEM

### Scope:

The Quality Manual System (QMS) includes or references all procedures necessary to produce product which conforms to customer specifications, from the receipt of a request for a quote through delivery of the product to the customer, and the subsequent determination of customer satisfaction. Siemens Mfg. Co., Inc will achieve customer satisfaction by continually improving the effectiveness of the QMS through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions, and management review. The Quality Manual System (QMS) also includes or references all procedures necessary for compliance to ISO 9001: 2008 requirements with the exception of Design and Development inasmuch as Siemens Mfg. Co., Inc does not perform any product design functions.

2.1. It is the responsibility of the Quality System Manager to establish, document, and maintain a quality system as a means of ensuring that product conforms to specified requirements. The Quality System Manager shall prepare a documented quality manual covering the requirements of ISO 9001: 2008 to carry out specific tasks/activities.

2.2. Specific procedures have been established for those activities where the skills and qualifications of the tasks require further instructions (ref. Section 18.1; Personnel Training).

2.3. The Siemens Quality System is structured in the following manner:

- A. Level I: The Quality Manual with procedures.
- B. Level II: Specific work instructions.
- C. Level III: Forms, records, and other supporting documents.

2.4. Procedures as part of the Quality Manual meet requirements of ISO 9001: 2008, and support the Quality Policy. Specific procedures (Level 2: not included as a part of the Quality System Manual) provide more details where needed to assist in specific methods.

2.5. The documented Quality System outlined in paragraph three is the method used by Siemens Mfg. Co., Inc. to produce assemblies that conform to product requirements. Quality planning is accomplished by completing Form QC 17.

- A. For contracts and products, quality planning is conducted using the Contract Review Procedure (see Section 3).
- B. Siemens Mfg. Co., Inc. directs its activities based on customer needs and expectations. Any project requiring quality planning comes from customer demands or requests. These projects are determined by a member of the management review board, and a Pre-Production Checklist (Form QC 17) will be filled out for each project.

2.6. The completed Form QC 17 records quality planning activities to ensure any updates, revisions, and clarifications of selected projects conform to the current Quality System and Quality Policy.

**RECORDS:** Form QC 17, Pre-Production Checklist

## SECTION 3 CONTRACT REVIEW

1. Siemens Mfg. Co., Inc. has established and maintains specific methods to conduct contract review as described in the Contract Review section (Section 3.1).
2. Section 3 outlines the process used for each contract to ensure that:
  - A. Requirements are adequately defined and documented.
  - B. Differences are resolved.
  - C. Siemens Mfg. Co., Inc. has the capability to produce and deliver product as required by the customer.
3. Any change to the contract (whether customer or Siemens initiated) is identified as described in the Contract Review procedure (Section 3.1). In addition, those functions within Siemens that are affected by the change are notified of the changes as stated in the same procedure. The Contract Review Problem form (Form QC 33) is used to communicate those changes.
4. Records of Contract Review are kept as stated in Section 16.

### SECTION 3.1 CONTRACT REVIEW PROCEDURE

- 3.1.1. Upon receipt of a Request for Quote (RFQ), the Sales and/or Quotations dept. personnel and/or Production Supervisor will review the customer product and delivery requirements, contact the customer for clarifications (if necessary), and generate a preliminary quote (computer generated form). The preliminary quote information will then be forwarded to the Siemens Mfg. Co., Inc. President or the Chief Operating Officer for approval.
- 3.1.2. The Siemens Mfg. Co., Inc. President will review the preliminary quote, determine whether or not Siemens Mfg. Co., Inc. has the capability to meet the contract or order requirements (including statutory or regulatory requirements), make any necessary changes, then indicate acceptance by initialing the preliminary quote. Approval can be verbal as long as it is noted on the preliminary quote that the approval was verbal. The quote package will then be forwarded to the Supervisor who originated the quote for drafting of a Formal Price Quotation.
- 3.1.3. The Supervisor who drafted the original preliminary quote will use the information on the approved preliminary quote to generate a draft of the Formal Price Quotation. The Formal Price Quotation will then be forwarded to the clerical personnel for data entry.
- 3.1.4. The clerical personnel will obtain a unique quote number from the Quote Estimator (if not already assigned) and then transfer all listed information from the draft of the Formal Price Quotation quote to the computer using the customized quote program. The clerical personnel will then print one copy of the Formal Price Quotation, and forward it to the Supervisor who drafted the Formal Price Quotation for review and approval.

3.1.5. That Supervisor will then compare the computer generated Formal Price Quotation to the approved preliminary quotation for accuracy. If the information on the two forms is identical, the Supervisor will sign the Formal Price Quotation and then have one copy of the formal quote made which will be stamped "Controlled Copy" and kept in the quote folder in the Quotations office. The signed original Formal Quotation will be delivered to the customer.

3.1.5a. If the information on the Formal Price Quotation and the preliminary quotation is not identical, the Supervisor will return the Formal Price Quotation to the clerical personnel for corrections to the computer and the generation of a revised Formal Price Quotation. The revised formal quote will be forwarded to an individual authorized to sign quotes (ref: Form QC 2) for review and, if acceptable, approval (signing). The signed Formal Price Quotation will then be delivered to the customer.

3.1.6. When a Purchase Order (P.O.) is received by Siemens Mfg. Co., Inc., the Customer Service rep. will:

- A. Compare the information on the P.O. to the Formal Price Quote for accuracy.
- B. Enter the order onto the computer using the order entry program.
- C. If all information is correct, the Customer Service rep. will stamp the P.O. "ENTERED" and "DATED", forward a copy of the P.O. to the Materials Control Manager and the original P.O. to clerical personnel who will set up a "Shipping" folder. If the P.O. value is \$30,000 or greater, then the Order Entry Clerk will forward the P.O. to the Siemens Co. President, Vice-President, or Chief Operating Officer for approval.
- D. Fill out and mail(E-Mail)/fax a P.O. acknowledgment to the customer. NOTE: Delivery dates are not confirmed at this time. Delivery approval is done at step 3.1.13.

3.1.6a. If the information on the P.O. is not the same as the information on the Formal Price Quotation, or if there is no written quote (verbal order, repeat order, etc.), the Customer Service Representative will fill out a Contract Review Problem form (Form QC 33) for resolution by a Contract Review team member.

3.1.6b. All customer initiated changes will be routed to the Customer Service Representative. If the change received was mailed (or E-Mailed) or faxed to Siemens and involves only changes to the delivery dates, then the Customer Service Representative will update the Sales Order on the computer as well as notifying the Director of Materials and Planning. If the change request does not involve delivery dates, then the Customer Service Representative will fill out Form QC 33 (unless already done) which will be forwarded to the Contract Review team. If the change request was received by phone, then the individual who took the call will forward all necessary information to the Customer Service Representative who will respond as noted above.

3.1.7. When a Contract Review member receives a Contract Review Problem form, the team member will work with the customer and take all steps necessary to resolve the problem(s) noted. The team member will then fill out the resolution portion of the "Problem" form (if not already completed). Ref. 3.1.7a for routing of the completed "Problem" form.

3.1.7a. If the “Problem” form received is from a person other than the Customer Service rep, a Contract Review team member will work with the customer to resolve the problem(s). If the quote must be changed, the Contract Review team member will then fill out the resolution portion of Form QC 33 (if not already completed), forward one copy of the completed form to the Sales Dept, and file the original in the business office. The Customer Service Representative will make any necessary changes to the controlled copy of the quote and affix the “problem” form to the revised quote. **Note:** The Sales Order can only be revised if the customer has given authorization, otherwise, the Customer Service rep will file the “Problem” form in the “Quote File” for the current job. This form can then be used as justification for changing the price on future quotes.

3.1.8. On receipt of the P.O., the Materials Control Manager will retrieve the quote package from the Quotation dept. and have a master Siemens Bill of Materials (B.O.M.) generated which will be forwarded to the documentation department for verification. The Materials Control Manager will then forward the quote package to Purchasing. It is, furthermore, the Materials Control Managers’ responsibility upon receipt of a purchase order to initiate the PRE-PRODUCTION CHECKLIST (Form QC 17). NOTE (Form QC 17 is to be used on new jobs and formal revision changes (ref: Table B) only, and will not be used on repeat jobs). The Materials Control Manager will fill out all of page one (with the exception of Test Procedures, under the Documentation Received section). If any discrepancies are found, the Materials Control Manager shall notify the customer within one work day requesting clarification. If the discrepancy involves the bill of materials (B.O.M.), then the order will be held until the problem is resolved. If the discrepancy does not involve the B.O.M., then the processing of the order will continue. Once all discrepancies are resolved, the Materials Control Manager shall forward the original PRE-PRODUCTION CHECKLIST with a copy of the quote and a copy of the P.O. to the Documentation Specialist (to be forwarded to the Engineering Mgr for completion). Rev change information will be listed in the note field of MANEX as well referenced on the Revision change summary section of the Pre-Production checklist.

3.1.8a. On receiving either an approved Equivalent Item Authorization form (Form QC 6) or an approved “Problem” form (Form QC 33), the Materials Control Manager will make all necessary changes to the computer database, generate a new master B.O.M., and then forward the new master B.O.M. and a copy of Form QC 6 (or “Problem” form as applicable) to the Document Control department for verification and to assist with incoming inspection. The Materials Control Manager will file the original Equivalent Item Authorization for reference. The Materials Control Manager will also, if necessary, send a copy of Form QC 6 (or “Problem” form indicating a parts replacement) to purchasing so that parts can be ordered. Once all B.O.M. changes have been made, the Materials Control Manager will forward the completed “Problem” form to a Customer Service rep for reference.

3.1.9. Once all parts are ordered, the Purchasing team will enter the date that the last part is due onto the copy of the P.O., and forward the P.O. to an Operations Committee member for approval. NOTE: Ref. Quality System Manual, Section 6.1 (Purchasing) for additional details about purchasing.

3.1.10. Ref. Quality System Manual, Section 6.1.

3.1.11. If the “Problem” form involves a price change to the quote, then the issue will be resolved by the Contract Review team.

3.1.12. On receipt of the P.O., an Operations Committee member will review the P.O., assign delivery commitment dates, and initial the delivery dates onto the P.O. The Operations Committee member will then forward the initialed form to clerical personnel for computer entry. If the dates assigned do not meet the customer requested dates, then the Chief Operating Officer, the Sales Manager, or the Customer Service Representative will work with the customer to resolve the issue.

3.1.13. On receipt of the P.O., the office personnel, Customer Service representative will enter the delivery commitment dates on the computer using the order entry program then generate another P.O. acknowledgment, which now will include delivery commitments, for delivery to the customer.. The initialed form will then be filed in the “Shipping” folder for reference.

3.1.14. If at any time during manufacturing, a Supervisor becomes aware of a problem that may affect the quote, that Supervisor will discuss the problem with the customer and the Siemens Supervisors responsible for that product line to resolve the issue. The recommended changes will be noted on the Contract Review Problem form (Form QC 33) resolution section which will be forwarded to the affected Supervisor for implementation.

3.1.15. Ref: para. 8a. **Exception:** The Materials Control Manager need not send a copy of the Equivalent Item Authorization Form to Documentation. This was already done by the engineering department personnel.

3.1.16. On receipt of an Equivalent Item Authorization form (Form QC 6), the Engineering Manager (or his designee) will contact the customer (unless Siemens has written authorization to use “or equivalent” parts) for authorization to make the indicated change(s) (per SOP-03-01, Pre-Production Manufacturing Guidelines). On receipt of an approved Equivalent Item Authorization form (Form QC 6), the Engineering Manager will forward the approved Form QC 6 to the Documentation Control person who will forward one copy to the Materials Control Manager and file the original for reference. **Note:** In addition to the Engineering Manager, the following personnel are authorized to approve an equivalent item: Technical Coordinator, the Technical Support person, the Quality System Manager, the Quality Supervisor, the Company President, and a Production Supervisor.

3.1.16 (additional). Upon receipt of the PRE-PRODUCTION CHECKLIST, the Engineering Manager shall make all arrangements necessary for the completion of the CHECKLIST. The Engineering Manager shall also:

- A. the PRE-PRODUCTION CHECKLIST will not be filled out for repeat jobs.
- B. In conjunction with the Quality System and/or Production Manager(s), review the PRE-PRODUCTION CHECKLIST.
- C. Forward the completed PRE-PRODUCTION CHECKLIST, the copy of the quote & the copy of the P.O., to the documentation control person, to be filed in the job folder for traceability.

3.1.17. All approved changes will be routed to the affected department Supervisors/Lead People.

**RECORDS:** Form QC 6, Equivalent Item Authorization      Form QC 33, Contract Review Problem  
Form QC 17, Pre-Production Checklist                      Form QC 18, Approval of Delivery Commitment

**REFERENCES:** SOP-03-01, Pre-Production Manufacturing Guidelines

SECTION 4

(CURRENTLY NOT APPLICABLE)

## SECTION 5 DOCUMENT AND DATA CONTROL

1. Siemens Mfg. Co., Inc. has established and maintains specific methods to control documents and data that relate to the requirements of ISO 9001: 2008 and the Siemens documented Quality System including, as applicable, customer supplied documents. These methods, as stated in Section 5.1, address the issues of document review and approval, availability, retention, and change, as well as removal of invalid and/or obsolete documents.

### SECTION 5.1 DOCUMENT AND DATA PROCEDURE (Electronic Assemblies)

5.1.1. Each job folder in the QC master file will contain a master list (Drawing and Specification Record, Form QC 3) of documents that are available for the production of that assembly.

5.1.2. The Quality System Manager will maintain a master list of Quality Procedures and reference material that pertain to conformity to product requirements (ANSI/J-STD-001, etc.).

5.1.3. The Technical Coordinator will maintain a Master list of test software.

5.1.4. Documents for the electronic assemblies(including test procedures) received for PCB production will be routed per Table B. The document control person will:

**A.** Pull the job folder for that assembly from the QC master file. If there is no job folder, then make one by taking a blank folder, stapling a Drawing and Specification Record ( Form QC 3) to the inside cover, and writing the Siemens Part number, customer and board name onto the folder tab.

**B.** Compare the documentation received to the documentation on file. If the documentation received is identical to the file copy, then throw away the documentation received. If the documentation received is not identical to the file copy, or if there is no file copy, then mark the documentation received with a date stamp and initial the date stamp.

**C.** Issue new/revised documentation (excluding test procedures) to the supervisor/lead person responsible for the production folder. Stamp all documentation issued with a red “Controlled Copy” stamp. Record the reason for the new issue (obsolete, original lost or not useable, etc.)

**D.** Issue new/revised test procedures to the lead technician.

**E.** Record the distribution of documents onto Form QC 3. **Note:** If there is no Revision number on the documentation received, then the date received will be used as the Revision number.

**F.** Dispose of all earlier versions of documents being replaced from the locations/persons listed on Form QC 3 with the exception of the QC file copy, which will be marked with a red “Obsolete” stamp and placed in the “Obsolete” file for reference.

**G.** Contact the Materials Control Manager to determine if Purchasing needs a controlled copy of the new document.

5.1.5. Siemens Process Sheets will be reviewed and approved by the lead person or Supervisor for that product line. Documentation personnel will issue one copy to the production and test folders. **Note:** There will not be a copy of the Process Sheet in the QC Master folder but it will be listed on the Drawing and Specification Record ( Form QC 3). Process sheets and In-Process checklists for units that are to be manufactured to RoHS compliance will be highlighted with GREEN or will be printed on GREEN paper; **note:** copies are still permitted even though the GREEN highlight becomes grey scale.

5.1.6. Data and documents (including test procedures and changes) received for PCB production via modem or floppy disk will be forwarded to the Technical Coordinator who will print one copy of each document received. The printed copy will then be handled per section 5.1.4.

5.1.7. Only the Documentation Control person, personnel who perform incoming inspection, and the Quality System Manager are authorized access to the QC Master file.

5.1.8. Only the lead technician, the senior technician, the Technical Coordinator, quality personnel and supervisors have access to the technician file.

5.1.9. Any Siemens employee has access to the production folder.

5.1.10. Any supervisor can authorize access of a production folder to a non-Siemens employee.

5.1.11. Customer supplied changes will be handled as per Section 5.1.4.

5.1.12. When the Technical Coordinator, Engineering Manager, Senior/Lead technician has been notified that a Siemens test procedure may not be accurate, the Technical Coordinator, Engineering Manager, Senior/Lead technician will review that test procedure. If changes are necessary, then the Technical Coordinator, Engineering Manager, Senior/Lead technician will:

- A. Rewrite the test procedure incorporating all necessary changes.
- B. Indicate on the new test procedure the revision number.
- C. Review/Approve the new procedure by signing and dating the procedure.
- D. Route the revised test procedure to the Documentation Control person who will follow the steps listed in section 5.1.4.

5.1.13. When the Technical Coordinator, Engineering Manager, Senior/Lead technician has been notified that a customer supplied test procedure may not be accurate, the Technical Coordinator, Engineering Manager, Senior/Lead technician will review that test procedure. If changes are necessary, then the Technical Coordinator, Engineering Manager, Senior/Lead technician will:

- A. Request an updated test procedure from the customer.
- B. Work with the customer to determine what the correct procedure should be if the customer is not able to provide an updated test procedure.
- C. Rewrite the test procedure incorporating all necessary changes (including Rev. # change).
- D. Forward a copy of the revised test procedure to the customer for approval.
- E. When customer approval is received, handle per section 5.1.4.

5.1.14. Changes can be made (reference 5.1.18; uncontrolled document) to the Siemens Process Sheets or work instructions by anyone as long as they contact the Quality System Manager and/or the Production Supervisor for approval. The person making the change will forward the change to Documentation for typing. The lead person or Supervisor for that product line will approve the retyped process sheet prior to use. Changes to Work instructions will be performed per QOP-5-1 (*Procedure for generating & maintaining work instructions when the "Master document" is to be stored in an electronic format*).

5.1.15. Temporary changes can be made to manufacturing documents by anyone as long as they contact the Quality System Manager and/or the Production Supervisor for approval. The person making the change will initial and date the change. The person making the change will also note the Supervisors initials as well the name of the customer representative who authorized the change (for customer controlled documents). The Quality System Manager/Production Supervisor will then route an uncontrolled copy of the document in question that has had all temporary changes made to it to the Documentation Specialist who will make the necessary changes to the QC file copy and re-issue that document.

5.1.16. Once the Technical Coordinator, Engineering Manager, Senior/Lead technician has been notified of temporary changes to SIEMENS controlled documents, he will make permanent changes to documents in the following manner:

**A.** Route an uncontrolled copy of the document in question that has had all temporary changes made to it, including the new revision number, to technical support who will make all necessary changes and then send to the Technical Coordinator one copy of the revised document.

**B.** Review the revised document and, if acceptable, approve by initialing and dating the document. If the revised document is not acceptable, then work with technical support to make the necessary corrections.

**C.** Distribute the revised document per section 5.1.4. **Note:** For changes to Mallinckrodt documents and processes, revised documents (with applicable validation data) will also be sent to Mallinckrodt for approval and will be implemented when the approved documents are returned.

5.1.17. Any person who is responsible for making changes to documentation or data shall have access to pertinent background information upon which to base their review and approval.

5.1.18. Uncontrolled copies of "Controlled" documents can be made by a lead person or supervisor for a specific function (additional copies for multiple lines, etc.) which will be stamped "Uncontrolled Copy" and assigned an expiration date (2 weeks from the day it is stamped). The uncontrolled copy will be disposed of when it is no longer needed for its intended function (the line has been shut down, etc.) or has exceeded its expiration date.

5.1.19. As repeat jobs are received, Documentation personnel (and update as necessary) will review the job folder to verify that all forms and documents used are the most current revision, and remain legible & readily identifiable.

5.1.20. The Technical Support person will maintain a master list of PWB data files.

5.1.21. Data received (PWB data) will be forwarded to the technical support personnel who will:

**A.** Copy the data onto a PC (personal computer) using a file name that is unique to that board.

**B.** Determine whether the data is for a new board or a revision to an existing board.

**C.** Data files for new boards will be added to the Master list.

**D.** Data files for revisions to existing boards will be added to the Master list using an indication of revision as a part of the file name ("Unicorn" becomes "Unicorn1").

**E.** The latest version and the version prior the latest version will be maintained on floppy disks.

**F. Note:** PWB data received from customers will not be reviewed by Siemens Mfg., Inc.

5.1.22. PWB data (including changes) generated by Siemens Mfg., Inc. will be Reviewed/Approved by the Technical Support person prior to release of the data by entering his initials into the Reviewed/Approved section of the Title block.

5.1.23. The Technical Support person will add the file name (or the revised file name for revised PWB data) of Siemens generated PWB data to the Master list.

5.1.24. Customer requested changes to customer supplied PWB data will be forwarded to the technical support personnel who will:

- A. Make the requested changes to the PWB data.
- B. Copy the revised data to a revised file which indicates the revision as a part of the file name ("Unicorn" becomes "Unicorn1").
- C. Send the revised data to the customer for approval.
- D. When written approval from the customer is received, add the revised file name to the Master list.

## QUALITY SYSTEM MANUAL CHANGE PROCEDURE

5.1.25. All change requests affecting forms or procedures that apply to the Quality System Manual, from any source, will be forwarded (inter office envelopes, E-Mail) to the Quality System Manager who will:

- A. Review the requested change with all affected supervisors and, if necessary, discuss the requested change during a management review meeting.
- B. Rewrite the affected section for all approved changes.
- C. Fill out the Quality System Manual Change & Review Record (Form QC 1).
- D. Update the master Quality System Manual (local PC: QCMAN1.wpd).
- E. Update the PC accessed Quality System Manual (network file QCMAN1.pdf).
- F. Determine, if necessary, a method of implementation for all approved changes (ref: Section 2.5.B, Quality Planning).
- G. Retrain all affected personnel (ref. Section 18.1.6).

### References:

QOP-5-1 (*Procedure for generating & maintaining work instructions when the "Master document" is to be stored in an electronic format*).

## SECTION 6 PURCHASING

1. Siemens Mfg. Co., Inc. has established and maintains specific methods to ensure that purchased product conforms to specified requirements. The Siemens purchasing procedure (Section 6.1) specifies methods to select and evaluate subcontractors, defines the type and extent of control that Siemens has over subcontractors, indicates what data shall be included on purchasing documents, defines verification requirements of purchased product, and details review and approval procedures for purchasing documents.
2. Records of acceptable subcontractors shall be kept per Section 16.
3. The Quality System Manager will establish and maintain procedures (QOP-06-01) to:
  - A. Evaluate subcontractor performance using incoming inspection records (ref: section 10.1.6).
  - B. Add suppliers to the list of approved suppliers.
  - C. Remove suppliers from the list of approved suppliers.
4. The Quality System Manager will (per QOP-06-01) maintain a master list (Form QC 25 for board houses, MANEX database for all others)) of approved suppliers.

### SECTION 6.1 PURCHASING PROCEDURE

- 6.1.1. When a quote folder (viewed on PC: Common drive\quote folder\quote number) for a new job is received from the Materials Control Manager, the Purchasing Agent will:
  - A. Contact approved suppliers to obtain price and delivery commitments for components.
  - B. Order components.
  - C. List the date that the last part is due onto the purchase order.
  - D. Review and approve purchasing requirements by signing the purchase order.
  - E. Make one copy of the purchase order
  - F. Forward the copy of the purchase order to the Director of Materials and Planning.
  - G. Forward the original purchase order to an Operations Committee member for delivery commitment of finished product from Siemens Mfg. to the customer (ref: Section 3.12).
  - H. Forward a copy of the Siemens Bill of Materials to the customer, if applicable, requesting delivery dates for customer supplied parts.
- 6.1.2. If a better price and/or delivery date is found during the purchasing phase, then the Purchasing team can order the cheaper part rather than using the quoted price and source as long as the replacement part is a customer approved part from an approved supplier.
- 6.1.3. For repeat jobs, the Purchasing team will review the purchasing file as well as the Quote folder for any customer changes or Equivalent Item Authorizations (Form QC 6) that may have been added since the last time that parts were ordered for that job.

6.1.4. The Purchasing team will order parts (ref: Bill of Materials, Equivalent Item Authorization Form (QC 6), and/or Contract Review Problem Form (QC 33) indicating a parts replacement/substitution). Any deviation from the Bill of Materials requires written approval from the customer (Ref: Form QC 6) unless the customer notes “or equivalent” on their BOM at which time an internal EIA will be filled out indicating a generic part is acceptable. If the Purchasing team cannot obtain an approved part, then he will fill out an Equivalent Item Authorization (Form QC 6) requesting a part substitution which will be forwarded to the Engineering Manager or the Technical Support person (Ref: Section 3.16). The Purchasing team can then order parts awaiting approval (note: these parts will be rejected at incoming inspection if received prior to approval.). **Exception:** resistors for which the customer has issued a blanket EIA do not require another EIA.

6.1.5. The Purchase Order shall contain data clearly describing the product ordered, including where applicable:

- A. Detailed component description.
- B. Manufacturer.
- C. Manufacturers part number.
- D. Quantity ordered.
- E. Quoted price.
- F. Type, grade, or class.
- G. Siemens part number.
- H. Title, number, and issue of the quality system standard to be applied.
- I. Drawing name and/or number including any revision number.
- J. Other relevant technical data.

6.1.6. If, at the time that parts are being purchased, the purchase price is significantly different from the quoted price, then the Purchasing team will fill out the Contract Review Problem Form (Form QC 33) which will be forwarded to an agent of the sales team (ref: Section 3.7a).

6.1.7. If Siemens Mfg. is informed by a supplier that they are not able to meet a delivery date, then the Purchasing team will:

- A. Attempt to locate the part elsewhere.
- B. Expedite the part from the supplier.
- C. Request an Equivalent Item Authorization (Form QC 6) per Section 6.4.
- D. If steps 6.7.A-C are not successful, then notify the Sales Manager/Customer Service Representative.

6.1.8. If Siemens Mfg. is unable to locate parts and will, therefore, be unable to meet a customers requested delivery date, then the Purchasing team will:

- A. Attempt to locate the part elsewhere.
- B. Expedite the part from the supplier.
- C. Request an Equivalent Item Authorization (Form QC 6) per Section 6.4.
- D. If steps 6.8.A-C are not successful, then notify the Sales Manager/Customer Service Representative.

6.1.9. Any additional controls (supply certificate of conformance, calibrate to manufacturers specifications, test prior to shipment, etc.) that Siemens Mfg. has over a supplier will be specified on the purchase order.

6.1.10. Procedures for the evaluation and selection of subcontractors can be found in QOP-06-01, SUBCONTRACTOR EVALUATION.

## VERIFICATION OF PURCHASED PRODUCT

6.1.11. Where Siemens Mfg. Co., Inc. proposes to verify purchased product at the subcontractors premises, Siemens shall specify verification arrangements and the method of product release in the purchasing documents.

6.1.12. Where specified in the contract, Siemens' customer or the customers representative shall be afforded the right to verify at the subcontractors premises and Siemens' premises that subcontracted product conforms to specified requirements.

**A.** Such verification shall not be used by Siemens as evidence of conformity to product requirements by the subcontractor.

**B.** Verification by the customer shall not absolve Siemens of the responsibility to provide acceptable product, nor shall it preclude subsequent rejection by the customer.

6.1.13 When Siemens Mfg. Co., Inc chooses to outsource a process that affects product conformity, Siemens shall ensure control over such processes. The method and extent of this control will be determined at a management meeting, and these requirements will be included as a part of the purchase order.

**RECORDS:** QC 6, Equivalent Item Authorization  
QC 25, Approved Supplier List (MANEX)  
QC 33, Contract Review Problem Form

**REFERENCE:** QOP-06-01, Subcontractor Evaluation Procedure

## SECTION 7

## CONTROL OF CUSTOMER SUPPLIED PRODUCT

1. Siemens Mfg. Co., Inc. has established and maintains specific methods to verify, store and maintain customer supplied product provided for the incorporation into customer products or for related activities. These methods are described in the Control of Customer Supplied Product Procedure (7.1).
2. Verification by Siemens does not absolve the customer from providing acceptable products. Discrepancies will be reported back to the customer.
3. Records of customer supplied products are kept per Section 16.

### SECTION 7.1

#### PROCEDURE FOR CONTROL OF CUSTOMER-SUPPLIED PRODUCT

7.1.1. It is the responsibility of the Parts Dept. personnel, upon receipt of customer-supplied parts, to inventory the kit using the Bill of Materials (B.O.M.) supplied with the parts kit. The kit will be checked for damaged parts, correct components and quantity. A "Customer Supplied" sticker (Form QC 19A) will then be affixed to the kit (if 100% customer supplied parts), or to each bag/box of components (if the kit also contains Siemens purchased components). (Note): If there is not a B.O.M. with the parts kit, the kit will be placed in the Shipping/Receiving Hold Area with a completed "Material Hold" card (Form QC 23), and the Materials Control Manager will be notified immediately who will notify the customer within two working days to resolve the discrepancy. Parts received on a skid will have a visible portion of the skid painted with BLUE paint to indicate "Customer Supplied".

7.1.2. Once the kit has been inventoried, it is the responsibility of the Parts Dept. personnel to fill out the In-Process Checklist (form QC 8A). (Note): If there is not a SIEMENS job number on the B.O.M., then it is the responsibility of the Parts Dept. personnel to call the Shipping Clerk to obtain a Siemens job number.

7.1.3. If there are no discrepancies, the kit, along with Form QC 8A, will be forwarded to production for assembly.

7.1.4. If there are any discrepancies, the Inventory Clerk will contact (E-Mail) the customer within two working days to resolve all discrepancies.

7.1.5. It is the responsibility of the Production Supervisor or the Quality System Manager to determine whether or not the discrepancies noted (ref. section 7.1.3) will impede manufacturing. If so, then the Parts Dept. Personnel will not issue the kit until all discrepancies are corrected. If not, then the Production Supervisor will authorize the release of the kit to production, pending resolution of the discrepancies.

7.1.6. If, during production, customer supplied **components** are lost or damaged, the lead person for that job will fill out a Purchase Requisition (Form QC 40) and forward the requisition (E-Mail), along with all damaged parts, to the Inventory Clerk. The Inventory Clerk will contact the customer (or purchase the part directly from an approved supplier) for component replacement and return the damaged components to the customer at this time, unless directed otherwise by the customer. Any rejected **product** shall be handled per section 13, Control of Nonconforming Product. A record of the request will be maintained.

7.1.7. When a job is complete, all excess parts will be returned to the Inventory Clerk who will store them on shelves by customer/job name or, after contacting the customer, return the parts to the customer.

7.1.8. Customer supplied forms will be handled in the following manner:

**A.** When a customer supplied form is received, the form will be routed to the Documentation Control person who will make (or take) one copy of the form and stamp the form with the date that the form was received.

**B.** The Documentation Control person will file the stamped copy in the QC file (by job name) and forward all remaining copies to the supervisor responsible for the area that the forms are used in. The Documentation Control person will record the final destination of the forms onto the Drawing and Specification Control Record (Form QC 3).

**C.** All shop copies of the customer supplied forms will be kept in a folder, by job name.

**D.** Additional copies can be made from the QC file copy.

**E.** Any additional copy received from the customer will be forwarded to the Documentation Control person who will compare the new copy to the QC file copy. If the new form is different, then the Documentation Control person will retrieve all shop copies as well as the QC file copy and deliver them to the Quality System Manager for disposal. The Documentation Control person will then distribute updated copies by following the procedure outlined in paragraph 10, steps A through D.

7.1.9. Customer supplied test fixtures will be labeled with a “Customer Supplied” sticker (Form QC 19A) and a label indicating what product the fixture is used for.

7.1.10. Customer supplied test fixtures will be controlled using the procedures listed in the Calibration Control section (Section 11.1)

7.1.11. The Technical Coordinator will notify the customer of any problems noted in steps 9 or 11 above and the resolution recorded in the history section of the Calibration Recall program (PC database).

**RECORDS:** QC 3, Drawing and Specification Control Record  
E-Mail (For customer notification)

SECTION 8  
PRODUCT IDENTIFICATION AND TRACEABILITY

1. Siemens Mfg. Co., Inc. has established and maintains specific methods to identify product using the Production Identification and Traceability procedure (Section 8.1).
2. All components and products will be identified by suitable means, from receipt and through all stages of production, delivery, and (where required) installation.
3. Traceability is not a specific customer requirement. However, in support of the Quality Policy and objectives, Siemens Mfg. incorporates limited traceability activities as described in the Product Identification and Traceability procedure (8.1).
4. Records of this identification for traceability are kept per Section 16.

SECTION 8.1  
PRODUCT IDENTIFICATION AND TRACEABILITY PROCEDURE

8.1.1. Upon receipt, components will be identified by an Inventory Clerk with a Parts Identification sticker (Form QC 13A), ref. Section 10 under Receiving Inspection. The components will remain in the labeled container as long as possible. When it becomes necessary to remove the parts from the original package, it is the responsibility of the Lead Person to ensure that the bin that the parts are put in shall be labeled with, as a minimum, the Siemens part number (use the customer part number for customer supplies parts that do not have a Siemens part number) and job name.

8.1.2. As electronic components are kitted, an inventory clerk will verify that all components kitted have an ID (ACC) # on the Identification sticker.

8.1.3. Subassemblies and in-process materials will be identified throughout production by the In-Process Checklist (Form QC 8a for or MANEX printout): ref Document# SOP-08-01 for authority and responsibility. **EXCEPTION:** Boards being transported between rework and washing do not need Form QC 8A if the boards are to be washed and returned immediately. Any job can use a computer generated Traveler instead of Form 8a.

8.1.4. Siemens product that is to be shipped shall be identified by having, as a minimum, the following information printed on the packing slip by the shipping clerk and (if used) on the Siemens shipping carton by the shipping personnel:

- A. The customer name.
- B. The P.O. number.
- C. The Siemens part number.
- D. The Siemens Job number.
- E. The quantity shipped (multiple boxes shall be noted as one of three etc.).

**RECORDS:** Material Hold work center transfer history in MANEX

**REFERENCE:** SOP-08-01, In-Process Checklist

## SECTION 9 PROCESS CONTROL

1. Siemens Mfg. Co., Inc. shall determine and plan the production, installation, and servicing processes which directly affect conformity to product requirements and shall ensure that these processes are carried out under controlled conditions. Controlled conditions incorporated as part of the Siemens Process Control procedure (Section 9.1) include equipment use and working environment, use of suitable equipment, compliance with reference standards, monitoring and control of process parameters, approval of processes and equipment, criteria for workmanship, equipment maintenance, and procedures defining the manner of production, installation, and servicing, where the absence of such procedures could adversely affect conformity to product requirements.
2. Records of qualified processes, equipment, and personnel are kept, as appropriate, per Section 16.

### SECTION 9.1 PROCESS CONTROL PROCEDURES

- 9.1.1. If required by contract, installation and servicing requirements can be implemented and a plan for implementation will be developed as part of the Contract Review procedure (ref: Section 3.1).
- 9.1.2. When a job is released for production, a Lead person will:
  - A. Determine which of the processes listed on the In-Process Checklist (Form QC 8A) apply to that job, and also determine the need for additional work instructions.
  - B. Contact the QC Manager to generate a master In-Process checklist.
  - C. Put the In-Process checklist into the production folder as a reference for additional copies of the In-Process Checklist to be made from (Ref: Product Identification and traceability, Section 8.1.3).
  - D. Fill out a Process Sheet, listing process settings and specific operations unique to the job, which will be reviewed for approval by the Quality System Manager.
  - E. Request Pie chart for defects noted on the previous work order of that part number.
- 9.1.3. The Production Supervisor will ensure that the equipment (hardware and software) and other resources (including information, workspace, utilities, buildings) used for production and testing of product is adequate, and that these functions are performed in a suitable work environment. An appropriate member of the Material review Board will ensure that any necessary supporting services (transportation, communication, information systems) are adequate.
- 9.1.4. The Production Supervisor will refer to the Siemens Manufacturing Company “Work Order” list to determine priorities for manufacturing and deliveries.
- 9.1.5. Siemens Mfg. Co., Inc. will ensure compliance with reference standards, quality plans, and/or documented procedures by monitoring and approving all processes listed on the In-Process Checklist that are followed by a “QC” sign off (ref. Section 10.1, First Article/In-Process Inspection, as well as Table “C”, the Process Flow chart).
- 9.1.6. Equipment requiring preventive maintenance (PM) will be listed on the calibrated equipment list. Preventive maintenance will be done using procedures found in the operators manual for the equipment requiring preventive maintenance. The results of the PM will be recorded on the PC database (Calibration Recall icon).

9.1.7. At this time, the New Athens Facility does not have any special processes. If a need for special processes does occur, then Siemens Mfg. Co., Inc. will use qualified operators (ref. Section 18.1, Personnel Training).

9.1.8 In any instance where the resulting output of a process cannot be verified by subsequent monitoring or measurement (defect is only apparent only after the product is in use), that process shall be validated. Validation parameters shall be established at a management meeting, and shall include (as a minimum);

- A. define criteria for review and approval of the process.
- B approval of equipment and qualification of personnel.
- C. use of specific methods and procedures.
- D. requirements for records.
- E. re-validation.

9.1.9. Workmanship standards for the processes listed on the In-Process Checklist are:

	<b>Process</b>	<b>Standard</b>
<b>A.</b>	Kitting	Bill of Materials
<b>B.</b>	SMD Assembly	Sample or Assembly Drawing
<b>C.</b>	QC SMD	Sample or Assembly Drawing
<b>D.</b>	SMD Inspect	Sample or Assembly Drawing; ANSI/IPC-A-610 (latest rev)
<b>E.</b>	Dip Insertion	Sample or Assembly Drawing
<b>F.</b>	QC Dip	Sample or Assembly Drawing
<b>G.</b>	Axial Insertion	Sample or Assembly Drawing
<b>H.</b>	QC Axial	Sample or Assembly Drawing
<b>I.</b>	Preline	Sample or Assembly Drawing
<b>J.</b>	QC Preline	Sample or Assembly Drawing
<b>K.</b>	Line	Sample or Assembly Drawing
<b>L.</b>	QC Line	Sample or Assembly Drawing
<b>M.</b>	Solder Wave	Process Sheet
<b>N.</b>	QC Wave	ANSI/J-STD-001 (Apr 92), ANSI/IPC-A-610 (latest rev)
<b>O.</b>	Board Cleanliness	ANSI/IPC-S-815 rev. B
<b>P.</b>	Off Line	Sample or Assembly Drawing
<b>Q.</b>	QC Offline	Sample or Assembly Drawing
<b>R.</b>	Board Trimming	ANSI/IPC-A-610 (latest rev)
<b>S.</b>	Inspection	ANSI/IPC-A-610 (latest rev); Sample or Assembly Drawing
<b>T.</b>	Testing	Test Procedure
<b>U.</b>	Rework/Repair	ANSI/IPC-R-700 rev. C
<b>V.</b>	Burn-In	Test Procedure
<b>W.</b>	Conformal Coating	Sample or Assembly Drawing
<b>X.</b>	Packaging	Packaging Log (Form QC 32)

**REFERENCES:**

**ANSI/J-STD-001 (Apr 92)**, Requirements for Soldered Electrical and Electronic Assemblies

**ANSI/IPC-A-610 (latest rev)**, Acceptability of Electronic Assemblies

**ANSI/IPC-R-700 rev. C**, Guidelines for Modification, Rework, and Repair of Printed Boards and Assemblies

**ANSI/IPC-S-815 rev B**, General Requirements for Soldering Electronic Interconnections

**Table C**, Process Flow chart

## SECTION 10 INSPECTION AND TESTING

1. Siemens Mfg. Co., Inc. has established and maintains specific methods for inspection and testing activities in order to verify that customer requirements for the product are met. If there are no specific customer requirements for inspection, then Siemens Mfg will use IPC-610 specifications. These methods are described in the Inspection and Testing Procedure, Section 10.0.
2. These procedures apply regardless of the amount of control exercised, or the types of inspection techniques used at a subcontractors facility.
3. The type of component inspected and inspection parameters are described in Section 10.1. No part, including urgent releases, will be used until it has been inspected and accepted.
4. Records of inspection and testing are kept per Section 16.

### SECTION 10.1 INSPECTION AND TESTING PROCEDURE

#### RECEIVING INSPECTION

- 10.1.1. Siemens purchased parts received will be inspected and/or tested for conformance and compliance to blueprint, drawing and/or specification requirements. When actual measurement values are required by purchase order or contract, the values will be recorded on an Inspection Report form (Form QC 14) for traceability. Otherwise, accept/reject criteria will be used (see Section 10.1.4&5). **No part will be used until the lot has been inspected and accepted.**
- 10.1.2. Components will be segregated into four categories which will also be in four separate locations.
  - A. Awaiting inspection (Incoming inspection area). Responsibility: Receiving personnel.
  - B. Inspected and approved (Kitting/stock area). Responsibility: Incoming Inspector.
  - C. Inspected and rejected (Rejected materials cabinet). Responsibility: Incoming Inspector.
  - D. Material Hold area. (Note: This area is the same physical location as the incoming inspection area). Responsibility: Incoming Inspector.
- 10.1.3. Product that is awaiting disposition (whether to accept, reject, scrap, awaiting shortages, etc.) will be kept in a Materials Hold area and will be labeled with a Material Hold card (Form QC 23).
- 10.1.4. **Incoming inspection for electronic components will be done in the following manner:**
  - A. The Incoming Inspector will open the Purchase Order from the PC; Fox Pro program (MANEX access). If all information listed is accurate (when compared to the part received), then the Inspector will inspect the parts. If the information is not accurate, then the Inspector will check the master file for an Equivalent Item Authorization form (Form QC 6) or a letter from the customer which will resolve the discrepancy. If there is no Form QC 6 or customer letter, then the Inspector will notify the Quality Supervisor who will resolve the issue.

#### 10.1.4. (Continued).

- B.** The Incoming Inspector will not inspect any given part until all P.O. discrepancies are resolved.
- C.** The incoming Inspector will verify that the proper part has been received (correct part number, authorized manufacturer, and proper value if applicable).
- D.** All parts inspected will be checked for physical damage (ref: ANSI/IPC-A-610, latest rev).
- E.** All custom/manufactured components will be compared to the latest drawing and all marked dimensions will be measured using calibrated calipers, with the inspection lot size determined by the Dodge and Romig single sampling plan, AOQL=5%.
- F.** All static sensitive components will be received in anti-static/shielded packaging or it will be rejected (ref. Section 13.1).
- G.** All static sensitive components will be handled only at static safe work stations.
- H.** All moisture sensitive surface mount I.C.s' received in factory sealed bags will be opened for inspection. The part number and manufacturer will be verified using the information on the factory parts ID sticker and the marking on the components. The bag will be re-sealed when inspection has been completed.
- I.** Resistors (through hole only) will be tested using the ohm scale of a calibrated multimeter whose resolution is ten times greater than the least significant digit of the part being tested (the least significant digit is determined after the tolerance has been factored into the nominal value of the part).
- J.** Capacitors (through hole only) will be tested using a calibrated capacitance meter whose resolution is ten times greater than the least significant digit of the part being tested (the least significant digit is determined after the tolerance has been factored into the nominal value of the part).
- K.** Other components received will be verified by checking the part number, manufacturer, and the physical description from the Purchase Order, with the inspection lot size determined by the Dodge and Romig single sampling plan, AOQL=5%.
- L.** Any components received that have a date code will have that date code entered into the incoming inspection database (MANEX System) for traceability purposes.

#### 10.1.5. Upon completion of incoming inspection of electronic components:

- A.** The Incoming Inspector will transcribe the ACC (lot) number from the computer screen(MANEX system) onto the packing slip, affix the printed label (Form QC13A which also contains the PC generated ACC number) onto the parts, then place the accepted parts on the shelf and forward the packing slip to the Accounting Dept if all criteria are met. If deficiencies are found, the parts will be labeled with a Rejection tag (Form QC 13C) and placed in the Reject Material cabinet.  
**Note:** Multiple reels of like items will additionally receive a letter suffix to differentiate each reel.(Example: Three reels are received & the ACC# is 12345. The first reel will be marked 12345A, the second reel will be marked 12345B, & the third reel will be marked 12345C.).
- B.** Nonconforming articles will be handled per Section 13.1 paragraph 1. The disposition of rejected material will be determined by a member of the Material Review Board. Where appropriate, a corrective action request (Form QC 16, or equivalent) will be included.

## FIRST ARTICLE/IN-PROCESS INSPECTION

10.1.6. Upon completion of the first assembly at any manufacturing step that is listed on the In-Process Checklist (Form QC 8A) as requiring a first article approval, the first item produced will be submitted to Quality personnel for First Article Inspection. First article verification for the surface mount lines will include recording the temperature profile used for reflow. A profile will be taken every morning, as well as anytime after the line is shut down for maintenance or setup for a different part number. **No further product will be produced at that step until an assembly has passed first article inspection.**

10.1.7. The quality control Inspector will inspect this first item to verify all blueprint/drawing configurations and requirements for the specific manufacturing operation and will, if the item complies, indicate acceptance by initialing the In-Process Check list, (Form QC 8A) in the space provided. For continuous runs, additional checks will be noted in the comments section of Form QC 8a. **The quality inspector will verify 100% for orientation and solder quality. The quality inspector will verify 1 component from each BOM line item for part number/value.**

10.1.8. Should the first (or random) item manufactured and inspected not meet blueprint/drawing configurations or requirements, the QC Inspector will notify the operator and/or the lead person that the product did not pass inspection. The operator will then correct the setup and submit a new item for First Article Inspection. **Rather than verifying that the correction has been made, the inspectors will do a 100% verification of the reject MODE. Example: If U1 is rejected for incorrect orientation, rather than verifying that U1 orientation is now correct, the inspector will verify ALL components for orientation.** If possible, the rejected item will be reworked by the end of the day and returned to manufacturing for further processing. If the item cannot be reworked by the end of the day, the Inspector will follow the procedure outlined in Section 13.1.4 (Nonconforming Materials).

10.1.9. For continuous runs, additional In-Process checks will be done (if required by the Siemens Process Sheet) by an Inspector at the following times on surface mount (SMD) assemblies: the first assembly of the day, the first assembly completed after each break, and the first assembly completed after lunch. Should the SMD assembly inspected not meet all blueprint/drawing configurations or requirements, the Inspector will follow the procedure outlined in Section 13.1.4 (Nonconforming Materials) and notify the operator and/or the lead person that the product did not pass inspection. The operator will then correct the setup and submit a new item for inspection. If possible, the rejected item will be reworked by the end of the day and returned to manufacturing for further processing. If the item cannot be reworked by the end of the day, the Inspector will tag the item with a Material Hold tag (Form QC 23) and place the rejected item in the Material Hold area for evaluation and disposition. The lead person will then have all assemblies that were produced after the last “accepted” In-Process check reinspected for the defect noted.

10.1.10. If any discrepancies are noted by the Inspector, then the lot will be rejected and the lead person will be notified. A rejected lot may be 100% inspected (if so directed by a supervisor) and then only the defective product (rather than the entire lot) will be rejected. The Inspector will then fill out a Reject tag (Form QC 13c). This record shall include, as a minimum, the quantity of items checked, the type and quantity of defect found, the job number, the date, and the Inspectors stamp/initials. If rework cannot be done by the end of the day, the Inspector will fill out a Material Hold form (Form QC 23), place the product in a hold area with the “Hold” form, and notify the Lead Person for the product placed on hold. The Lead Person will then notify the Supervisor who is responsible for that product line who will determine the disposition: rework to meet specifications, use as is, re-grade for alternative applications, return to supplier, or scrap. When the disposition of In-Process rejects has been determined, the product will be forwarded to the appropriate department for disposition and the “Hold” form and Reject tag will be disposed of.

## LINE/ROVING INSPECTION

10.1.11 The Line Inspector will:

- A. Verify all hand placed parts conform to specifications ( correct part, orientation, etc.).
- B. Inform the line assembler of any defect noted so the assembler can correct the defect.
- C. Contact the Lead Person for that line as well as the Quality System manager immediately any time excessive (more than 10 per type per day) defects are noted.
- D Record all defects noted on Form QC 14, and place a card between inspected & uninspected boards.
- E. Roving inspection will verify that written procedures are being followed.
- F. Verify SMD line setup by comparing component location to the location list (PC generated).

### VISUAL INSPECTION (NEW ATHENS FACILITY)

10.1.12. Upon completion of all assembly operations listed on the In-Process Checklist ( Form QC 8A) all product will be forwarded to the inspection department.

10.1.13. All inspection personnel are trained in inspection and rework techniques as well as in the use of ANSI/IPC-A-610, (latest rev), Class II, which will be used for accept/reject criteria.

10.1.14. When directed by a Production Supervisor or the Quality System Manager, printed circuit assemblies will be inspected using the MVP AutoInspection Machine (Model 1840).

- A. The MVP operator will load the board into the machine (the datalog will be turned on).
- B. The MVP operator will notify a qualified inspector when there are boards to be reviewed for rework.
- C. The inspector will mark the in process checklist when the review and rework for that assembly has been completed.
- D. The inspector will notify the MVP operator when the review and rework has been completed on that run of boards.
- E. When notified by an inspector that the run has been reviewed and reworked, the MVP operator will generate a computer printout summary of defects found and reworked on that run of boards which will be forwarded to the Quality System Manager. This printout is an Inspection record.

10.1.15. All assemblies will then be final inspected against blueprint/drawing and ANSI/IPC-A-610, (latest rev), Class II requirements and an inspection report (Form QC 14) will be filled out. 100% of the printed circuit assemblies will be inspected unless specified otherwise by the customer or the Process Sheet for that job. The Quality System Manager will determine (unless prohibited by contractual requirements) whether or not a lot sampling plan can be used for a given job. If a sampling plan is to be used, the Quality System Manager will add to the Process Sheet what sampling plan is to be used for that job.

10.1.16. If the items comply with blueprint/drawings specifications and purchase order requirements, then the In-Process Checklist (Form QC 8A) will be initialed in the space provided.

10.1.17. All discrepancies found manually (i.e. not found by the vision inspection machine) will be noted

on the inspection report (Form QC 14) and reworked at this time by the Inspector (exception: surface mount rework will be forwarded to the surface mount department if the Inspector does not have the training or equipment necessary to perform the required rework). If the item cannot be reworked by the end of the day, the Inspector will tag the item with a Material Hold tag (Form Q.C. 23) and place the rejected item in the Material Hold area for evaluation and disposition.

10.1.18. The Inspectors will notify the Quality System Manager of any discrepancies that they feel should be brought to the immediate attention of the Quality System Manager. This will allow the Quality System Manager to immediately investigate the problem and, if possible, correct the process that is producing the discrepancies. If the magnitude of the problem exceeds established limits (0.5% of the opportunities for their occurrence for defects listed in “Defects” Table 11-1 of J-STD-001, or 5.0% of the opportunities for their occurrence for Process Indicators listed in section 9.1.1 of J-STD-001), then written corrective action (Form QC 16, or equivalent) must be initiated by the Supervisor responsible for that product line. If a process change to a given product is necessary, then it will be noted by the Lead Person responsible for that product line on the process sheet. If a change to the Quality System is necessary, then the Corrective Action Request will be reviewed during the next management meeting to determine the most appropriate method for implementation. The results of the management review will be recorded. The supervisor will also follow up on the corrective action to verify that the actions taken were effective.

#### ELECTRICAL TESTING (NEW ATHENS FACILITY)

10.1.19. Printed circuit assemblies will be tested as required by contract and will be tested using customer supplied test procedures. If the test procedure is to be supplied by Siemens, then the procedure will be approved by the customer.

10.1.20. Printed Circuit assemblies that pass an electrical test will be labeled (if there is room on the board) Cal 1 (or per customer requirements) and, if required, Cal 2 by the person performing the test (ref: Section 12, Inspection and Test Status). The In-Process Checklist will then be initialed by the person performing the test on the appropriate line and the product will be forwarded to the shipping department. If the size of the item does not make labeling feasible, then the in process checklist (Form QC 8A) that is kept with the units will be used as the indicator of test status. If additional tests are required by the customer, the method of indicating that the units have passed the test will be indicated on the Process Sheet.

10.1.21. Printed Circuit assemblies that fail testing will be, if possible, reworked and/or repaired by the end of the day. If the printed circuit assemblies cannot be reworked and/or repaired by the end of the day, then the assemblies will be labeled with a Material Hold card (Form QC 23) and placed in a Material Hold area until rework is possible (ref. also Section 13.1).

10.1.22. All component rework and repair will conform to ANSI/IPC-A-610 (latest rev), and/or customer requirements and specifications.

10.1.23. All rework and repair of the printed circuit boards will conform to ANSI/IPC-R-700C, Rev C and/or customer requirements and specifications.

10.1.24. The person performing the test will fill out a Test Report (Form QC 14f) indicating the technicians

name, the date, the job number, the test equipment used (listed by SMC number), the quantity of assemblies tested, the quantity of boards failed. 10.1.24. The person performing repairs will fill out a Repair Report (Form QC 14e) indicating the quantity of boards repaired, as well as what was done to rework/repair each assembly ( removed solder bridge, replaced C2, etc.).

## FINAL INSPECTION

10.1.25. When product is ready for shipment, the QC Inspector will be notified. The Inspector will pull the job folder (if not already with the product) and check to verify that all certifications, reports, and documents that are listed on the Process Sheet (for New Athens, the file drawing for Freeburg) as required are on file. A Certificate of Conformance (Form QC 35) will be filled out by the QC Inspector at this time, if required by contract, for the process indicated by the contract. The original will be forwarded to the customer and a copy will be kept in the QC folder for traceability.

10.1.26. The inspection lot size for Final Inspection will be determined by the Dodge and Romig single sampling plan, AOQL=5%. (exception: RoHS compliant boards will be 100% checked for the WO/date label, verifying that all labels have an “R” on them).

10.1.27. The QC Inspector will verify that the product has all required stamps/labels ( date, inspection, etc.).

10.1.28. The QC Inspector will check the product for any physical damage.

10.1.29. The QC Inspector will verify that all required sections of the In-Process Checklist (Form QC 8A) have been checked off.

10.1.30. Upon approval of all accompanying shipping paperwork and/or required documents, the Inspector will transfer the units to “Finished Goods” in MANEX.. The accepted product will then be placed on the shelf labeled “Inspected & ready to ship”.

10.1.31. If any discrepancies are noted by the Inspector, then the lot will be rejected and the lead person will be notified. A rejected lot may be 100% inspected (if so directed by a supervisor) and then only the defective product (rather than the entire lot) will be rejected (ref. also Section 13.1). The Inspector will then fill out a Reject tag (Form QC 13c). This record shall include, as a minimum, the quantity of items checked, the type and quantity of defect found, the job number, the date, and the Inspectors stamp/initials. If rework cannot be done immediately, the Inspector will fill out a Material Hold form (Form QC 23), place the rejected product in a hold area with the “Hold” form, and notify the Lead Person for the product placed on hold. The Lead Person will then notify the Supervisor who is responsible for that product line and/or the Quality System Manager who will determine the disposition: rework to meet specifications, use as is, regrade for alternative applications, return to supplier, or scrap. When the disposition of In-Process rejects has been determined, the product will be forwarded to the appropriate department for disposition, and the “Hold” form will be disposed of. The Reject tag will be forwarded to the Quality System Manager once the disposition has been determined.

## FIRST ARTICLE

(Customer Approval)

10.1.32. When an assembly that has not been previously been manufactured at Siemens Mfg. is to be built, the first assembly (or whatever quantity the customer requests) built and ready for shipment will be forwarded to QC personnel (along with a First Article Inspection form, Form QC 17b) who will inspect the assembly per the sections for Visual Inspection and Final Inspection. If the lot is acceptable, it will be shipped to the customer along with Form QC 17b. **No additional product will be shipped until the customer releases the product to be built.** Customer approval is only required on new assemblies, not revisions to existing assemblies. If there is no specification on the contract for a FIRST ARTICLE APPROVAL, it is the responsibility of a Production Supervisor or the Quality System manager to contact the customer to determine if a FIRST ARTICLE APPROVAL is required. If the customer does not require FIRST ARTICLE APPROVAL, then this procedure does not apply.

**RECORDS:**

QC 35, Certificate of Conformance  
QC 6, Equivalent Item Authorization of Electronic Assemblies  
QC 16, Corrective Action Request  
QC 17b, First Article Inspection  
QC 22, Shipping Information  
Work center transfer history in MANEX

Information from the following forms will be transferred to MANEX where it will be stored as a record: MVP printout, QC 14 Inspection Report, QC 14d Technician Report form QC 14e Repair Report, QC 14f Test Report.

**REFERENCES:**

**ANSI/IPC-A-610 (latest rev)**, Acceptability of Electronic Assemblies  
**J-STD-001 (Apr 92)**, Requirements for Soldered Electrical and Electronic Assemblies  
**ANSI/IPC-R-700C rev C**, Guidelines for Modification, Rework, and Repair of Printed Boards and Assemblies  
Process Sheet

## SECTION 11 CALIBRATION CONTROL

1. Siemens Mfg. Co., Inc. has established and maintains specific methods to control, calibrate, and maintain inspection, measuring, and test equipment. These methods are described in the Calibration Control Procedure (Section 11.1). Records of calibration are kept per Section 16.
2. Test software or hardware that is used as suitable forms of inspection shall be included as part of the calibration procedure.
3. When required by contract, technical data pertaining to measurement equipment shall be made available to the customer.

### SECTION 11.1 CALIBRATION CONTROL PROCEDURE

11.1.1. When Siemens specified testing or calibration is required, the Quality System Manager, Technical Coordinator, and/or the Senior Technician will determine the measurements to be made and the accuracy required, and then select equipment with a known measurement uncertainty that is capable of the necessary accuracy and precision. The measurement and equipment requirements will then be recorded on the product test/calibration procedure.

11.1.2. When customer specified testing or calibration is required, the customer will specify and/or approve the measurements to be made and the accuracy required. The Quality System Manager, Technical Coordinator, and/or the Senior Technician will then select the appropriate equipment that is capable of the necessary accuracy and precision. The measurement requirements will be recorded on the customer supplied test procedure, and the equipment used will be recorded on the Quality Control Report (Form QC 14a, rev. a).

11.1.3. The Quality System Manager will identify all inspection, measuring, and test equipment that can affect conformity to product requirements with a sticker that has a unique SMC number typed on it. All in-house equipment calibration records and procedures for equipment listed on the Master Calibration list (Calibration Recall program, Computer Printout) will be filed by this SMC number.

11.1.4. Due to the controlled environment at both facilities, temperature is not a significant influence for on-site calibration and measurement. When equipment is to be used off-site, the Technical Coordinator will select equipment to ensure that temperature will not have a significant effect on measured values.

11.1.5. The Quality System Manager will determine calibration intervals for all calibrated equipment. The calibration interval will be recorded as part of the Calibration Recall program (computer program on PC). The calibration interval can be adjusted upward or downward, in one month increments, based on the calibration history of the equipment in question. Calibration shall occur within 1 month of the calibration expiration date

11.1.6. The Quality System Manager will determine whether a given piece of inspection, measuring, or test equipment is to be calibrated in-house or sent out to a calibration lab. This information will be recorded on Calibration Recall program (computer program on PC).

11.1.7. All inspection, measuring, and test equipment requiring calibration will be calibrated against certified equipment having a known valid relationship to nationally or internationally recognized standards. Where no such standard exists, the basis used for calibration will be documented.

11.1.8. The Quality System Manager and/or the Technical Coordinator will define in writing the procedure for all in-house calibration of inspection, measuring, and test equipment detailing the type of equipment to be calibrated, the SMC number of the equipment to be calibrated, the location (by area: Tech area, inspection area, etc.) of the equipment to be calibrated, the calibration interval, the specific method for calibration including the type and uncertainty of the calibration equipment to be used, the acceptance criteria, and the action to be taken when the calibration results are unsatisfactory.

11.1.9. Upon completion of an in-house calibration, the person performing the calibration will fill out and affix to the calibrated equipment a Calibration Certification label (Form QC 13b), record the calibration results onto the Calibration Record (Form QC 7b), and forward the Calibration Record to the Quality System Manager for traceability.

11.1.10. All in-house calibration will be performed by qualified personnel.

11.1.11. All equipment requiring calibration that is not calibrated in-house will be calibrated by a qualified (ANSI/NCSL Z540-1 compliant) and approved (by a review of the Quality System Manual of the calibration facility) calibration laboratory. Calibration must be performed to manufacturer specifications in accordance with ANSI/NCSL Z540-1 requirements. A **Report of Calibration** must accompany all returned calibrated equipment, which shall include the measurements take. The report shall also include any actions taken to repair or re-calibrate the equipment.

11.1.12. Inspection, measuring, or test equipment that is returned from a calibration lab as calibrated will have a Calibration Certification label affixed to it, and the results of the calibration will be recorded on a Certificate of Calibration which will be forwarded to the Quality System Manager for traceability.

11.1.13. The Quality System Manager and/or the Technical Coordinator will review all calibration records and assess and document (Form QC 7a) the validity of previous inspection and test results when Inspection, measuring, or test equipment is found to be out of calibration.

11.1.14. The Quality System Manager and/or the Technical Coordinator will ensure that the handling, preservation, and storage of inspection, measuring, and test equipment is such that the accuracy and fitness for use are maintained.

11.1.15. The Quality System Manager will, through training and/or physical methods, safeguard inspection, measuring, and test facilities, including both test hardware and test software, from adjustments which would invalidate the calibration setting.

**RECORDS:** QC 7a, Calibration Evaluation  
QC 7b, Calibration Record

## SECTION 12 INSPECTION & TEST STATUS

1. Siemens Mfg. Co., Inc. has established and maintains specific methods to indicate the inspection and test status of conforming and nonconforming product. These methods are described in the Procedure for the Indication of Inspection and Test Status, Section 12.1.
2. The Quality System Manager will make certain that items will retain an indication of their inspection and test status at all times. This is accomplished through the use of the In Process Checklist (Form QC 8A), red "Reject" tags (Form QC 13C), and/or individual inspection and test stamps/label when required by the customer.
3. The identification of inspection and test status will be maintained throughout production, instillation, and servicing of the product to ensure that only product that has passed the required tests and inspections is released for further processing or use.
4. Records of inspection and test status are kept per Section 16.

### SECTION 12.1 PROCEDURE FOR INSPECTION & TEST STATUS

12.1.1. Nonconforming product will be identified per Siemens Quality Manual, Section 13.1

12.1.2. If required by the customer, product which has been checked and found to be acceptable will receive the appropriate label (if there is enough room for the label), and the process line will be initialed on the In-Process Checklist by the person performing the indicated activity. If there is not room on the product for a label then the initialed In-Process Checklist will be used as an indication of inspection status. If there is no specific requirement for indication of test/inspection status, a single label will be applied to the board indicating that all manufacturing steps have been completed, and the product is ready to be shipped. The format of the label will be the date (month/year) and the Siemens work order.

12.1.3. Additional label configuration (if used) are shown below:

Cal = 1st Calibration: The item has passed an electrical test prior to shipping or, if required, burn-in.

Burn in = Burn-In: The item has been burned in.

Cal 2= 2nd Calibration: The item has passed an electrical test following a burn-in procedure.

ICT = In circuit test (Agilent 3070)

**RECORDS:** Work center transfer history in MANEX

## SECTION 13 CONTROL OF NONCONFORMING PRODUCT

1. Siemens Mfg. Co., Inc. has established and maintains specific methods to ensure that product that does not conform to specific requirements is prevented from unintended use or installation.
2. These methods, which are described in the Procedure for Control of Nonconforming Product (Section 13.1), provide for identification, documentation, evaluation, segregation (as practical), disposition of nonconforming product, and for notification to the functions concerned.
3. Records of nonconforming product are kept per Section 16.

### SECTION 13.1 PROCEDURE FOR CONTROL OF NONCONFORMING PRODUCT

13.1.1. When nonconforming items are found during receiving inspection, the Incoming Inspector will note the defect(s) on the Rejection Report-Log ( "QC Parts" database on computer). If there are enough defects to cause the lot to be rejected, the inspector will identify the lot as nonconforming with a computer generated "Rejected" report (Form QC 11C), and place the lot in a nonconforming area. If there are not enough defects to reject the lot, the nonconforming items will be identified (Form QC 11C) and placed in a nonconforming area. It is the responsibility of the Incoming Inspector to fill out all sections of the "Reject" form, with the exception of "Disposition". The Incoming Inspector will then print out a Rejected Material Report, Form QC 11 ("QC Parts" database, from the Rejection report-log) and forward per table "D" for product disposition. A rejected lot may be 100% inspected (if so directed by a supervisor) and then only the defective product (rather than the entire lot) will be rejected and placed in the nonconforming area for disposition.

13.1.2. When the disposition of the rejected material is determined, the action taken will be recorded on the Rejected Material Report, and the "Reject" report will be forwarded to Incoming inspection to be recorded on the QC Parts database. The Reject Report will then be disposed of (Exception: see section 13.7).

13.1.3. If, during production, customer supplied electronic components are lost or damaged the lead person for that job will fill out a Purchase Requisition (Form QC 40) and forward the requisition (along with all damaged parts) to the Inventory Clerk who will record the shortage on PC (Personal computer, Database program). Siemens purchased components that were damaged during production will be dispositioned by the lead person and replaced at Siemens expense. Siemens purchased components that were received damaged will be returned to the supplier for replacement. Customer supplied components that were received damaged will be returned to the customer and replaced at the customers expense.

13.1.4. When defects are found during In-House Inspection, the Inspector will fill out an Inspection Report (Form QC 14 for New Athens, Form QC 13c for Freeburg). This record shall include, as a minimum, the quantity of items checked, the type and quantity of defect found, the job number, the date, and the Inspectors stamp/initials. The Inspector will then, if possible, rework the defective product. If rework is not possible at this time, the Inspector will fill out a Material Hold form (Form QC 23), place the product in a hold area with the "Hold" form, and notify the Lead Person for the product placed on hold. When the disposition of In-House rejects has been determined, the product will be forwarded to the appropriate department for disposition, and the "Hold" form will be disposed of. If product is damaged beyond normal rework criteria (damaged board, excessive cost, etc.), the Lead Person will fill out a red "Rejected" tag (Form QC 13C), then notify the Supervisor for that product line and/or the Quality System Manager who will determine the disposition: rework to meet specifications, use as is, re-grade for alternative applications, return to supplier, or scrap. The Lead Person will forward the assembly, along with the completed "Rejected" tag to the Documentation Specialist who will fill out the Reject Material Report. The Documentation Specialist will forward one copy of the Reject Material Report to the Quality System Manager and one copy to the Customer Service Representative. The Supervisor or Quality System manager will notify the customer if it has been determined that defective material has been shipped.

13.1.5. If a problem is found that will delay production or delivery, or could affect product already in use by the customer, the customer will be notified by a member of the Material Review Board (MRB)/Sales Department within one working day. **Example:** Product cannot be manufactured or repaired to customer specifications, and Siemens requests a "use as is" disposition from the customer.

13.1.6. If the discrepancy is attributed to a supplier, expedient action will be taken by the Materials Control Manager to obtain a response from the supplier.

13.1.7. If the disposition of any product is SCRAP, then the Customer Service representative or the Quality Control manager will notify the customer (if applicable).

13.1.8. Repaired and/or reworked product shall conform to ANSI/ IPC-R-700C, rev. C (as well as IPC 610 current rev), and/or customer requirements and specifications, and be reinspected (by the person performing the repair/rework) for conformance to requirements (ref: QC Manual, section 10: inspection and testing). When the proposed use or repair does not conform to specific requirements, the Quality System Manager shall notify the customer and request disposition. Any deviations from the customer will be recorded on the Reject tag (for product), Form QC 13c, or on an Equivalent Item Authorization (for components), Form QC 6.

#### Returned Material

13.1.9. Defective product may be returned to Siemens Mfg. Co. for repair and/or rework for conformance to contractual requirements. The return of material to Siemens shall be accomplished as follows:

A. The customer will notify a Siemens Mfg. Co. Customer Service Representative of the need to return material to Siemens. The representative shall issue an RMA (Return Material Authorization) number to the customer authorizing product return. The representative will log the RMA number onto the Siemens job list (computer entry, MANEX).

**B.** Once received, the RMA specialist shall count and verify the product returned, start a repair folder, start a tech report (Form QC 14d), and key the sales order and work order into MANEX. The RMA specialist shall forward a copy of the RMA paperwork to the Quality System Manager for data entry (computer program: Nonconforming Tracking System, ver. 1.05).

**C.** If there are any discrepancies, the RMA specialist will immediately notify a Customer Service/support member as well as the Quality System Manager of the nature and extent of the discrepancies, and place the returned materials, with a Tech report (Form QC 14d), in the Hold area until the discrepancies are resolved by the Quality System Manager.

**D.** All steps taken to repair the product, (parts replaced, recalibration, etc.), shall be recorded on the technical report (Form Q.C. 14d), for traceability.

**E.** All product shall be retested (if required) after all repairs are completed. Retested units will receive a “CAL 1 RMA” label ( if there is room for the label).

**F.** The technician performing product repairs will inspect their work to ensure that all repairs conform to applicable standards (IPC-R-700C, etc.), drawings and/or purchase order requirements (ref also: Siemens QC Manual, section 13.1, Nonconforming Product).

**G.** All boards will be packaged properly and returned to the customer (ref: Siemens QC Manual, Section 15.1. Packaging.1).

**H.** The technician will forward one copy of the technician report (Form QC 14d) to the Shipping supervisor who will place them in the “Outgoing RMA” folder and forward the “Outgoing RMA” folder to the Quality System Manager for data entry (computer program; Nonconformance Tracking System). When data entry is complete, the Quality System Manager will return the “Outgoing RMA” folder to the RMA specialist who will forward the technician report to the office for billing purposes, (this copy will be filed in the job folder, for traceability).

**I.** If the disposition of returned material is “scrap”, then a copy of the Scrap report will be forwarded to the Customer service rep for that customer.

**RECORDS:** QC 6, Equivalent Item Authorization  
QC 11, Rejected Material Report  
Work center transfer history in MANEX

Information from the following forms will be transferred to MANEX where it will be stored as a record: MVP printout, QC 14 Inspection Report, QC 14d Technician Report form QC 14e Repair Report, QC 14f Test Report.

**REFERENCE:** ANSI/IPC-R-700C rev C, Guidelines for Modification, Rework, and Repair of Printed Boards and Assemblies  
**ANSI/IPC-A-610 (latest rev)**, Acceptability of Electronic Assemblies

## SECTION 14 CORRECTIVE AND PREVENTIVE ACTION

1. Siemens Mfg. Co., Inc. has established and maintains specific methods for implementing corrective and preventive action. These methods are described in the Corrective and Preventive Action Procedure (Section 14.1). Corrective action procedures address the issues of handling customer complaints, investigating nonconformities, determining corrective action, and applying controls to ensure that corrective action is taken and that it is effective. Preventive action procedures address the issues of defect analysis, determination and implementation of preventive action, application of controls to ensure that preventive action is effective, and is reported for management review.
2. Any corrective or preventive action taken shall be to a degree appropriate to the magnitude of the problem and commensurate with the risks encountered.
3. Records of corrective and preventive action are kept per Section 16.

### SECTION 14.1 CORRECTIVE AND PREVENTIVE ACTION PROCEDURE

#### Corrective action:

14.1.1. The Quality System Manager will analyze the data from Quality Control Reports (Form QC 14a), Inspection Reports (Form QC 14), Technician Reports (Form QC 14E & F), Reject Material Reports (Form QC 11), and any Customer Complaints to identify problem areas. The Quality System manager will, if necessary, work with the Production Supervisors to determine what modifications need to be made to the processes and/or work instructions which affect conformity to product requirements to achieve a reduction in future nonconformities.

14.1.2. Any time a customer complaint is received the person being notified will forward the complaint to the Supervisor responsible for that product line. That Supervisor will then investigate the problem to determine the root cause of the nonconformity. If the nature of the problem involves the conformity to product requirements, then the Supervisor will notify the Quality System Manager and will, if necessary, work with the Quality System Manager to determine what corrective action is necessary to eliminate the cause of the nonconformity as well as what controls are necessary to ensure that corrective action is taken and that it is effective.

14.1.3. If the magnitude of the problem exceeds established limits (0.5% of the opportunities for their occurrence for defects, or 5.0% of the opportunities for their occurrence for Process Indicators), then a Corrective Action Request (Form QC 16, or equivalent format) must be initiated by the Supervisor responsible for that product line (**EXCEPTION:** For sample sizes of 200 and smaller, more than 2 defects will cause corrective action to be initiate) . If a process change to a given product is necessary, then it will be noted by the Lead Person on the process sheet. If a change to the Quality System is necessary, then the Corrective Action Request form will be reviewed during the next management meeting to determine the most appropriate method for implementation (ref. Section 5.1. Quality System Manual Change Procedure). The results of the management review will be recorded and will be filed in the New Athens QC office. The Production Supervisor will also follow up on the corrective action to verify that the actions taken were effective. Once completed, the Corrective Action Request results will be maintained on-line.

14.1.4. If the magnitude of the problem does not exceed established limits, then it is up to the discretion of the Production Supervisor as to whether or not formal corrective action will occur. If that Supervisor does decide that corrective action is necessary, then the procedures outlined above (Corrective Action, paragraph 2) will apply.

#### Preventive Action:

14.1.5. The Quality System manager will, as necessary, work with the Production Supervisors to determine what modifications need to be made to the processes and/or work instructions which affect conformity to product requirements to reduce potential nonconformities.

14.1.6. If a change to the Quality System (ref. Section 5.1. Quality System Manual Change Procedure) or a significant change to a process is necessary, then the problem will receive a management review to determine the most appropriate course of action. The results of the review will be recorded (ref; Contract review problem form).

14.1.7. The Supervisor who is responsible for the area that is being reviewed is responsible for the implementation of preventive action as well as follow-up activities to verify that the preventive action is effective. That Supervisor will then submit relevant information on actions taken for management review. The results of the review will be recorded.

#### **RECORDS:** Management Review

QC 16, Corrective Action (Customer supplied form, or an equivalent format that addresses root cause and corrective action) can be used in place of QC16)

Work center transfer history in MANEX

QC 33 Contract Review Problem Form

**REFERENCE:** **IPC-610 (current rev)**, Requirements for Soldered Electrical and Electronic Assemblies  
**IPC-R-700C rev C**, Guidelines for Modification, Rework, and Repair of Printed Boards and Assemblies

**IPC-7711/7721** Rework/repair of electronic assemblies

## SECTION 15

1. Siemens Mfg. Co., Inc. has established and maintains specific methods for handling, storage, packaging, preservation, and delivery of product as described in Section 15.1.

### SECTION 15.1 HANDLING, STORAGE, PACKAGING, PRESERVATION, AND DELIVERY PROCEDURES

#### **HANDLING:**

15.1.1. Printed circuit assemblies will be transported from one location to another using conductive racks, bins or boxes. Printed circuit assemblies that are large, heavy (PC mount transformer), or have surface mount devices on both sides will be transported in bins with inserts or racks only.

15.1.2. Transformers may be transported in any container appropriate for the size and weight.

15.1.3. ESD procedures (ref. SOP-15-01) will be followed when handling ESD sensitive devices.

15.1.4. Components will remain in factory packaging for as long as practical. Batteries will remain in factory packaging until they are inserted into the final product for shipping.

15.1.5. Any special handling procedures that are required by contract or unique to a given product will be listed on the job process sheet for that product.

15.1.6. Qualified people are trained for handling techniques to prevent damage or deterioration (see Section 18.1: Training).

#### **STORAGE/RECEIVING:**

15.1.7. Software will be stored in an climate controlled area.

15.1.8. In order to detect deterioration, the condition of product in stock will be assessed during the annual inventory. Items found to be questionable will be brought to the attention of a supervisor who will determine whether to scrap (ref. also, Section 13.1: Nonconforming Product) or, if applicable, recondition the items.

15.1.9. First in, First Out techniques will be used for stock items.

15.1.10. Siemens purchased components will be accepted into the stock room only if there is a purchase order for those components. Customer supplied parts will be accepted if there is a packing slip and an open Siemens job using the parts received.

15.1.11. A job traveler (computer printout, MANEX) delivered to the transformer Production Supervisor and/or the Inventory Clerk authorizes the purchasing of components for a given transformer job and releases stock parts to production.

15.1.12. When a job kit is complete the Inventory clerk or the appropriate supervisor will release the kit to production.

15.1.13. Tape and reel components and components released as replacement for shortages will be issued to production with a Requisition/Shortage card (Form QC 37), which will be signed by the lead person responsible for that product line, returned to the stock room, and filed for reference.

15.1.14. The In-Process checklist signed by the person who performed a listed process step, authorizes receipt to and dispatch from storage areas.

15.1.15. Bulk storage (Warehouse) will be accomplished in the following manner:

**A.** Check the parts in using the purchase order (for Siemens purchased material) or the packing slip (for customer supplied material) to verify that the proper part and quantity of parts was received. All cartons will be inspected for physical damage at this time. Any damage will be noted and reported to the supervisor responsible for that product line. Rejected product will be handled per Section 13.1, Control of Nonconforming Product.

**B.** Customer Supplied stickers (Form QC 19A) will be applied when a skid is broken down.

**C.** For parts ordered for a specific job or for customer supplied parts, the Inventory clerk or a Production Supervisor will enter into the computer (System 36) and/or onto the B.O.M. for that job the quantity received.

15.1.16. When a job is complete, all excess customer supplied parts will be returned to the Inventory Clerk who will store them on shelves by customer/job name or, after contacting the customer, return the parts to the customer. Excess Siemens parts with an inventory code of A through H will be returned to the inventory clerk to be de-kitted and put back into inventory.

15.1.17. Left over Siemens supplied parts will be labeled with a Parts Identification label (Form QC 13A) which will have, as a minimum the Siemens part number.. The lead person will then return the parts to the stock room. The Inventory Clerk will enter the part number and the quantity for the stock parts onto the PC (MANEX De-Kit module) and store the parts in the stock area by Siemens part number. SMD parts that were received with a desiccant and humidity indicator will have the desiccant and the humidity indicator repackaged with the parts. When these parts are then reused, the humidity indicator will be checked when the package is opened. If the humidity indicator indicates a humidity level in excess of 20%, then the components and the desiccant will be baked according to the components manufacturer specifications.

15.1.18. If electronic components (New Athens only) are needed to complete a job because they were lost or damaged (ref. also Section 13.1: Nonconforming Product), then the lead person requiring the component will fill out a Purchase Requisition (Form QC 40) and send it to the Inventory Clerk. If the Inventory Clerk has the parts in stock, then the parts will be issued. The requisition will be marked “filled” and filed for reference. If the Inventory clerk does not have the part or if the part issued is taken from another kit, then the requisition will be forwarded to a Purchasing team, who will then order the parts.

15.1.19. If electronic components are needed to repair printed circuit assemblies (New Athens), the technician will fill out a Purchase Requisition and forward the requisition to Inventory or technical support personnel. If the parts in stock, then the parts will be issued. If the parts in stock, the Inventory personnel will forward the purchase requisition to a Purchasing team, who will then order the parts.

15.1.20. Control of materials (i.e. chemicals) with a specified shelf life shall be accomplished in the following manner(this applies only to Humiseal 1B73, solder paste, liquid flux (1gal or larger), all Hysol/Loctite products, RTV, flux thinner (1 gal or larger), & the customer specific materials listed below):

<b>RESIN</b>	<b>HARDENER</b>
<b>EL-CAST BLACK</b>	<b>4123</b>
<b>EN-4</b>	<b>EN-12</b>
<b>EN-2523 part A</b>	<b>EN-2523 part B</b>
<b>T-Set EP 20</b>	<b>T-Set EP 698</b>

- A. The receiving Inspector will affix to the container a Shelf Life sticker (Form QC 36) **ONLY** if the expiration is not already printed on each individual container. The label will have the date of receipt, the expiration date, and the Inspectors stamp or initials.
- B. A monthly audit of storage areas will be conducted by the QC Manager (per QOP-15-1).
- C. Chemicals that are found to have an expired shelf life will be disposed of according to OSHA and EPA approved methods.

### **PACKAGING:**

15.1.21. All product will be packaged according to customer requirements. If there are no customer supplied requirements, then the Production / Shipping and Receiving Supervisor will work with the customer to determine the extent of packaging necessary to protect the product during shipment. The SIEMENS developed packaging requirements will be recorded on the packaging log (Form QC 32) which will be reviewed/approved by the Production Supervisor or the Quality System Manager, and kept in their respective packaging area.

15.1.22. The Shipping Information form (Form QC 22) signed by QC personnel authorizes product shipment.

15.1.23. All shipping information affixed to the SIEMENS boxes will be neat, legible, and durable. The following information, as a minimum, will be affixed to all SIEMENS boxes prior to shipment:

- A. The packing slip (computer generated).
- B. The customers name.
- C. The customers shipping address.
- D. The purchase order number.
- E. The quantity.
- F. The serial number(s) (if serialized).
- G. The SIEMENS job number.
- H. The box count (if more than one box).

### **PRESERVATION/SEGREGATION:**

15.1.24. Components will be segregated into four categories which will be in four separate locations.

- A. Awaiting incoming inspection (Incoming inspection area).
- B. Inspected and approved (Kitting/stock area).
- C. Inspected and rejected (Rejected materials cabinet).
- D. Material Hold area.

15.1.25. Product that is awaiting disposition (whether to accept, reject, scrap, awaiting shortages, etc.) will be kept in a Materials Hold area and will be labeled with a Material Hold card (Form QC 23). Finished units that are shipped more than 30 days after the inspection date will have the date label replaced to reflect the actual ship date (for warranty purposes).

15.1.26. Components that have been approved and released for production (per MANEX Pick List) will be labeled (ref: Section 8, Product Identification) and placed into kits or, if no kit, a stock area.

15.1.27. Solder paste will be stored in a refrigerator when not in use.

15.1.28. Product storage: **A.** Siemens Mfg. is committed to achieving 100% on-time delivery.

**B.** Finished product is shipped based on a Siemens order driven process.

**C.** Therefore, finished product storage is kept to a minimum.

**DELIVERY:**

15.1.29 Where contractually required, the protection of the product shall be extended to include delivery to its final destination. Any additional packing requirements will then be recorded on the packaging log (Form QC 32).

**REFERENCE:** SOP-15-01, ESD Handling Procedures

QOP-15-1, Control procedure for materials that have a specified shelf life.

## SECTION 16 QUALITY RECORDS

1. Siemens Mfg. Co., Inc. has established and maintains specific methods for the identification, collection, indexing, access, filing, storage, maintenance, and disposition of quality records (including pertinent subcontractor quality records) as described in Section 16.1 to demonstrate conformance to specific requirements and the effective operation of the quality system.

All quality records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times shall be established and recorded. Where agreed contractually, quality records shall be made available for evaluation by the customer or the customer's representative for an agreed period.

### SECTION 16.1 PROCEDURES FOR CONTROL OF QUALITY RECORDS

16.1.1. Documents pertaining to the conformity to product requirements of articles being manufactured shall be filed and maintained in designated job folders or any other designated area for easy access (see table 1).

16.1.2. Records shall be held for a minimum of three (3) years, unless otherwise required by purchase order or contract. The person responsible (ref. Table 1) for the records will then decide whether to maintain the records or dispose of them.

16.1.3. Records maintained to substantiate our quality control system shall include the following:

- A.** Certifications and test reports for purchased materials (if required by contract).
- B.** Completed in-process checklist (controlled copy). Ref. Section 10.1
  
- C.** Copies of all shippers. Ref. Sections 7.1, 10.1, 15.1
- D.** Purchase orders. Ref. Section 6.1
- E.** Data from Inspection Reports. Ref. Section 10.1
- F.** Test/technician (Quality Control) reports. Ref. Sections 10.0 & 11.1
- G.** Copies of "Certificates of Conformance" issued. Ref. Section 10.1
- H.** Inspection and test equipment calibration records. Ref. Section 11.1
- I.** Personnel training. Ref. Section 18.1
- J.** Records of any other related documents pertaining to the quality system and purchase order and/or contractual requirements.
- K.** Audit reports. Ref. section 17.1
- L.** Management review reports. Ref. Section 1.1
  - 1. Supplier records. Ref. Section 6.1
  - 2. Subcontractor records. Ref. Section 6.1
  - 3. RMA's (Data from technician reports). Ref. Section 13.1
- M.** Corrective action reports. Ref. Section 14.1
- N.** Quotes. Ref. Section 3.1
- O.** Contract Review Problem form. Ref. Section 3.1

16.1.4. The person who is responsible for the records listed is responsible for the access, collection, indexing, filing, storage, maintenance, and disposition of quality records.

16.1.5. All records are available for review by the customer.

16.1.6. All records are used as a basis for management review of quality systems effectiveness.

16.1.7. All records shall be legible and contain, as a minimum, the Siemens Job number and/or part number.

16.1.8. All quality records shall be stored and retained in such a way that they are identifiable and readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss.

TABLE 1

QUALITY SYSTEM MANUAL SECTION #	SIEMENS FORM #	RESPONSIBILITY	FILE LOCATION
16.3.a	Not Applicable	QC MANAGER	QC FILE
16.3.c	QC 22	VICE PRESIDENT	Thrown away when product is shipped
16.3.d	Not Applicable	PURCHASING AGENT	PURCHASING FILE
16.3.e	QC 14	QC MANAGER	PC
16.3.f	QC14a	QC MANAGER	PC
16.3.g	QC 35	QC SUPERVISOR	QC Master Folder (BY Job Name)
16.3.h	Not Applicable	QC MANAGER	PC
16.3.j	Computer file	QC manager	PC
16.3.k	As applicable	QC MANAGER	QC OFFICE
16.3.l	QC 29	QC MANAGER	QC OFFICE
16.3.m	Mgt report	QC MANAGER	PC
16.3.n	QC 16 (ref section 14.1.3)	QC Mgr	PC
16.3.o	Not applicable	SALES MANAGER	QUOTE OFFICE

SECTION 17  
INTERNAL QUALITY AUDIT

1. Siemens Mfg. Co., Inc. has established and maintains specific methods for planning and implementing internal quality audits to verify whether quality activities and related results comply with planned arrangements and to determine the effectiveness of the quality system. These methods, as described in the Internal Quality Audit Procedure (Section 17.1), address audit scheduling, corrective action on deficiencies found during an audit, follow-up audit activities to verify corrective action, as well as Auditor independence.
2. Records of Quality Audits, as well as the results of the audits, shall be maintained per section 16.

SECTION 17.1  
INTERNAL QUALITY AUDIT PROCEDURE

17.1.1. Quality System Manager is responsible for planning and implementing internal quality audits, and establishing an audit schedule. A minimum of two process audits and one compliance audit will be performed per year. The Quality System Manager can revise the audit schedule based on information or data analysis and the importance of the area being audited as well as the results of previous audits.

17.1.2. Qualified auditors will audit all in-house Quality System policies and procedures (exception: auditors will **not** audit their own work). The auditor will be trained (Certified by a 3<sup>rd</sup> party) to perform the assigned function or shall have sufficient experience ( 2 years auditing to ISO or equivalent standards) in auditing to accomplish the task.

17.1.3. Auditors will be selected ( if not already certified) by an interview process using criteria listed on the Auditor Job posting. Successful candidates will then be sent to a 3<sup>rd</sup> party for training /certification.

17.1.4 Auditors will be re-trained when changes occur to the Quality System manual or to the ISO standards. Auditors, additionally, will be evaluated annually by the Quality Manager. (Observe & evaluate an audit, as well as a written test)

17.1.5. Auditors are independent of the area being audited. The auditor will be made available when it is time to perform an audit or a follow-up audit.

17.1.6. The results of the audit will be recorded on Form QC 29 which will be forwarded to the Supervisor responsible for the area being audited for review. The Supervisor responsible for the area audited shall take corrective action (Form QC 16, or equivalent) within 30 days on deficiencies found during the audit. Form QC 16 will be filed with the Quality System Manager for follow-up purposes.

17.1.7. A follow-up audit will verify and record (Form QC 29) the implementation and effectiveness of the corrective action taken. The follow-up audit will also record unresolved deficiencies.

17.1.8. The results of the audit and corrective action will be forwarded to the Quality System Manager for Management Review and, if necessary, further corrective action.

**RECORDS:** Management Review  
QC 16, Corrective Action

SECTION 18  
PERSONNEL TRAINING

1. Siemens Mfg. Co., Inc. has established and maintains specific methods for determining training needs and provide for the training of all personnel performing tasks affecting conformity to product requirements.
2. Personnel performing specific assigned tasks shall be qualified on the basis of education, training and/or experience, as required.
3. Quality System Manager is responsible through training and monitoring for having personnel correctly and consistently use various forms, cross-referenced in this manual. This will assure traceability through documentation, from the beginning of the contract to the shipping of product. The Quality System Manager is also responsible for submitting copies of the Quality System Manual to designated personnel to insure proper preparation and training in all applicable facets of this quality system and will ensure that training is provided by qualified personnel.
4. It is the responsibility of the Supervisor in charge of a given department to determine training needs and ensure that all personnel in their department that require training, are trained and competent.
5. Records of personnel training are kept as stated in Section 16.

SECTION 18.1  
PERSONNEL TRAINING

18.1.1. When job assignments, special processes, inspection or testing requires special skills or knowledge in manufacturing, production, or quality control (ref: Training Log, computer file), then personnel shall be trained (and competency determined) by reviewing relevant procedures and providing hands-on training where applicable . The person doing the training is responsible for filling out the training record.

18.1.2. A Training Log (computer file) shall be maintained by the QC manager (or the HR Mgr) for all personnel, and is available for review. The log will include, as a minimum, the person's name, and the type and date of skill trained in.

18.1.3. Training is provided also, when applicable, to inspection, manufacturing, production, and management personnel to familiarize them with procedures and instructions given in the quality system manual and respective forms within 30 days of employment(ref: training checklist), as well as with in-plant defects and the Siemens Quality Policy.

18.1.4. Technicians (who troubleshoot defective product) must have scored at least 60% (those hired after 1 July 1998) on the Siemens technician test **and** have at least a 2 year degree/certificate in a related field. 4 years experience in a related field can be substituted for the 2 year degree/certificate **or** the test. Other jobs at Siemens have no minimal requirements, however, related experience is beneficial.

18.1.5. Employees shall be retrained when a supervisor has determined that a significant change has occurred in the manufacturing plant procedures and/or processes applicable to their area, or when proficiency or quality performance becomes substandard. Personnel who are involved in the manufacturing of medical devices will be retrained in those procedures if more than 6 months have passed since the last

work order.

**RECORDS:** Training Log: computer file

## SECTION 19 SERVICING

1. If required by contract, servicing can be implemented and a plan for implementation will be developed as part of Quality Planning (ref: SECTION 2).
2. The Quality Plan will address the issues of establishing and maintaining documented procedures for performing, verifying, and reporting that the servicing meets the specified requirements.

## SECTION 20 STATISTICAL TECHNIQUES

1. Siemens Mfg. Co., Inc. has established and maintains specific methods to implement and control the application of statistical techniques, and these methods are described in Section 20.1.

### SECTION 20.1 STATISTICAL TECHNIQUES

20.1.1. All components will be inspected using the DODGE and Romig single sampling plan, AOQL=5%.

20.1.2. Outgoing inspection at both plants will be performed using the DODGE and Romig single sampling plan, AOQL=5%

20.1.3. All inspections are performed using the criteria of accept the lot on zero defects and reject the lot on one or more defects.

20.1.4. If required by contract, SPC can be implemented and a plan for implementation will be developed as part of Quality Planning (ref: SECTION 2).

20.1.5. Ionic Residue limits are outlined in the Joint Industry Standard ANSI/J-STD-001, Apr. 92 ver., Section 8.5.6.

#### **REFERENCES:**

**Sampling Inspection Tables**, Dodge & Romig (Sept. 1956)

**QUALITY SYSTEM MANUAL  
CHANGE & REVIEW RECORD**

Section & Paragraph:	Effective Date:	Approved By:	Description of Revision
3.1.7a Page 9	21 Sept 96	Perry Danford QC Manager	Was "Shipping Clerk". Changed to "Order Entry Clerk"
5.1.16 Page 15	21 Sept 96	Perry Danford QC Manager	Now reads "temporary changes <b>to SIEMENS controlled documents</b> "
3.1.8 line 9 Page 9	11 Nov 96	Perry Danford QC Manager	Was "will dispose of" Is "will file for reference"
3.1.6.A Page 8	1 Apr 97	Perry Danford QC Manager	defined database program as "Access"
3.1.6a Page 8	1 Apr 97	Perry Danford QC Manager	Was "forward to John III" Is " forward to an Operations Committee member"
3.1.8 line 9 Page 9	1 Apr 97	Perry Danford QC Manager	Was "Materials Control Manager will transcribe" Is "the Purchasing Agent will transcribe"
3.1.8a,9,12 Page 10	1 Apr 97	Perry Danford QC Manager	Replaced "John III" with " an Operations Committee member"
3.1.16 line 4 Page 11	1 Apr 97	Perry Danford QC Manager	The Technical Coordinator no longer sends a copy of QC 6 to the Materials Control Manager
5.1.10.E Page 17	1 Apr 97	Perry Danford QC Manager	Was "Dispose of obsolete documents" Is "Stamp obsolete documents ... file for reference"
6.1.1H Page 19	1 Apr 97	Perry Danford QC Manager	Replaced "John III" with "an Operations Committee member"
6.1.8.D Page 20	1 Apr 97	Perry Danford QC Manager	Replaced "John III" with "an Operations Committee member"
10.1.4 Page 31	1 Apr 97	Perry Danford QC Manager	Added "(if required by the Siemens Process Sheet; Form QC 8)"
14.1.2 line 5 Page 44	1 Apr 97	Perry Danford QC Manager	Added "Exception:..."
15.1.12 line 6 Page 47	1 Apr 97	Perry Danford QC Manager	Added "SMD parts that were received with a desiccant..."

**QUALITY SYSTEM MANUAL  
CHANGE & REVIEW RECORD**

Section & Paragraph:	Effective Date:	Approved By:	Description of Revision
1.7 line 1 Page 5	26 Nov 97	Perry Danford QC Manager	Was: Every three months... Is: Every twelve months...
3.1.6a lines 4 & 5 Page 8	26 Nov 97	Perry Danford QC Manager	Was: ...the Sales Manager... Is: ...the Sales Manager/Customer Service ...
3.1.7 lines 1, 2, & 4 Page 9	26 Nov 97	Perry Danford QC Manager	Was: ... the Sales Manager... Is: ...the Sales Manager/Customer Service ...
3.1.7a lines 2 & 4 Page 9	26 Nov 97	Perry Danford QC Manager	Was: ... the Sales Manager... Is: ...the Sales Manager/Customer Service ...
3.1.12 line 4 Page 10	26 Nov 97	Perry Danford QC Manager	Was: ... the Sales Manager... Is: ...the Sales Manager/Customer Service ...
5.1.4.D Page 13	26 Nov 97	Perry Danford QC Manager	Was: ...the senior technician. Is: ...the senior/lead technician.
5.1.8 Page 14	26 Nov 97	Perry Danford QC Manager	Was: Only technicians... Is: ... the lead tech., senior tech, Tech. Coordinator...
5.1.10 Page 17	26 Nov 97	Perry Danford QC Manager	Was: ...Production Supervisor... Is: ...Production Supervisor (or his designee)...
6.1.7.D Page 20	26 Nov 97	Perry Danford QC Manager	Was: ... the Sales Manager... Is: ...the Sales Manager/Customer Service ...
7.1.6 line 1 Page 22	26 Nov 97	Perry Danford QC Manager	Was: ...the Production Supervisor... Is: ... Supervisor or the Quality System Manager...
7.1.9 line 2 Page 23	26 Nov 97	Perry Danford QC Manager	Was: ...shelves by job name... Is: ...shelves by customer/job name...
7.1.9 line 2 Page 23	26 Nov 97	Perry Danford QC Manager	Was: ...if required by contract... Is: ...after contacting the customer...
10.1.1 line 5 Page 28	26 Nov 97	Perry Danford QC Manager	Was: ...until it has been inspected... Is: ...until the lot has been inspected...
10.1.4.E,F,I&J Page 29	26 Nov 97	Perry Danford QC Manager	Deleted: (Siemens part #, first two digits ...)

Form QC 1

**QUALITY SYSTEM MANUAL  
CHANGE & REVIEW RECORD**

Section & Paragraph:	Effective Date:	Approved By:	Description of Revision
5.1.16.c .Note Page 15	16 July 98	Perry Danford QC Manager	Modified note to require Mallinckrodt approval on documents & processes prior to implementation.
18.1.4 & 7 Page 53	16 July 98	Perry Danford QC Manager	Combined & clarified lines 4 & 7
Section 10 Page 36	9/3/99	Perry Danford QC Manager	Added First Article (Customer Approval)
Section 16 Page 51	9/3/99	Perry Danford QC Manager	Form QC 28 is responsibility of the Training Specialist
Section 18 Page 53	9/3/99	Perry Danford QC Manager	Form QC 28 deleted
Section 5.1.D Page 18	10/1/99	Perry Danford QC Manager	was: ...update QC master list is: update ... (local PC: QCMAN1.wpd).
Section 5.1.E Page 18	10/1/99	Perry Danford QC Manager	was: update unissued Quality System manuals is: update ...(network file QCMAN1.pdf).
Section 8.1.2 Page 24	02/03/00	Perry Danford QC Manager	Added note: 8.1.2 "...does not apply to transformer components".
Section 15.1.14 Page 48	02/10/00	Perry Danford QC Manager	Added a list of materials that would be tracked.
RE-INDEX ALL	2/23/00	Perry Danford QC Manager	Eliminated repeating paragraph numbers within a section. Went to sequential paragraph numbering.
Section 10.1.6.B Page 30	6/6/00	Perry Danford QC Manager	Added: "Note: Multiple reels of like items...".
Section 15.1.25 Page 50	7/11/00	Perry Danford QC Manager	Added: "Finished units that are shipped more than 30 days..."
Section 5.1.4 Page 13	8/30/00	Perry Danford QC Manager	Added Table B for routing document Rev changes.
Section 3.1	3/1/01	Perry Danford QC Manager	Changed responsibilities from " Order Entry" to "Customer Service"
Section 10.1.25 Page 34	8/3/01	Perry Danford QC Manager	Added " If additional tests are required by the customer, ...".

Section 10.1.1 Page 30	8/3/01	Perry Danford QC Manager	Was “ Inspection personnel shall transcribe...” Now is “Data entry personnel shall transcribe...”
Section 3.1.4 Page 7	10/31/01	Perry Danford QC Manager	Was ”clerical personnel shall assign a quote number” Now is “quote estimator assigns the quote number”
Section 3.1.6.C Page 8	10/31/01	Perry Danford QC Manager	Was “... stamp P.O ACCEPTED...” Now is “...stamp the P.O. ENTERED and DATED”
Section 3.1.6b Page 8	10/31/01	Perry Danford QC Manager	Was “...fill out form QC 18...” Now is “update the Sales Order computer...”
Section 3.1.8 Page 9	10/31/01	Perry Danford QC Manager	Added “forwarded to the documentation department for verification.”
Section 3.1.8 Page 9	10/31/01	Perry Danford QC Manager	Added “QC 17 to be used on formal rev changes”
Section 3.1.8a Page 9	10/31/01	Perry Danford QC Manager	Added “ forwarded to the document department for verification”
Section 6.1.1 Page 19	10/31/01	Perry Danford QC Manager	Was “... form QC 18” Now is “... purchase order”
Form QC 2	12 19/01	Perry Danford QC Manager	Modified organizational chart to reflect changes within the purchasing dept.
Section 18.1.2 Page 53	1/31/02	Perry Danford	Was “Training Specialist responsibility” Now is “QC Manager responsibility”.
Section 18.1.3 Page 53	2/13/02	Perry Danford	added training checklist
Section 10.1.16 Page 32	3/5/02	Perry Danford	Added 10.1.16.F
Section 10.1 41 Page 36	3/6/02	Perry Danford	Added “sign the In Process Checklist...”
Section 5.1 7 Page 14	8/22/02	Perry Danford	Added “...personnel who perform incoming inspection...” to access the QC master file.
Section 7.1.1 Page 22	9/04/02	Perry Danford	Added “...Blue paint to indicate Customer Supplied.”
Section 7.1.2 Page 22	12/5/02	Perry Danford	Deleted form QC 24
Section 71.3 Page 22	12/5/02	Perry Danford	Kits are no longer double checked
Section 9.1 5 Page 25	12/5/02	Perry Danford	Added Table C

Section 5.1.19 Page 14	5/9/02	Perry Danford	Added "... and remain legible & readily identifiable."
Section 2	12/9/02	Perry Danford	Deleted form QC 5
Section 6 pages 19 & 20	12/10/02	Perry Danford	Updated section per minutes from November management meeting.
Index	1/14/03	Perry Danford	Added Form QC 20 Customer Satisfaction survey
Various	1/17/03	Perry Danford	Changed Q9000, 1994 to ISO 9001: 2000
Various	5/22/03	Perry Danford	Deleted Form QC 17a
Section 8.1.3 Page 22	9/23/03	Perry Danford	Added "...Computer generated Traveler can be used instead of Form 8a.
Various	2/19/04	Perry Danford	Added Form QC 41
Various	5/3/04	Perry Danford	Rev A of Form QC 8a (In-Process Checklist)
12.1.2	6/21/04	Perry Danford	Eliminated requirement for many stamps, and added the requirement for a single label (date & work order number).
11.1.11 Pg 32	7/26/04	Perry Danford	Added requirements for selection of a calibration facility
15.1.20	8/9/04	Perry Danford	added Humiseal 1B73 to shelf life materials
13.1.9.B Pg 37	10/18/04	Perry Danford	replaced "shipping clerk" with RMA specialist".
5.1.18 Pg 14	10/20/04	Perry Danford	Added an expiration date to uncontrolled documents.
14.1.3 Pg 38	11/30/04	Perry Danford	Added "... or customer specified format"
Misc	1/12/06	Perry Danford	Was...2 production folders Is... one production folder
5.1.5 Pg	1/12/06	Perry Danford	Added the requirement for GREEN paper or highlights for the process sheet and the In-Process checklist for RoHS compliant units.
10.1.7 & 10.1.8	8/4/06	Perry Danford	Changed re-inspection of 1 <sup>st</sup> article to re-inspect 100% for the reject MODE rather than just verifying that the rejected component was corrected
10.1.26	10/18/06	Perry Danford	added "...RoHS compliant boards will be 100% checked for..."
Various	4/18/07	Perry Danford	Deleted form QC 14a, replaced with QC 14 e & 14 f

15.1.20	9/23/07	Perry Danford	Was... Loctite 348 Is...all Loctite products
15.1.20.B	9/24/07	Perry Danford	Added SOP-15-1 shelf life procedure
Various	1/11/08	Perry Danford	Deleted Form QC 39
18.1.1	5/25/08	Perry Danford	Added the person doing the training...
5.1.14	8/8/08	Perry Danford	Added QOP-5-1 ...work instructions...stored in an electronic format
17.1.1	7/1/09	Perry Danford	Added.”..two process audits and one compliance audit per year”
14.1.3	7/1/09	Perry Danford	Was “...maintain corrective action results in New Athens...” Is “...Maintain corrective action results on line”.
17.1.3	7/2/09	Perry Danford	Added Auditor selection criteria
Various	7/20/09	Perry Danford	Changed ISO 9001: 2000 to ISO 9001: 2008
various	9/16/09	Perry Danford	Deleted obsolete forms (transformer dept eliminated)
5.1.5 & 5.1.14	6/11/2010	Perry Danford	Was “QC manager approves typed process sheets.” Is “Lead person or supervisor for that product line shall approve typed process sheets”.
Various	6/11/2010	Perry Danford	Removed the form number from the Process Sheet because they are all different, and the format does not matter.

Form QC 1