

SIEMENS MANUFACTURING COMPANY INC. QUALITY SYSTEM MANUAL

APPROVED BY: John Siemens III
PRESIDENT

DATE: 01/03/2018

APPROVED BY: Perry Danford
QUALITY SYSTEM MANAGER

DATE: 01/03/2018

SIEMENS MANUFACTURING CO., INC. QUALITY POLICY

Siemens Manufacturing Company delivers electronic solutions that exceed customer expectations by continuously monitoring & improving processes, training & partnerships for success in today's business environment

Table of Contents

Section 1: Quality System Policies & Leadership Responsibilities	2
Section 2: Quality System	3
Section 3: Contract Review.....	4
Section 3.1: Contract Review Procedure	4
Section 4: (<i>Currently Not Applicable</i>)	5
Section 5: Document & Data Control (Documented Information).....	6
Section 5.1: Document & Data Procedure (Electronic Assemblies)	6
Quality System Manual Change Procedure.....	8
Organizational Knowledge	8
Section 6: Purchasing	9
Section 6.1: Purchasing Procedure.....	9
Verification Of Purchased Product.....	10
Section 7: Control Of Customer Supplied Product	11
Section 7.1: Procedure For Control Of Customer-Supplied Product	11
Section 8: Product Identification & Traceability.....	12
Section 8.1: Product Identification & Traceability Procedure	12
Section 9: Process Control.....	13
Section 9.1: Process Control Procedures.....	13
Section 10: Inspection & Testing	15
Section 10.1: Inspection & Testing Procedure	15
Receiving Inspection	15
First Article/In-Process Inspection	16
Line Inspection	16
Roving Inspection.....	16
Visual Inspection	16
Electrical Testing	17
Final Inspection	17
First Article (Customer Approval).....	17
Section 11: Calibration Control.....	19
Section 11.1: Calibration Control Procedure.....	19
Section 12: Inspection & Test Status	21
Section 12.1: Procedure For Inspection & Test Status	21
Section 13: Control Of Nonconforming Product	22
Section 13.1: Procedure For Control Of Nonconforming Product.....	22
Returned Material.....	22
Section 1: Corrective Action/Continual Improvement	24
Section 14.1: Corrective Action Procedure.....	24
Corrective Action.....	24
Continual Improvement Procedure	24
Section 15.1: Handling, Storage, Packaging, Preservation, & Delivery Procedures	26
Handling	26
Storage/Receiving	26
Packaging	27
Preservation/Segregation	27
Section 16: Quality Records.....	28
Section 16.1: Procedures For Control of Quality Records	28
Section 17: Internal Quality Audit	30
Section 17.1: Internal Quality Audit Procedure.....	30
Section 18: Personnel Training.....	31
Section 18.1: Personnel Training.....	31
SECTION 19: (This Section Left Blank Intentionally)	31
Section 20: Statistical Techniques	32
Section 20.1: Statistical Techniques	32

Section 1: Quality System Policies & Leadership Responsibilities

1.1. Organizational relationships for Siemens Mfg. Co., Inc. are defined & documented in the organizational chart form QC2.

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

1.3. The department managers of Siemens Manufacturing are responsible for: planning, reviewing, implementing & maintaining quality system policies & procedures as outlined in this manual.

1.4. The Documentation Department is responsible for maintaining current outlined policies & procedures in this manual & for making them available as needed.

1.5. The Quality Department is responsible for determining & providing resources (including information, equipment, & 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 Department is responsible for determining & providing resources needed to enhance customer satisfaction by meeting customer requirements.

1.6. The Siemens Mfg. Co. President shall preside over (as a minimum) quarterly management meetings. The Siemens Mfg. Co. leadership team shall have the authorities & responsibilities to establish, implement, maintain, & continually improve the quality system to ISO 9001:2015 (excluding design) version requirements. The Quality Department will report on the performance of the quality system for management review.

1.7. The Quality Department is responsible for determining opportunities for improvement (corrective actions) using 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) & for presenting these opportunities to a management review meeting to determine objectives with measurable goals. Any additional analysis will be determined at the management review meeting. The Quality Department is also responsible for determining an index of customer satisfaction by monitoring returned material & on time delivery, & for presenting this index at the management meeting.

1.8. The Quality Department is responsible for determining opportunities for improvement (preventive/corrective action) using trend analysis of information related to customer satisfaction.

1.9. Every 12 months, as a minimum, Siemens Mfg. Co., Inc. performs a management review to review the suitability & effectiveness of the Quality System, Quality Policy, as well as Quality Objectives & Quality Management System changes set at the management review meeting. The results of the review shall be recorded.

1.10. The leadership team shall determine the relevant interested parties for Siemens as well as determine the requirements of those interested parties that are relevant to Siemens Mfg. Co. This list of interested parties shall be reviewed annually.

1.11. The leadership team shall assure that the Quality Policy and Goals & Objectives are compatible with the strategic direction of the company, determining an action plan when established goals are not met, & promoting the process & risk-based thinking as well as communicating those objectives to the employees.

RECORDS:

Management Review

Section 2: Quality System

Scope:

The Quality Management System (QMS) includes or references 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 & 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 actions, requirements of relevant interested parties, & management review. The Quality Management System (QMS) also includes or references all procedures necessary for compliance to ISO 9001:2015 requirements with the exception of Design & 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, & 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 9001:2015 to carry out specific tasks/activities.

2.2. Specific procedures have been established for those activities where the skills & qualifications of the tasks require further instructions.

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, & other supporting documents.

2.4. Procedures as part of the Quality Manual meet requirements of ISO 9001:2015, & support the Quality Policy. Specific procedures provide more details where needed to assist in specific methods.

2.5. The documented Quality System outlined in Section 3 is the method used by Siemens Mfg. Co., Inc. to produce assemblies that conform to product requirements. Quality planning is accomplished by completing form QC17, Pre-Production Checklist.

- A.** Siemens Mfg. Co., Inc. directs its activities based on customer requirements & expectations. Any project requiring quality planning comes from customer demands or requests. These projects are determined by quote & production DFM meetings, & a Pre-Production Checklist (form QC17) will be filled out for each new high level assembly number.
- B.** For contract & product changes, quality planning is conducted using the Engineering Change Notification (see Section 3).

2.6. The completed form QC17 records quality planning activities, evaluating risk & opportunities. The Engineering Change Notification form (QC33) documents any updates, revisions, & clarifications of selected projects.

2.7. Factors used to determine the Scope of this QMS include internal & external issues, requirements of relevant interested parties, and products & services of Siemens Mfg. Co. See Quality Policy for company Purpose.

RECORDS:

Form QC17, Pre-Production Checklist

Form QC33, Engineering Change Notification

Section 3: Contract Review

1. Siemens Mfg. Co., Inc. has established & 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 & documented.
 - B. Differences are resolved.
 - C. Siemens Mfg. Co., Inc. has the capability to produce & 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 Engineering Change Notification form (QC33) 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 customer service personnel will review the customer product & delivery requirements, contact the customer for clarifications (if necessary), & request a preliminary quote (computer generated form) from the quote department. The Quote Department will hold a quote DFM meeting to evaluate the requirements for risk & opportunities. The preliminary quote information will then be forwarded to the Siemens Mfg. Co., Inc. President (or his designee) for approval.
- 3.1.2. The Siemens Mfg. Co., Inc. President (or his designee) 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 a Customer Service/Sales team member for drafting of a Formal Price Quotation.
- 3.1.3. A Customer Service/Sales team member will use the information on the approved preliminary quote to generate the Formal Price Quotation.
- 3.1.4. The Customer Service Sales team member will then print one copy of the Formal Price Quotation.
- 3.1.5. Left blank intentionally.
- 3.1.6. When a purchase order (P.O.) is received by Siemens Mfg. Co., Inc., the Customer Service representative 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. "DATED", forward a copy of the P.O. to the BOM Department (if no Siemens part number exists) & the original P.O. to clerical personnel who will set up a folder.
 - D. Email 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.), a Customer Service Representative will resolve the issue with the customer.
- 3.1.6b. All customer-initiated changes will be routed to the Customer Service Representative. If the change received by Siemens involves only changes to the delivery dates, then the Customer Service Representative will update the Sales Order on the computer as well as notify Purchasing Department. If the change request does not involve delivery dates, then the Customer Service Representative will fill out form QC33 (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 (in conjunction with customer service) receives form QC33, the team member will work with the

customer & take all steps necessary to resolve the problem(s) noted. The team member will then fill out the resolution portion of the form (if not already completed). Ref. 3.1.7a for routing of the completed form.

3.1.7a. If a resolution specified on form QC33 requires a new quote, Customer Service will forward the request to the Quote Department.
Note: The Sales Order can only be revised if the customer has given authorization.

3.1.8. On receipt of the P.O. for a new part number, the BOM Department will reference the information from the electronic quote file & have a Siemens Bill of Materials (B.O.M.) generated which will be forwarded to the Documentation Department for verification. It is, furthermore, the BOM Department's responsibility upon receipt of a purchase order to initiate the Pre-Production Checklist (form QC17).
NOTE: Form QC17 is to be used on new jobs only, & will not be used on repeat jobs. The BOM Department will fill out all of page one (with the exception of first article quantity, test required, or test procedures, under the Documentation Received section). Remainder of form to be completed during Production DFM meeting.

3.1.8a. Upon receiving either an approved Equivalent Item Authorization form (QC6) or an approved Engineering Change Notification form (QC33), the BOM Department will make all necessary changes to the computer database, generate a new Siemens B.O.M., & send a copy of form QC6 (or QC33 form as applicable) to Documentation for verification. The BOM Department will forward the Equivalent Item Authorization to Documentation for reference.

3.1.9. Left blank intentionally.

3.1.10. Left blank intentionally.

3.1.11. Left blank intentionally.

3.1.12. If at any time during manufacturing, a supervisor becomes aware of a problem that may affect the cost, that supervisor will discuss the problem with the customer & the Siemens supervisors responsible for that product line to resolve the issue in conjunction with Customer Service. The recommended changes will be noted on the Engineering Change Notification form (QC33) resolution section which will be forwarded to the affected Supervisor for implementation.

3.1.13. Left blank intentionally.

3.1.14. On receipt of an Equivalent Item Authorization form (QC6), 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). Approved Equivalent Item Authorization form (QC6) will be forwarded to the BOM Department.

Note: In addition to the Engineering Manager, the following personnel are authorized to approve an equivalent item: The Quality System Manager & the Company President.

3.1.15. Left blank intentionally.

3.1.16. All approved changes will be routed to the affected department supervisors/lead people.

RECORDS:

Form QC6, Equivalent Item Authorization
Form QC33, Engineering Change Notification
Form QC17, Pre-Production Checklist

Section 4: (Currently Not Applicable)

Section 5: Document & Data Control (Documented Information)

1. Siemens Mfg. Co., Inc. has established & maintains specific methods to control documents & data that relate to the requirements of ISO 9001:2015 & 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, approval, availability, retention, change, & removal of invalid and/or obsolete documents.

Section 5.1: Document & Data Procedure (Electronic Assemblies)

5.1.1. Each assembly part number shall have a digital assembly folder that will contain a master list of documents that are available for the production of that assembly.

5.1.2. The Documentation Department will maintain a master list and/or system for creating & maintaining quality procedures & reference material that pertain to conformity to product requirements (i.e. ANSI/J-STD-001, IPC-610, miscellaneous issued documents, etc.). Posted documents shall have (but not limited to) an approval name, date of approval, & (as applicable) a revision number. The master list shall list the date of approval or revision number.

5.1.3. Left blank intentionally.

5.1.4. Customer data & documents pertaining to assembly (including test procedures & changes) received will be forwarded to the BOM Department. Copies received from the BOM Department will be handled as listed below.

- A. For new assemblies, the BOM Department will create a Siemens BOM package (part number, Siemens Bill of Material, & Pre-Production Checklist). For revision changes, the BOM department will update the BOM package (ECN, updated part number, updated documentation).
- B. BOM department will forward Siemens BOM package along with customer documentation to the Documentation Department.
- C. For a new assembly part numbers, the Documentation Department will create a digital Master folder & production folder. The master folder will contain all documents (including E-mails) issued by the customer & any documents created by Siemens (PPCL, Quotes, POs).
- D. The Documentation Department will compare the documentation received to the documentation on file. If the documentation received is not identical to the file copy or if there is no file copy, assign a document number.
- E. Retrieve/dispose of all earlier versions of documents being replaced from the locations/persons listed on the master list with the exception of the QC file copy, which will be moved to the digital Obsolete folder (within the master folder) for reference.
- F. Issue new/revised documentation to the digital production folder.
- G. Record the distribution of documents onto the master list. **Note:** If there is no revision number on the documentation received, then use the revision date listed on the document. If there is no revision number or date, use the date the document was received.
- H. First article folders will be printed out for new part numbers with an active job. Any document on the master list that is issued to the production folder will have its document number on it, a "Controlled Copy When Red" & date stamp. If the assembly is leaded, all documents will be kept in a blue folder. If the assembly is ROHS, all documents will be kept in a green folder. First article folders are to be labeled by customer name, Siemens assembly number & customer assembly number/description. First article folders are to be given to the lead person responsible for running the assembly.

5.1.5. Siemens process sheets will be reviewed & approved by the lead person or supervisor for that product line. Documentation personnel will issue one copy to the digital production folder.

Note: The original process sheet is located in the digital Master folder.

5.1.6. Left blank intentionally.

5.1.7. Only the Quality Department is authorized to have editing rights to the digital Master file.

5.1.8. Siemens employees have access to view their location's process sheets, digital master folders or digital production folders.

5.1.9. Left blank intentionally.

5.1.10. Left blank intentionally.

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

5.1.12. Siemens Test Procedures: Upon notification that a Siemens Mfg. test procedure may not be accurate, the Engineering Department will review that test procedure. If changes are necessary, then the Engineering Department 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 & 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. Customer Test Procedures: Upon notification that a customer supplied test procedure may not be accurate, the Engineering Department will review that test procedure. If changes are necessary, then the Engineering Department will work with Customer Service and:

- 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 revision number 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 to (reference 5.1.18; uncontrolled document) the Siemens Process Sheets or work instructions can be requested by anyone as long as they contact the lead person for approval. The person making the change will forward the change to Documentation or lead person for updating. The lead person for that product line or production manager will approve the updated 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. Deviations can be requested by anyone with approval from the Quality System Manager, Engineering Manager, &/or the Production Supervisor. The person requesting the change will initial & date the change. The person requesting the change will also note the Supervisors initials as well as 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 & distribute to appropriate personnel.

5.1.16. Left blank intentionally.

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 & approval.

5.1.18. Uncontrolled copies of "Controlled" documents can be made, which will be stamped "Uncontrolled Copy" & assign a job number or expiration date (2 weeks from the day it is stamped). The uncontrolled copy will be discarded when the job has been closed or has exceeded its expiration date.

5.1.19. Left blank intentionally.

5.1.20. The Engineering Department will maintain a master list of PWB data files.

5.1.21. Data received (PWB data) will be forwarded to the Engineering Department who will:

- A. Copy the data electronically 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 & the version prior the latest version will be maintained electronically.
- F. **Note:** PWB data received from customers will only be reviewed by Siemens Mfg., Inc. for manufacturability.

5.1.22. PWB data (including changes) generated by Siemens Mfg., Inc. will be reviewed/approved by the Engineering Department prior to release of the data by entering his initials into the Reviewed/Approved section of the title block.

5.1.23. Left blank intentionally.

5.1.24. Customer requested changes to customer supplied PWB data will be forwarded to the Engineering Department 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 (interoffice envelopes, E-Mail) to the Quality Department personnel who will:

- A. Review the requested change with all affected supervisors &, 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 QC1).
- D. Update the master Quality System Manual electronically.
- E. Update the Quality System Manual electronically.
- F. Determine, if necessary, a method of implementation for all approved changes (ref: Section 2.5.B, Quality Planning).
- G. Retrain all affected personnel if required (ref. Section 18.1.6).

Organizational Knowledge

5.1.26. Siemens Mfg. Co. shall maintain records (PC database) of knowledge gained from experience/process improvements as appropriate (corrective actions, changes to process sheets, projects etc.) as well as maintaining current revisions of relevant standards as appropriate).

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 & maintains specific methods to ensure that purchased product conforms to specified requirements. The Siemens purchasing procedure (Section 6.1) specifies methods to select & evaluate suppliers, defines the type & extent of control that Siemens has over suppliers, indicates what data shall be included on purchasing documents, defines verification requirements of purchased product, & details review & approval procedures for purchasing documents.
2. Records of acceptable suppliers shall be kept per Section 16.
3. The Quality & Purchasing Departments will establish & maintain procedures (QOP-06-01) to:
 - A. Evaluate subcontractor performance using incoming inspection records.
 - B. Add suppliers to the list of approved suppliers.
 - C. Remove suppliers from the list of approved suppliers.
4. The Quality & Purchasing Departments will (per QOP-06-01) maintain a master list (EPICOR database) of approved suppliers.

Section 6.1: Purchasing Procedure

- 6.1.1. When a job is available to purchase on the "Buyer Stoplight" Smartsheet, the designated buyer will:
 - A. Order components & obtain delivery commitments for components.
 - B. Follow the steps in the Program Part Decision Tree (form QC10) in conjunction with Engineering & the BOM group. Program Part information will be documented on form QC9.
 - C. List the date that the last part, for the job being purchased, is due on "Buyer Stoplight" Smartsheet.
 - D. Make one copy of each purchase order for filing & to be used by the Accounting Department.
- 6.1.2. If a better price and/or delivery date is found during the purchasing phase, then the Purchasing team can order the less expensive part rather than using the quoted price & source as long as the replacement part is a customer approved part from an approved supplier. For non-custom items, an approved supplier is a distributor franchised to sell that part.
- 6.1.3. The Purchasing team will buy parts to the latest B.O.M.
- 6.1.4. The Purchasing team will order parts to the latest B.O.M. Any deviation from the Bill of Materials requires written approval from the customer (Form QC6) unless the customer has a blanket EIA or 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 the buyer will contact the Purchasing manager/Engineering manager/Customer Service (as appropriate). The Purchasing team can then order parts awaiting approval (**note:** these parts will be rejected at incoming inspection if received prior to approval).
- 6.1.5. The Purchase Order shall contain data clearly describing the product ordered, including where applicable:
 - A. Detailed component description.
 - B. Manufacturer.
 - C. Manufacturer's part number.
 - D. Quantity ordered.
 - E. Quoted price.
 - F. Type, grade, or class.
 - G. Siemens part number.
 - H. Title, number, & issue of the quality system standard to be applied.
 - I. Drawing name &/or number including any revision number.
 - J. Other relevant technical data.
- 6.1.6. Left blank intentionally.
- 6.1.7. If Siemens Mfg. is unable to locate parts & will, therefore, be unable to meet a customer's requested delivery date, then the Purchasing team will:
 - A. Attempt to locate the part elsewhere (franchised distributor).
 - B. Expedite the part from the supplier.
 - C. Request an Equivalent Item Authorization (Form QC6) per Section 6.4.
 - D. Attempt to locate parts from a non-franchised distributor (broker) that has controls in place to assure component traceability

back to the manufacturer or adequate inspection to mitigate counterfeit parts. Parts from these suppliers shall require inspection from Siemens QC personnel prior to receiving. Prior to ordering from a non-franchised distributor, buyer will complete a Non-Approved Vendor Agreement form (Form QC52), submit the form to customer service & receive signed form back.

6.1.8. 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.

6.1.9. Procedures for the evaluation & selection of suppliers can be found in QOP-06-01, SUBCONTRACTOR EVALUATION.

Verification Of Purchased Product

6.1.10. Left blank intentionally.

6.1.11. Left blank intentionally.

6.1.12. When Siemens Mfg. Co., Inc chooses to outsource a process that could affect product conformity, Siemens shall ensure control over the results of such processes. Relevant documents shall be sent to supplier with the purchase order. Supplier or component shall have inspection required in Epicor.

RECORDS:

QC6 Equivalent Item Authorization

QC33 Engineering Change Notification

QC52 Non-Approved Vendors Agreement

REFERENCE:

QOP-06-01 Subcontractor Evaluation Procedure

Section 7: Control Of Customer Supplied Product

1. Siemens Mfg. Co., Inc. has established & maintains specific methods to verify, store & maintain customer supplied product provided for 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 Receiving Department personnel, upon receipt of customer-supplied parts, to inventory the material using the customer supplied documentation or Siemens consigned PO. The material will be checked for damaged parts & quantity (for reels, sealed bags, cut tape, & hardware the quantity printed on the bag/box will be used). A Siemens label with a part number containing customer information will be affixed to the material (if 100% customer supplied parts), or to each bag/box of components (if the material also contains Siemens purchased components).

7.1.2. Customer supplied forms will be filled out per customer procedures unless violating another section of this manual.

7.1.3. Left blank intentionally.

7.1.4. Left blank intentionally.

7.1.5. Left blank intentionally.

7.1.6. Left blank intentionally.

7.1.7. Left blank intentionally.

7.1.8. Customer supplied parts will be given a unique Siemens part number to differentiate from Siemens & other customer material.

7.1.9. Customer supplied test fixtures will be labeled with a "Customer Supplied" sticker as well as a unique identification sticker (SMC-xxx). Fixtures that are comprised of multiple components can all have the same SMC sticker number because they are all a part of the same fixture.

7.1.10. Customer supplied test fixtures or electronic test equipment (o'scopes, meters, etc.) will be controlled using the procedures listed in the Calibration Control section (Section 11.1)

7.1.11. The Engineering Department will notify the customer of any problems noted in steps 9 or 10 above.

RECORDS:

E-Mail (For customer notification)

Section 8: Product Identification & Traceability

1. Siemens Mfg. Co., Inc. has established & maintains specific methods to identify product using the Production Identification & Traceability procedure (Section 8.1).
2. All components & products will be identified by suitable means, from receipt & through all stages of production, delivery, & (where required) installation.
3. Siemens Mfg. incorporates limited traceability activities as described in the Product Identification & Traceability procedure (8.1).
4. Records of this identification for traceability are kept per Section 16.

Section 8.1: Product Identification & Traceability Procedure

8.1.1. Upon receipt, components will be identified by an Incoming inspector with a Parts Identification sticker (Computer printout), ref. Section 10 under Streamline Receipt Entry. 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 into which the parts are placed shall be labeled with, as a minimum, the Siemens part number.

8.1.2. As electronic components are kitted, an employee will verify that each component kitted has a unique lot code on the Identification sticker.

8.1.3. Subassemblies & in-process materials will be identified throughout production by the Job traveler. **EXCEPTION:** Boards being transported between rework & washing do not need a Job traveler if the boards are to be washed & returned immediately.

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 & (if used) on the Siemens shipping carton by the shipping personnel:

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

RECORDS:

Assembly transfer history in EPICOR

REFERENCE:

Job Traveler

Section 9: Process Control

1. Siemens Mfg. Co., Inc. shall determine & plan the production, installation, & servicing processes which directly affect conformity to product requirements & 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 & working environment, use of suitable equipment, compliance with reference standards, monitoring & control of process parameters, approval of processes & equipment, criteria for workmanship, equipment maintenance, & procedures defining the manner of production, installation, & servicing, where the absence of such procedures could adversely affect conformity to product requirements.
2. Records of qualified processes, equipment, & personnel are kept, as appropriate, per Section 16.

Section 9.1: Process Control Procedures

- 9.1.1. If required by contract, installation & servicing requirements can be implemented & a plan for implementation will be developed as part of the Contract Review procedure (ref: Section 3.1).
- 9.1.2. When a released job arrives at a production line the Lead person will:
 - A. First time builds, get a first article folder from Documentation & create a process sheet.
 - B. If repeat build, review process sheet to ensure accuracy.
 - C. Supervise operators in following process sheet.
- 9.1.3. The Production Supervisor will ensure that the equipment (hardware & software) & other resources (including information, workspace, utilities, buildings) used for production & testing of product is adequate, & that these functions are performed in a suitable work environment. Management will ensure that any necessary supporting services (transportation, communication, information systems) are adequate.
- 9.1.4. The Production Supervisor will refer to the Epicor job date & priority to determine priorities for manufacturing & will refer to the Sales Order list to determine priorities for deliveries.
- 9.1.5. Siemens Mfg. Co., Inc. will ensure compliance with reference standards, quality plans, and/or documented procedures by monitoring & approving all processes listed on the Job traveler (ref. Section 10.1, First Article/In-Process Inspection, as well as form QC53, the Process Flow chart).
- 9.1.6. Productions equipment requiring preventive maintenance (PM) will be listed on the maintenance software list. Preventive maintenance will be done using procedures found in the operator's manual for the equipment requiring preventive maintenance. The results of the preventive maintenance will be recorded on the maintenance software.
- 9.1.7. At this time, Siemens Mfg. Co., Inc 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 apparent only after the product is in use), that process shall be validated. Validation parameters shall be established by Line Lead person, Production Supervisor, Quality Engineer or Management, & shall include (as a minimum);
 - A. Define criteria for review & approval of the process.
 - B. Approval of equipment & qualification of personnel.
 - C. Use of specific methods & procedures.
 - D. Requirements for records.
 - E. Re-validation.

9.1.9. Workmanship standards for the operations listed on the Job traveler are:

	Process	Standard
A.	Issue Parts to Job	Bill of Materials
B.	SMD Assembly	Sample or Assembly Drawing, ANSI/IPC-A-610 (latest rev)
C.	QC SMD	Sample or Assembly Drawing, ANSI/IPC-A-610 (latest rev)
D.	SMD Inspect	Sample or Assembly Drawing, ANSI/IPC-A-610 (latest rev)
E.	Dip Insertion	Sample or Assembly Drawing, ANSI/IPC-A-610 (latest rev)
F.	QC Dip	Sample or Assembly Drawing, ANSI/IPC-A-610 (latest rev)
G.	Axial Insertion	Sample or Assembly Drawing, ANSI/IPC-A-610 (latest rev)
H.	QC Axial	Sample or Assembly Drawing, ANSI/IPC-A-610 (latest rev)
I.	Pre-Line	Sample or Assembly Drawing, ANSI/IPC-A-610 (latest rev)
J.	QC Pre-Line	Sample or Assembly Drawing, ANSI/IPC-A-610 (latest rev)
K.	Line	Sample or Assembly Drawing, ANSI/IPC-A-610 (latest rev)
L.	QC Line	Sample or Assembly Drawing, ANSI/IPC-A-610 (latest rev)
M.	Solder Wave	Process Sheet, ANSI/IPC-A-610 (latest rev)
N.	QC Wave	ANSI/J-STD-001 (2005 version), ANSI/IPC-A-610 (latest rev)
O.	Board Cleanliness	ANSI/IPC-S-815 rev. B
P.	Off Line	Sample or Assembly Drawing, ANSI/IPC-A-610 (latest rev)
Q.	QC Offline	Sample or Assembly Drawing, ANSI/IPC-A-610 (latest rev)
R.	Board Trimming	ANSI/IPC-A-610 (latest rev)
S.	Inspection	ANSI/IPC-A-610 (latest rev); Sample or Assembly Drawing
T.	Testing	Test Procedure
U.	Rework/Repair	IPC-7711/7721 Rework/repair of electronic assemblies
V.	Burn-In	Test Procedure
W.	Conformal Coating	Sample or Assembly Drawing, ANSI/IPC-A-610 (latest rev)
X.	Packaging	Process sheet

REFERENCES:

- ANSI/J-STD-001 (2005 version), Requirements for Soldered Electrical & Electronic Assemblies
- ANSI/IPC-A-610 (latest rev), Acceptability of Electronic Assemblies
- ANSI/IPC-S-815 rev B, General Requirements for Soldering Electronic Interconnections
- Form QC53, Process Flow chart

Section 10: Inspection & Testing

1. Siemens Mfg. Co., Inc. has established & maintains specific methods for inspection & 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 class II specifications. These methods are described in the Inspection & Testing Procedure, Section 10.1.
2. These procedures apply regardless of the amount of control exercised, or the types of inspection techniques used at a supplier's facility.
3. The type of component inspected & inspection parameters are described in Section 10.1. No part, including urgent releases, will be used until it has been inspected & accepted.
4. Records of inspection & testing are kept per Section 16.

Section 10.1: Inspection & Testing Procedure

Receiving Inspection

10.1.1. Siemens purchased parts received will be inspected &/or tested for conformance & compliance to blueprint, drawing and/or specification requirements. When actual measurement values are required by purchase order or contract, the values will be recorded as required for traceability. Otherwise, accept/reject criteria will be used (see Section 10.1.4 & 5). **No Siemens purchased part will be used until the lot has been inspected & accepted.**

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

- A. Awaiting inspection (Receiving area). Responsibility: Receiving personnel.
- B. Inspected & approved (Kitting/stock area). Responsibility: Parts Department.
- C. Inspected & rejected (Rejected materials cabinet). Responsibility: Receiving personnel
- D. Material Hold area. (Note: Each Lead Person has their own Hold area at their line).

10.1.3. Product that is awaiting disposition (whether to accept, reject, scrap, awaiting shortages, etc.) will be kept in a Materials Hold area & will be identified with a REJECT label (computer printout).

10.1.4. Incoming inspection for electronic components will be done in the following manner:

- A. The Incoming Inspector will open the streamline receipt entry screen (EPICOR access). If all information listed does not match the requirements, the parts will be rejected & the buyer will be notified.
- B. The Incoming Inspector will not inspect any given part until all P.O. discrepancies are resolved.
- C. All parts inspected will be checked for physical damage (ref: ANSI/IPC-A-610, latest rev), & will have the quantity received verified (for reels, sealed bags, cut tape, & hardware the quantity printed on the bag/box will be used).
- D. All custom/manufactured components will be compared to the latest drawing & all marked dimensions will be measured using calibrated tools, with the inspection lot size for dimensional measurements of one unless otherwise noted.
- E. All static sensitive components will be received in anti-static/shielded packaging or it will be rejected (ref. Section 13.1).
- F. All static sensitive components (more than 2 leads as a guideline. Reference also ESD & component ID training) will be handled only at static safe work stations.
- G. Moisture sensitive surface mount I.C.s received in factory sealed bags will not be opened for inspection, unless needed to verify quantity or to check for damage from shipping. The manufacturer part number & manufacturer will be verified using the information on the factory parts ID sticker & the marking on the components. The bag will be re-sealed with the desiccant when inspection has been completed.
NOTE: parts with labels (programmed parts) will NOT have the label removed for inspection purposes.
- H. Other components received will be verified by checking the manufacturer's part number, manufacturer, & the physical description from the Purchase Order, with the inspection lot size determined by the Dodge & Romig single sampling plan, AOQL=5%.
- I. Any components received that have a date code will have that date code from the manufacturer's label (or from the component) entered into the incoming inspection database for traceability purposes.
- J. The inspector will take a photo of the manufacturing label (or another attached label). The photo will be saved to PC file by lot code.

10.1.5. Upon completion of incoming inspection of electronic components:

- A. The Incoming Inspector will transcribe the lot code & quantity from the computer screen (EPICOR system) onto the packing slip, affix the printed bar code label onto the parts, then place the accepted parts on the shelf & 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 & 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 lot code is 12345. The first reel will be marked 12345A, the second reel will be marked 12345B, & the third reel will be marked 12345C.
- Note:** Only ONE part number will be processed at a time. The part will be completely processed, & the printed label attached before the next part number is placed on the receiver's desk for processing.
- 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 QC55, or equivalent) will be included.

First Article/In-Process Inspection

10.1.6. A first article is required upon completion of the first assembly at any manufacturing step. First article jobs will receive a first article folder from Documentation. First article folder will contain the first article form to be filled out per First Article Process. A First Piece inspection will also be done with a REVISION change. The verification will be limited to the changes that are noted in Epicor (BOM notes) subsequent to previously verified changes.

10.1.7. Should the first (or random) item manufactured & inspection not meet documented requirements, follow First Article Process instructions.

10.1.8. If any discrepancies are noted by the Inspector, then the lot will be rejected & the lead person will be notified. A rejected lot may be 100% inspected (if directed by a supervisor) & then only the defective product (rather than the entire lot) will be rejected.

10.1.9. Left blank intentionally.

10.1.10 Left blank intentionally.

Line Inspection

10.1.11. Personnel performing inspections will:

- A. Verify all hand placed parts conform to specifications (correct part, orientation, etc.).
- B. Inform the assembler of any defect noted so the assembler can correct the defect.
- C. Contact the Lead Person for that line as well as a Quality Engineer immediately any time excessive (more than 10 per type per day) defects are noted.
- D. Record all defects noted on Form QC14 or enter in ERP system directly. Follow non-conformance process as applicable.

Roving Inspection

10.1.11.5. Roving inspection will verify that written procedures are being followed.

Visual Inspection

10.1.12. Assemblies will get visual inspection per process sheet.

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

10.1.14. Printed circuit assemblies will be inspected using the AOI Automated Optical Inspection Machine as indicated in the process sheet.

10.1.15. All assemblies will then be final inspected per process sheet & defects will be entered into ERP or fill an Inspection Report (Form QC14). 100% of the printed circuit assemblies will be inspected unless specified otherwise by the customer or the Process Sheet for that job. The Quality Department 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 Department will add to the Process Sheet what sampling plan is to be

used for that job.

10.1.16. Left blank intentionally.

10.1.17. All discrepancies found manually (i.e. not found by the vision inspection machine) will be entered into the ERP system or noted on the inspection report (Form QC14). Non-conforming material shall be dispositioned per Section 13.

10.1.18. The Quality Department shall be notified of any major discrepancies. This includes issues where defects may have escaped the facility or indicate a large or continuing trend. This will allow the Quality Department to immediately investigate the problem &, if possible, correct the process that is producing the discrepancies. If the magnitude of the problem exceeds established limits (per Risk Assessment tab of Siemens CAR Form), then written corrective action (form QC55, or equivalent) must be initiated. If a process changes 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.

Electrical Testing

10.1.19. Left blank intentionally.

10.1.20. Printed Circuit assemblies that pass an electrical test will be labeled per work instructions (if there is room on the board).

10.1.21. Printed Circuit assemblies that fail testing or inspection will follow the red tag process.

10.1.22. All component rework & repair will conform to ANSI/IPC-A-610 (latest rev), &/or customer requirements & specifications, & will be re-tested (if applicable).

10.1.23. All rework & repair of the printed circuit boards will conform to **IPC-7711/7721**) Rework/repair of electronic assemblies) and/or customer requirements & specifications & will be re-tested (if applicable).

10.1.24. The person performing the test will fill out a Test Report (form QC14F) indicating the technicians name, the date, the job number, the quantity of assemblies tested, the quantity of boards failed. The person performing repairs will fill out a Repair Report (form QC14E) 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. A Certificate of Conformance will be printed out with the packing list & included with the shipment.

10.1.26. Left blank intentionally.

10.1.27. Left blank intentionally.

10.1.28. Left blank intentionally.

10.1.29. Left blank intentionally.

10.1.30. Left blank intentionally.

10.1.31. Left blank intentionally.

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 & ready for shipment will be forwarded to QC personnel (along with a First Article Inspection Form, form QC59) who will inspect the assembly per the sections for Visual Inspection & Final Inspection. If the lot is acceptable, it will be shipped to the customer along with Form QC59. **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, Quality System manager, or

Customer Service 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.

10.1.33. When required by the customer, the First Article procedure will include the use of AIAG PPAP procedure. This will include, where appropriate, requiring that the PPAP procedure be followed by our suppliers of custom parts.

RECORDS:

QC6, Equivalent Item Authorization of Electronic Assemblies

QC55, Corrective Action Response

QC59, First Article Inspection

Assembly transfer history in EPICOR

BOM printout (First Piece inspection)

EPICOR BOM note (First Piece inspection; rev change).

Information from the following forms will be transferred to EPICOR where it will be stored as a record: AOI printout, QC14 Inspection Report, QC55 Technician Report-CAR form, QC4E Repair Report, QC14F Test Report.

REFERENCES:

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

J-STD-001 (2005 version), Requirements for Soldered Electrical & Electronic Assemblies

IPC-7711/7721 Rework/repair of electronic assemblies

Process Sheet

Creating & maintaining a reject standard: SOP-10-01

Section 11: Calibration Control

1. Siemens Mfg. Co., Inc. has established & maintains specific methods to control, calibrate, & maintain inspection, measuring, & test equipment. These methods are described in the Calibration Control Procedure (Section 11.1). Records of calibration are kept per Section 16.
2. Test equipment that is used as suitable forms of inspection shall be included as part of the calibration control procedure.
3. Proof of calibration shall be made available for all calibrated equipment.
4. Where a Gage R & R is required, the acceptable gage R & R total variability shall be less than 10%.

Section 11.1: Calibration Control Procedure

11.1.1. When Siemens specified testing or calibration is required, the Quality department personnel, Engineering department personnel will determine the measurements to be made & the accuracy required, & then select equipment that is capable of the necessary accuracy & precision. The measurement & equipment requirements will then be recorded on the product test/calibration procedure. If calibration is not required, the item will be labeled as "Calibration not required".

11.1.2. When customer specified testing or calibration is required, the customer will specify and/or approve the measurements to be made & the accuracy required. The Quality department personnel, Engineering department personnel will then select the appropriate equipment that is capable of the necessary accuracy & precision. The measurement requirements will be recorded on the customer supplied test procedure.

11.1.3. The Quality department personnel will identify all inspection, measuring, & test equipment that can affect conformity to product requirements with a sticker that has a unique SMC sequential number typed on it. All in-house equipment calibration records & procedures for equipment listed on the Master Calibration list will be filed by this SMC number. Any unit found to be out of calibration will not be used, & Quality department personnel will be notified (handheld units will be given to the QC dept).

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

11.1.5. The Quality department will determine calibration intervals for all calibrated equipment. The calibration interval will be recorded as part of the master calibration list. The calibration interval can be adjusted based on the calibration history of the equipment in question.

11.1.6. The Quality department or the Engineering department 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 the master calibration list.

Note: Torque wrenches will not be calibrated individually but will be verified as accurate prior to use (same day) against a calibrated torque standard.

11.1.7. All inspection, measuring, & 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 in the master calibration list.

11.1.8. The Quality System Manager and/or Engineering will determine the procedure for all in-house calibration of inspection, measuring, & 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 & uncertainty of the calibration equipment to be used, the acceptance criteria, & 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 record the calibration results onto the Calibration Record (form QC7B), & forward the Calibration Record to the Quality department for traceability. A label, which shall show the calibration/verification due date, will be placed near the items SMC number.

11.1.10. All in-house calibration will be performed by qualified personnel (QC Mgr, Engineering, technician).

11.1.11. All equipment requiring calibration that is not calibrated in-house will be calibrated by a qualified (traceable to National Standards) & 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 National Standards requirements. A **Report of Calibration** must accompany all returned calibrated equipment, which shall include the measurements taken. 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 (with calibration date & due date) affixed to it, & the results of the calibration will be recorded on a Certificate of Calibration which will be forwarded to the Quality department for traceability.

11.1.13. The Quality department and/or the Engineering department will review all calibration records, assess & document (Form QC7A) the validity of previous inspection & test results when inspection, measuring, or test equipment is found to be out of calibration.

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

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

RECORDS:

QC7A, Calibration Evaluation

QC7B, Calibration Record

Section 12: Inspection & Test Status

1. Siemens Mfg. Co., Inc. has established & maintains specific methods to indicate the inspection & test status of conforming & nonconforming product. These methods are described in the Procedure for the Indication of Inspection & Test Status, Section 12.1.
2. The Quality department will make certain that items will retain an indication of their inspection & test status at all times. This is accomplished through the use of the Job traveler, red "Reject" tags, and/or individual inspection & test stamp(s)/label(s) when required by the customer.
3. The identification of inspection & test status will be maintained throughout production, installation, & servicing of the product to ensure that only product that has passed the required tests & inspections is released for further processing or use.
4. Records of inspection & 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 & found to be acceptable will receive the appropriate label (if there is enough room for the label, laser etch as appropriate). If there is not room on the product for a label then Epicor transactions 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, & the product is ready to be shipped. The format of the label will be the date (MM/YY R job number) the R is used only for RoHS identification or per work instructions if different format. Customer instructions supersede this format.

RECORDS:

Assembly transfer history in EPICOR

Section 13: Control Of Nonconforming Product

1. Siemens Mfg. Co., Inc. has established & 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, & 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 follow procedure RECV-010_Incoming-Broker Rejects process.

13.1.2. Left blank intentionally.

13.1.3. If, during production, customer supplied electronic components are lost or damaged the lead person for that job will fill out a shortage requisition (QC43.7) & forward the requisition (along with all damaged parts to be returned to the supplier, if applicable) 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 & replaced at Siemens expense. Siemens purchased components that were received damaged will be returned to the supplier for replacement using the Non-Conformance DMR process. Customer supplied components that were received damaged will be returned to the customer & replaced at the customer's expense.

13.1.4. When defects are found during in-house inspection, the Inspector will fill out an Inspection Report (form QC14), if there is not a touchscreen available). This record shall include, as a minimum, the quantity of items checked, the type & quantity of defect found, the job number, the date, & the Inspectors initials. The inspector will then, if possible, rework the defective product. If rework is not possible at this time, the board will be tagged & forward to the appropriate person for repair. The red toe tag will be disposed of once the rework has been inspected. If product is damaged beyond normal rework criteria (damaged board, excessive cost, etc.), the lead person will scrap the board in Epicor, adding a comment as the reason for scrap.

13.1.5. If a problem is found that will delay production or delivery, or could affect product already in use by the customer, Customer Service will be notified by a member of the Material Review Board (MRB)/Sales Department. **Example:** Product cannot be manufactured or repaired to customer specifications, & 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 buyer to obtain a response from the supplier.

13.1.7. If the disposition of any product is SCRAP, a red REJECT tag will be filled out & attached to the scrap board(s). The scrap board(s) will be forwarded to the Lead Person who will then notify the Supervisor who is responsible for that product line and/or the appropriate quality department personnel for final resolution. The Customer Service representative will notify the customer (if applicable).

13.1.8. Repaired and/or reworked product shall conform to **IPC-7711/7721** (Rework/repair of electronic assemblies) as well as IPC 610 current rev, and/or customer requirements & specifications, and be re-inspected for conformance to requirements (ref: QC Manual, [section 10](#): inspection & testing). When the proposed use or repair does not conform to specific requirements, Customer Service shall notify the customer & request disposition.

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. The representative shall issue an RMA (Return Material Authorization) number to the customer authorizing product return.
- B. Once received, product & count will be verified. The appropriate documentation will be generated & it will be received into Epicor.
- C. Any discrepancies will be reported to Customer Service who will work with the customer to resolve them.

- D. All steps taken to repair the product shall be recorded on the technical report (Form QC55) for traceability.
- E. All tested product shall be tested when received (to verify the customer complaint) & retested (if required) after all repairs are completed.
- F. The technician performing product repairs will inspect their work to ensure that all repairs conform to applicable standards (IPC-7711/7721 Rework/repair of electronic assemblies, etc.), drawings &/or purchase order requirements (ref also: Siemens QC Manual, section 13.1, Nonconforming Product).
- G. The Technician will complete their portion of the tech report & give it to the appropriate quality personnel for review & sign off.
- H. All boards will be packaged properly & returned to the customer with a completed copy of the tech report. All remaining RMA documents will be forwarded to accounting for billing purposes. (ref: Siemens QC Manual, Section 15.1. Packaging.1).
- I. Left blank intentionally.

RECORDS:

QC6, Equivalent Item Authorization
Assembly transfer history in EPICOR

Information from the following forms will be transferred to EPICOR where it will be stored as a record:

QC55 Technician Report

REFERENCES:

IPC-7711/7721 Rework/repair of electronic assemblies
ANSI/IPC-A-610 (latest rev), Acceptability of Electronic Assemblies

Section 1: Corrective Action/Continual Improvement

1. Siemens Mfg. Co., Inc. has established & maintains specific methods for implementing corrective actions as well as continual improvement. These methods are described in this section (Section 14.1). Corrective action procedures address the issues of handling customer complaints, investigating nonconformities, determining corrective action, & applying controls to ensure that corrective action is taken & that it is effective. Continual Improvement procedures address actions taken at Siemens Mfg. to improve product quality, the overall effectiveness of the Quality Management System, or any supporting manufacturing or business practice.

2. Any corrective action taken shall be to a degree appropriate to the magnitude of the problem & commensurate with the risks encountered.

3. Records of corrective actions are kept per Section 16.

4. Siemens Mfg. Co., Inc. shall comply with any additional customer requirements (use of customer specific 8D forms, accessing customer portals, rapid response (containment, sorting), etc). Note: If the customer required format does not include a section for Verification of Corrective action, use Siemens form QC55.

Section 14.1: Corrective Action Procedure

Corrective Action

14.1.1. The Quality department will analyze the data from appropriate sources and 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, at the minimum: the Supervisor, Quality & Customer Service. The quality department will complete the risk assessment on the CAR & then, if appropriate, along with Production lead or supervisor, will then investigate the problem to determine the root cause & corrective action.

14.1.3. Left blank intentionally.

14.1.4. The format used (unless otherwise specified by the customer) shall be the Correct Action Response (CAR) form. This form can be initiated by a customer complaint, an RMA, a request (based on problems noted) by Production, Engineering or Quality Department personnel. The CAR form includes directions for the filling out of the various sections of the checklist, as well as which department has the responsibility for that section. The checklist also includes a section for the determination of other part numbers to be put on hold based on a risk assessment for that issue (look across).

Continual Improvement Procedure

14.1.5. The Leadership Team of Siemens Manufacturing shall establish & maintain an effective system to ensure continual improvement throughout the organization. This system will consist of the following:

- Each member of the Leadership Team is responsible for maintaining a list of potential continual improvement actions for his/her department on the shared Smartsheet file location. Each is responsible for soliciting & capturing ideas from within their respective teams. Examples of potential areas for continual improvement include but are not limited to:
 - Environmental Impact
 - Labor efficiency
 - Production methods/automation
 - Facilities/use of floor space
 - Business transactional processes
 - Supplier management/Procurement
 - Project management
 - Inventory management
 - New business capture
 - Information technology
 - Customer service

- During the quarterly Management meetings, the Leadership Team will review all new potential continual improvement actions in conjunction with Company Annual Goals & Metrics. They will then determine which continual actions will proceed immediately or require further analysis.
- Upon approval of specific continual improvement actions/projects, senior management will ensure that the necessary resources e.g. people, funding, are made available for successful completion of these actions/projects.

RECORDS:

Management Review

QC55 Tech Report-CAR form

Assembly transfer history in EPICOR

QC33 Engineering Change Notification form

REFERENCE:

IPC-610 (current rev), Requirements for Soldered Electrical & Electronic Assemblies

IPC-7711/7721 Rework/repair of electronic assemblies

IPC/WHMA-A-620 Requirements & acceptance for cable & wire harness assemblies

Section 15.1: Handling, Storage, Packaging, Preservation, & 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.** Assemblies in cases may be transported in any container appropriate for the size & weight.
- 15.1.3.** ESD procedures 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.** Left blank intentionally.
- 15.1.8.** In order to detect deterioration, the condition of product in stock will be assessed during the cycle count. 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 inventory management.
- 15.1.10.** Siemens purchased components will be accepted into the stock room only if there is a purchase order for those components or a scheduled current dem&. Customer supplied parts will be accepted if there is a packing slip & an open Siemens job using the parts received.
- 15.1.11.** Parts “sampled in” will be processed through our normal inspection process.
- 15.1.12.** When a job kit is complete, the Expediter will release the kit to production.
- 15.1.13.** Left blank intentionally.
- 15.1.14.** Left blank intentionally.
- 15.1.15.** Material will be brought into inventory following the RECV-001_EPICOR STREAMLINED ENTRY PROCEDURE.
- 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.
- 15.1.17.** Left over purchased parts will be scrapped or labeled with a Parts Identification label (computer printout) which will have, as a minimum the Siemens part number, lot code & manufacturer part number. The lead person will then return the parts to SMC inventory. Parts that were received with a desiccant & humidity indicator will have the desiccant & 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 & the desiccant will be baked according to the components manufacturer specifications.
- 15.1.18.** Left blank intentionally.

- 15.1.19.** Left blank intentionally.

- 15.1.20.** Control of materials (i.e. chemicals) with a specified shelf life shall be accomplished in the following manner:
- A.** Receiving inspector will enter the expiration date into Epicor during receiving & affix a Siemens part label to the container. If an expiration date is not shown, they will enter 2 years from the date received. Receiving inspector will also apply a GHS label if the GHS label is absent from the manufactures packaging.
 - B.** A monthly audit of storage areas will be conducted by Quality personnel.
 - C.** Chemicals that are found to have an expired shelf life will be disposed of according to OSHA & EPA approved methods.
 - D.** Solder paste logs & the monthly refrigerator shelf-life audit checklist shall be forwarded to Documentation/QC to be scanned for reference.

Packaging

15.1.21. All product will be packaged according to customer requirements. If there are no customer supplied requirements, then the Production personnel will determine the extent of packaging necessary to protect the product during shipment. The SIEMENS developed packaging requirements will be recorded on the Process sheet.

15.1.22. The in-stock quantity on the EPICOR shipping screen authorizes product shipment. Any shipping holds are indicated by RED fields. IE: Part number quality holds will be a red part number field.

15.1.23. All shipping information affixed to the SIEMENS boxes will be neat, legible, & 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 customer's name.
- C.** The customer's shipping address.
- D.** The purchase order number.
- E.** The quantity.
- F.** The SIEMENS job number.

Preservation/Segregation

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

- A.** Awaiting incoming inspection (Incoming inspection area).
- B.** Inspected & approved (Kitting/stock area).
- C.** Inspected & rejected (Rejected materials cabinet).

15.1.25. Left blank intentionally.

15.1.26. Left blank intentionally.

15.1.27. Solder paste will be stored in a designated refrigerator prior to first use.

15.1.28. Left blank intentionally.

Section 16: Quality Records

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

All quality records shall be legible & shall be stored & retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration & to prevent loss. Retention times shall be established & 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 & maintained in designated assembly and/or 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 along with the responsible parties & file locations shown in the table below:

Type of Record	Form	Responsibility	File Location	Reference
Certifications & test reports for purchased materials (if required by contract).	N/A	Supply Chain Manager	Scanned to server	
Completed job operation in Epicor.	N/A	Quality Manager	Epicor	Section 10.1
Copies of all packing slips.	N/A	Director of Operations	Epicor	
Purchase orders.	N/A	Supply Chain Manager	Epicor	Section 6.1
Data from Inspection Reports.	N/A	Quality Manager	Epicor	Section 10.1
Data from Test/technician (Quality Control) reports.	N/A	Quality Manager	Epicor	Sections 10.0
Copies of "Certificates of Conformance" issued (Cs of C computer generated for shipping do not need copies maintained).	Customer Specific Certifications & Reports	Quality Manager	Common drive or Master folders	Section 10.1
Inspection & test equipment calibration records.	N/A	Quality Manager	NEWG Drive	Section 11.1
Personnel training.	N/A	Quality Manager	Epicor	Section 18.1
Audit reports.	QC29CVR	Quality Manager	NEWG Drive	Section 17.1
Management review reports.	Management Review Agenda	Quality Manager	NEWG Drive	Section 1.1
RMA’s Technician Reports	QC55		NEWG Drive	Section 13.1
Corrective action reports.	QC55	Quality Manager	NEWG Drive	Section 14.1
Quotes	N/A	Quote Department	Common Drive	Section 3.1
Engineering Change Notification form. Ref	QC33	Quality Manager	NEWG Drive	Section 3.1

16.1.4. Left blank intentionally.

16.1.5. Quality records may be made available for review by the customer upon request.

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 & contain, as a minimum, the Siemens Job number &/or part number, as applicable.

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

Section 17: Internal Quality Audit

1. Siemens Mfg. Co., Inc. has established & maintains specific methods for planning & implementing internal quality audits to verify whether quality activities & related results comply with planned arrangements & 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 or certified Lead Auditor is responsible for planning & implementing internal quality audits, & establishing an audit schedule. A minimum of two process audits will be performed per year. The Quality System Manager or Lead Auditor can revise the audit schedule based on information or data analysis & 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 & procedures (exception: auditors will **not** audit their own work). The auditor will be trained (Certified by a 3rd 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. Left blank intentionally.

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).

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 QC29CVR, the results of which will be presented to management. The Supervisor responsible for the area audited shall take corrective action (QC55, or equivalent) within 90 days on Minor deficiencies found during the audit. The Supervisor responsible for the area audited shall take corrective action (Form QC55, or equivalent) within 30 days on Major deficiencies found during the audit. A Major finding shall be defined as more than 3 Minor findings in the same category, or any finding involving safety, Form QC55 will be filed with the Quality System Manager for follow-up purposes.

17.1.7. A follow-up audit will verify & record (Form QC55) the implementation & effectiveness of the corrective action taken. A follow up audit will be conducted within 90 days for Minor findings, & within 30 days for Major findings. The follow-up audit will also record unresolved deficiencies.

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

RECORDS:

Management Review

QC55 Corrective Action

QC29CVR Quality System Audit

Section 18: Personnel Training

1. Siemens Mfg. Co., Inc. has established & maintains specific methods for determining training needs & 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 for auditing the training records to ensure that all personnel are trained & competent.
4. It is the responsibility of the Supervisor in charge of a given department to determine training needs & ensure that all personnel in their department that require training, are trained & competent. Training shall be recorded.
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 database), personnel shall be trained (& competency determined) by reviewing relevant procedures & providing hands-on training where applicable. The person doing the training is responsible for ensuring training is recorded.

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

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

18.1.4. Left blank intentionally.

18.1.5. Employees shall be retrained when a supervisor has determined that a significant change has occurred in the procedures and/or processes applicable to their area, or when proficiency or quality performance becomes substandard. In the event of a process change or audit finding, all affected personnel in all plant locations will be re-trained.

18.1.6 As competency needs evolve (new skills needed, new equipment is added, etc.), Siemens Mfg. Co, will determine the training needs & provide the resources necessary (send affected personnel to off-site training locations, etc.) or work with outside sources to bring the needed competencies to Siemens Mfg. Co. (bring in outside trainers, work through Human resources to hire personnel with the required competencies, etc.).

RECORDS:

Training database

Section 19: (This Section Left Blank Intentionally)

Section 20: Statistical Techniques

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

Section 20.1: Statistical Techniques

20.1.1. Components will be inspected using the DODGE & Romig single sampling plan, AOQL=5%.

20.1.2. Outgoing inspection at both plants will be performed as noted on the Siemens Process sheet.

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

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

20.1.5. Left blank intentionally.

REFERENCES:

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

QC1
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	Was "Shipping Clerk". Changed to "Order Entry Clerk"
5.1.16, Page 15	21 Sept 96	Perry Danford	Now reads "temporary changes to SIEMENS controlled documents "
3.1.8, Line 9 Page 9	11 Nov 96	Perry Danford	Was "will dispose of". Is "will file for reference"
3.1.6.A, Page 8	1 Apr 97	Perry Danford	defined database program as "Access"
3.1.6a, Page 8	1 Apr 97	Perry Danford	Was "forward to John III". Is "forward to an Operations Committee member"
3.1.8, Line 9, Page 9	1 Apr 97	Perry Danford	Was "Materials Control Manager will transcribe". Is "the Purchasing Agent will transcribe"
3.1.8a, Line 9 & 12 Page 10	1 Apr 97	Perry Danford	Replaced "John III" with "an Operations Committee member"
3.1.16, Line 4, Page 11	1 Apr 97	Perry Danford	The Engineering Dept no longer sends a copy of QC 6 to the Materials Control Manager
5.1.10.E, Page 17	1 Apr 97	Perry Danford	Was "Dispose of obsolete documents" Is "Stamp obsolete documents ... file for reference"
6.1.1H, Page 19	1 Apr 97	Perry Danford	Replaced "John III" with "an Operations Committee member"
6.1.8.D, Page 20	1 Apr 97	Perry Danford	Replaced "John III" with "an Operations Committee member"
10.1.4, Page 31	1 Apr 97	Perry Danford	Added "(if required by the Siemens Process Sheet; Form QC 8)"
14.1.2, Line 5, Page 44	1 Apr 97	Perry Danford	Added "Exception:..."
15.1.12, Line 6, Page 47	1 Apr 97	Perry Danford	Added "SMD parts that were received with a desiccant..."
1.7, Line 1, Page 5	26 Nov 97	Perry Danford	Was: Every three months... Is: Every twelve months...
3.1.6a, Lines 4 & 5, Page 8	26 Nov 97	Perry Danford	Was: ...the Sales Manager... Is: ...the Sales Manager/Customer Service ...
3.1.7, Lines 1, 2, & 4, Page 9	26 Nov 97	Perry Danford	Was: ... the Sales Manager... Is: ...the Sales Manager/Customer Service ...
3.1.7a, Lines 2 & 4, Page 9	26 Nov 97	Perry Danford	Was: ... the Sales Manager... Is: ...the Sales Manager/Customer Service ...
3.1.12, Line 4, Page 10	26 Nov 97	Perry Danford	Was: ... the Sales Manager... Is: ...the Sales Manager/Customer Service ...
5.1.4.D, Page 13	26 Nov 97	Perry Danford	Was: ...the senior technician. Is: ...the senior/lead technician.
5.1.8, Page 14	26 Nov 97	Perry Danford	Was: Only technicians... Is: ... the lead tech., senior tech, Tech. Coordinator...
5.1.10, Page 17	26 Nov 97	Perry Danford	Was: ...Production Supervisor... Is: ...Production Supervisor (or his designee)...
6.1.7.D, Page 20	26 Nov 97	Perry Danford	Was: ... the Sales Manager... Is: ...the Sales Manager/Customer Service ...
7.1.6, Line 1, Page 22	26 Nov 97	Perry Danford	Was: ...the Production Supervisor... Is: ... Supervisor or the Quality System Manager...
7.1.9, Line 2, Page 23	26 Nov 97	Perry Danford	Was: ...shelves by job name... Is: ...shelves by customer/job name...
7.1.9, Line 2, Page 23	26 Nov 97	Perry Danford	Was: ...if required by contract... Is: ...after contacting the customer...
10.1.1, Line 5, Page 28	26 Nov 97	Perry Danford	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	Deleted: (Siemens part #, first two digits ...)
5.1.16.c .Note, Page 15	16 July 98	Perry Danford	Modified note to require Mallinckrodt approval on documents & processes prior to implementation.
18.1.4 & 7, Page 53	16 July 98	Perry Danford	Combined & clarified lines 4 & 7

Section 10, Page 36	9/3/99	Perry Danford	Added First Article (Customer Approval)
Section 16, Page 51	9/3/99	Perry Danford	Form QC 28 is responsibility of the Training Specialist
Section 18, Page 53	9/3/99	Perry Danford	Form QC 28 deleted
Section 5.1.D, Page 18	10/1/99	Perry Danford	was: ...update QC master list is: update ... (local PC: QCMAN1.wpd).
Section 5.1.E, Page 18	10/1/99	Perry Danford	was: update unissued Quality System manuals is: update ...(network file QCMAN1.pdf).
Section 8.1.2, Page 24	02/03/00	Perry Danford	Added note: 8.1.2 "...does not apply to transformer components".
Section 15.1.14, Page 48	02/10/00	Perry Danford	Added a list of materials that would be tracked.
RE-INDEX, ALL	2/23/00	Perry Danford	Eliminated repeating paragraph numbers within a section. Went to sequential paragraph numbering.
Section 10.1.6.B, Page 30	6/6/00	Perry Danford	Added: "Note: Multiple reels of like items..."
Section 15.1.25, Page 50	7/11/00	Perry Danford	Added: "Finished units that are shipped more than 30 days..."
Section 5.1.4, Page 13	8/30/00	Perry Danford	Added Table B for routing document Rev changes.
Section 3.1	3/1/01	Perry Danford	Changed responsibilities from "Order Entry" to "Customer Service"
Section 10.1.25, Page 34	8/3/01	Perry Danford	Added "If additional tests are required by the customer, ...".
Section 10.1.1, Page 30	8/3/01	Perry Danford	Was "Inspection personnel shall transcribe..." Now is "Data entry personnel shall transcribe..."
Section 3.1.4, Page 7	10/31/01	Perry Danford	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	Was "... stamp P.O ACCEPTED..." Now is "...stamp the P.O. ENTERED & DATED"
Section 3.1.6b, Page 8	10/31/01	Perry Danford	Was "...fill out form QC 18..." Now is "update the Sales Order computer..."
Section 3.1.8, Page 9	10/31/01	Perry Danford	Added "forwarded to the documentation department for verification."
Section 3.1.8, Page 9	10/31/01	Perry Danford	Added "QC 17 to be used on formal rev changes"
Section 3.1.8a, Page 9	10/31/01	Perry Danford	Added "forwarded to the document department for verification"
Section 6.1.1, Page 19	10/31/01	Perry Danford	Was "... form QC 18" Now is "... purchase order"
Form QC 2	12 19/01	Perry Danford	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, Page14	5/9/02	Perry Danford	Added "... & 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, & 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 & the In-Process checklist for RoHS compliant units.
10.1.7 & 10.1.8	8/4/06	Perry Danford	Changed re-inspection of 1 st 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 & 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: 2015
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, & the format does not matter.
Various	8/6/2010	Perry Danford	Changed the format of Form QC 17b
10.1.6	8/23/2010	Perry Danford	added "Exception:..."
5.1.3	9/7/2010	Perry Danford	added Form QC 42 (Software revision change checklist)
10.1.6	6/16/11	Perry Danford	modified to include 1 st Piece verification for rev changes
11.1.15	7/15/11	Perry Danford	Removed the line "calibration shall occur within 1 month of the calibration expiration date".
5.1.4. C, D & F	5/18/12	Perry Danford	Was "issue the new Document then retrieve the old". Is "retrieve the old document then issue the new".
5.1.19	8/27/12	Perry Danford	Added "Quality Inspection Alert" list to issued document requirements.
10.1.4	7/1/13	Perry Danford	Deleted the requirement to verify the value of through hole resistors & capacitors
10.1.4	7/1/13	Perry Danford	Added "K", requirement to photo mfg ,label indicating RoHS compliance
5.1.4	11/26/13	Perry Danford	Added steps for creation of "new part number" folder
3.1.9	3/6/14	Perry Danford	Deleted. No longer applicable as it is noted as a part of MANEX.
Ref QC manual review sections 1-5	3/26/14	Perry Danford	Ref QC manual review sections 1-5
Ref QC manual review section 6	4/24/14	Perry Danford	Ref QC manual review section 6
Ref QC manual review sections 7 & 8	5/20/14	Perry Danford	Ref QC manual review section 7 & 8

Ref QC manual review sections 9&10	6/25/14	Perry Danford	Ref QC manual review sections 9 & 10
Ref QC manual review sections11&12	7/22/14	Perry Danford	Ref QC manual review sections 11 & 12
Ref QC manual review sections13	8/19/14	Perry Danford	Ref QC manual review sections 13
Ref QC manual review sections14	9/22/14	Perry Danford	Ref QC manual review sections 14
Ref QC manual review sections15	10/28/14	Perry Danford	Ref QC manual review sections 15
17.1.1	11/24/14	Perry Danford	Eliminated compliance audit
Ref QC manual review sections16-20	2/24/15	Perry Danford	Ref QC manual review sections 16-20
Form index	6/1/15	Perry Danford	QC 17 pre production checklist changed to rev K
5.1.4.D	10/28/16	Perry Danford	Controlled copy stamp no longer needs to be RED
11.1.11	12/9/16	Perry Danford	Added... If calibration is not required, the item will be labeled as "Calibration not required".
Index	1/20/17	Perry Danford	Updated Org chart to rev M
11.1.11	2/17/17	Perry Danford	Removed ANSI Z540-1 compliant, & replaced it with traceable to a National Standard
14.4	8/27/17	Perry Danford	Added: Note: If the customer required format does not include a section for Verification of Corrective action, include with the Corrective action a document (excel, word, power point, etc) noting how the verification of Corrective Action was determined.
Revised to 2015 version	1/3/18	Perry Danford	ISO 9001:2015 Update
17.1.6	8/16/18	Perry Danford	Changed time frame for corrective actions from 30 days to 90 days to better allow for CAR verification.
11.1.6	9/4/18	Perry Danford	Added: torque wrenches will be...verified the day of use...
10.1.14	2/1/19	Perry Danford	Deleted model number of the AOI
Various	2/1/19	Perry Danford	Replaced In process checklist (Form QC8a) with Job traveler
Various	2/1/19	Perry Danford	Replaced Material Hold tag with red Reject tag
11.1.9	2/22/19	Perry Danford	Specified the location of the calibration certification sticker
15.1.20	2/23/19	Perry Danford	Added solder paste log & monthly refrigerator audit checklist storage requirement
5.1.2	2/23/19	Perry Danford	Added requirements for posted documents
10.1.9, 10.1.10, 10.1.17, 10.1.21, 10.1.31	2/23/19	Perry Danford	Clarified when to use a RED Rejected tag & when to use a blank red toe tag.
forms	3/1/19	Perry Danford	Added updated org chart
10.1.33	3/12/19	Perry Danford	Added the use of the PPAP procedure where customer required
14.1.4	5/7/19	Perry Danford	Added the QHCL as the format for root cause investigation & corrective actions.
14.1, 14.1.5	7/8/19	Perry Danford	Added 14.1.5 Continual Improvement procedure
14.1.4	1/30/20	Perry Danford	Renamed QHCL. Is now Corrective Action Response (CAR)
Various	5/29/20	Perry Danford	Replaced RMA specialist with Documentation personnel
Various	5/29/20	Perry Danford	Replaced MANEX with EPICOR
6.1.1.G	5/29/20	Perry Danford	Deleted. Yellow sheet replaced with SmartSheet
Various	6/1/2020	Perry Danford	Replaced MANEX with EPICOR
18.1.5	6/8/20	Perry Danford	Added "for process changes & audit finding, affected personnel in all plant locations will be re-trained."
10.1.4.g	6/16/20	Perry Danford	Added: exceptions for parts in trays, & programmed parts.
3.1.1-3.1.5	9/22/2020	Perry Danford	Revised Contract review to align with EPICOR ERP system
10.1.18	10/12/20	Perry Danford	CAR analysis per Risk assessment tab of CAR Form
17.1.6	10/12/20	Perry Danford	Updated Form QC 29a to rev B
11	3/2/21	Perry Danford	Added Gage R & R <10% error
15.1.13	3/18/21	Perry Danford	Added form QC 43.7 Shortage request
6.1.1.B	4/2/21	Perry Danford	Added form QC9 & QC 10, & section 6.1.1.B

Table of forms	11/1/21	Perry Danford	Updated QC2 org chart
Table of forms	2/10/22	Perry Danford	Removed QC 19 as the form number for a "Customer supplied" sticker
7.1.9	2/10/22	Perry Danford	Added requirement for unique identification (SMC number)
7.1.10	2/10/22	Perry Danford	Added customer supplied electronic test equipment to require calibration per customer instructions.
7.1.6	5/27/22	Perry Danford	Defined criteria for Major audit findings as well as defining time frame for follow up audits.
10.1.5.A	6/22/22	Perry Danford	Added note specifying only 1 part number is to be on a receiver's desk as a time.
	9/14/22	Perry Danford	Revised quality policy
Table of forms	1/20/2023	Mike Siemens	Updated org chart
Table of forms	4/7/2023	Mike Siemens	Updated Corrective Action Form.
Table of forms	4/7/23	Mike Siemens	Added New SMC Equipment Application
Sections 1 thru 10	1/16/24	Mike Siemens	Updated for clarity. See color coded manual.
Sections 11 thru 20	4/18/24	Mike Siemens	Sections 11 thru 20 updated for clarity. See color coded manual.