SIEMENS MFG. CO., INC.
QUALITY SYSTEM MANUAL

APPROVED BY: John Siemens III
PRESIDENT

DATE: 03 Jan 18

APPROVED BY: Perry Danford
QUALITY SYSTEM MANAGER

DATE: 03 Jan 18

SIEMENS MANUFACTURING CO., INC. QUALITY POLICY

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

QUALITY SYSTEM MANUAL
TABLE OF CONTENTS

Section:

SECTION 1
QUALITY SYSTEM POLICIES AND LEADERSHIP RESPONSIBILITIES

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

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

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

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

1.5. The Quality Department is responsible for determining and providing resources (including information, equipment, and the assigning of competent personnel) (see Section 18) for the performance of verification activities (other than testing of Siemens assembled product) including internal quality audits. The Quality Department is responsible for determining and 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 and responsibilities to establish, implement, maintain, and 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 and test results, customer complaints, returned material, etc.) to determine conformity to product requirements (to determine what to work on) in conjunction with trend analysis (to determine if progress is being made) and for presenting these opportunities to a management review meeting to determining objectives with measurable goals. Any additional analysis will be determined at the management review meeting. The Quality Department is also responsible for determining an index of customer satisfaction by monitoring returned material and on time delivery, and 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 and effectiveness of the quality system, quality policy, as well as quality objectives and quality management system changes set at the management review meeting. The results of the review shall be recorded.

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, and promoting the process and 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, and the subsequent determination of customer satisfaction. Siemens Mfg. Co., Inc will achieve customer satisfaction by continually improving the effectiveness of the QMS through the use of the quality policy, quality objectives, audit results, analysis of data, corrective actions, requirements of relevant interested parties, and 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 and Development inasmuch as Siemens Mfg. Co., Inc does not perform any product design functions.

2.1. It is the responsibility of the Quality System Manager to establish, document, and maintain a quality system as a means of ensuring that product conforms to specified requirements. The Quality System Manager shall prepare a documented quality manual covering the requirements of ISO 9001: 2015 to carry out specific tasks/activities.

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

2.3. The Siemens Quality System is structured in the following manner:
- **A.** Level I: The Quality Manual with procedures.
- **B.** Level II: Specific work instructions.
- **C.** Level III: Forms, records, and other supporting documents.

2.4. Procedures as part of the Quality Manual meet requirements of ISO 9001: 2015, and 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 and expectations. Any project requiring quality planning comes from customer demands or requests. These projects are determined by Quote and Production DFM meetings, and a Pre-Production Checklist (Form QC17) will be filled out for each new high level assembly number.
- **B.** For contract and 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 and opportunities. The Engineering Change Notification form (QC33) documents any updates, revisions, and clarifications of selected projects.

2.7 Factors used to determine the Scope of this QMS include internal and external issues, requirements of relevant interested parties, and products and 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 and maintains specific methods to conduct contract review as described in the Contract Review section (Section 3.1).

2. Section 3 outlines the process used for each contract to ensure that:
- **A.** Requirements are adequately defined and documented.
- **B.** Differences are resolved.
- **C.** Siemens Mfg. Co., Inc. has the capability to produce and deliver product as required by the customer.

3. Any change to the contract (whether customer or Siemens initiated) is identified as described in the Contract Review procedure (Section 3.1). In addition, those functions within Siemens that are affected by the change are notified of the changes as stated in the same procedure. The Engineering Change Notification form (Form QC33) is used to communicate those changes.

4. Records of Contract Review are kept as stated is 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), and request a preliminary quote (computer generated form) from the Quote Department. The Quote department will hold a quote DMF meeting to evaluate the requirements for risk and 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, and 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) and 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 and 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, and 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, and 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. On receiving either an approved Equivalent Item Authorization form (Form QC6) or an approved Engineering Change Notification form (Form QC33), the BOM Department will make all necessary changes to the computer database, generate a new Siemens B.O.M., and 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 and 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 (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 (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 (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 and 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 AND DATA CONTROL
(Documented Information)

1. Siemens Mfg. Co., Inc. has established and maintains specific methods to control documents and data that relate to the requirements of ISO 9001: 2015 and the Siemens documented Quality System including, as applicable, customer supplied documents. These methods, as stated in Section 5.1, address the issues of document review, approval, availability, retention, change, and removal of invalid and/or obsolete documents.

SECTION 5.1
DOCUMENT AND 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 and maintaining quality procedures and reference material that pertain to conformity to product requirements (i.e. ANSI/J-STD-001, IPC-610, miscellaneous issued documents, etc.). New posted documents shall have an approval name, date of approval, and (as applicable) a revision number. The master list shall list the date of approval or revision number.

5.1.3. The Engineering Dept will maintain a Master list of test software.

5.1.4. Customer data and documents pertaining to assembly (including test procedures and changes) received will be forwarded to the BOM Dept. Copies received from the BOM Dept 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, and 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 and production folder. The master folder will contain all documents (including E-mails) issued by the customer and 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" and 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 and 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 and 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 and dating the procedure.
- **D.** Route the revised test procedure to the Documentation Control person who will follow the steps listed in section 5.1.4.

5.1.13. 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, and/or the Production Supervisor. The person requesting the change will initial and 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 and 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 and approval.

5.1.18. Uncontrolled copies of “Controlled” documents can be made, which will be stamped “Uncontrolled Copy” and assigned an expiration date (2 weeks from the day it is stamped). The uncontrolled copy will be discarded when it is no longer needed for its intended function (the line has been shut down, etc.) or has exceeded its expiration date.

5.1.19 Left blank intentionally.

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

5.1.21. Data received (PWB data) will be forwarded to the Engineering Dept 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 and 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 Dept 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 Dept 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 and, if necessary, discuss the requested change during a management review meeting.
- **B.** Rewrite the affected section for all approved changes.
- **C.** Fill out the Quality System Manual Change & Review Record (Form 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 and maintains specific methods to ensure that purchased product conforms to specified requirements. The Siemens purchasing procedure (Section 6.1) specifies methods to select and evaluate suppliers, defines the type and extent of control that Siemens has over suppliers, indicates what data shall be included on purchasing documents, defines verification requirements of purchased product, and details review and approval procedures for purchasing documents.

2. Records of acceptable suppliers shall be kept per Section 16.

3. The Quality and Purchasing Departments will establish and 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 and 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 and obtain delivery commitments for components.
- **B.** Follow the steps in the Program Part Decision Tree (Form QC10) in conjunction with Engineering and 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 and 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 and 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 (Ref: 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, and issue of the quality system standard to be applied.
- **I.** Drawing name and/or number including any revision number.
- **J.** Other relevant technical data.

6.1.6 Left blank intentionally.

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

- **A.** Attempt to locate the part elsewhere (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 and 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 and 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
QC25, Approved Supplier List (EPICOR)
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 and maintains specific methods to verify, store and 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 and quantity (for reels, sealed bags, cut tape, and 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 and 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 (oscilloscopes, meters, etc.) will be controlled using the procedures listed in the Calibration Control section (Section 11.1)

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

RECORDS: E-Mail (For customer notification)

SECTION 8
PRODUCT IDENTIFICATION AND TRACEABILITY

1. Siemens Mfg. Co., Inc. has established and maintains specific methods to identify product using the Production Identification and Traceability procedure (Section 8.1).

2. All components and products will be identified by suitable means, from receipt and through all stages of production, delivery, and (where required) installation.

3. Siemens Mfg. incorporates limited traceability activities as described in the Product Identification and Traceability procedure (8.1).

4. Records of this identification for traceability are kept per Section 16.

SECTION 8.1
PRODUCT IDENTIFICATION AND TRACEABILITY PROCEDURE

8.1.1. Upon receipt, components will be identified by an 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 and in-process materials will be identified throughout production by the Job traveler. **EXCEPTION:** Boards being transported between rework and washing do not need a Job traveler if the boards are to be washed and 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 and (if used) on the Siemens shipping carton by the shipping personnel:

- **A.** The customer's name.
- **B.** The purchase order number.
- **C.** The Siemen's part number.
- **D.** The quantity shipped (multiple boxes shall be noted as one of three etc.).

RECORDS: Assembly transfer history in EPICOR

REFERENCE In-Process Checklist

SECTION 9
PROCESS CONTROL

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

adversely affect conformity to product requirements.

2. Records of qualified processes, equipment, and personnel are kept, as appropriate, per Section 16.

SECTION 9.1
PROCESS CONTROL PROCEDURES

9.1.1. If required by contract, installation and servicing requirements can be implemented and a plan for implementation will be developed as part of the Contract Review procedure (ref: Section 3.1).

9.1.2. When a released job arrives at a production line the Lead person will:

- **A.** First time builds, get a first article folder from Documentation and 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 and software) and other resources (including information, workspace, utilities, buildings) used for production and testing of product is adequate, and that these functions are performed in a suitable work environment. 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 and priority to determine priorities for manufacturing and 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 and approving all processes listed on the Job traveler (ref. Section 10.1, First Article/In-Process Inspection, as well as Table “C”, 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 PM 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, and shall include (as a minimum);

- **A.** Define criteria for review and approval of the process.
- **B.** Approval of equipment and qualification of personnel.
- **C.** Use of specific methods and procedures.
- **D.** Requirements for records.
- **E.** Re-validation.

9.1.9. Workmanship standards for the 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-7711/772**1 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 and Electronic Assemblies
ANSI/IPC-A-610 (latest rev), Acceptability of Electronic Assemblies
ANSI/IPC-S-815 rev B, General Requirements for Soldering Electronic Interconnections
Table C, Process Flow chart

SECTION 10
INSPECTION AND TESTING

1. Siemens Mfg. Co., Inc. has established and maintains specific methods for inspection and testing activities in order to verify that customer requirements for the product are met. If there are no specific customer requirements for inspection, then Siemens Mfg. will use IPC-610 class II specifications. These methods are described in the Inspection and 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 and inspection parameters are described in Section 10.1. No part, including urgent releases, will be used until it has been inspected and accepted.

4. Records of inspection and testing are kept per Section 16.

SECTION 10.1
INSPECTION AND TESTING PROCEDURE

RECEIVING INSPECTION

10.1.1. Siemens purchased parts received will be inspected and/or tested for conformance and compliance to blueprint, drawing and/or specification requirements. When actual measurement values are required by purchase order or contract, the values will be recorded 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 and 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 and approved (Kitting/stock area). Responsibility: Parts Department.
- **C.** Inspected and 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 and 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 and 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), and will have the quantity received verified (for reels, sealed bags, cut tape, and hardware the quantity printed on the bag/box will be used).
- **D.** All custom/manufactured components will be compared to the latest drawing and 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 and manufacturer will be verified using the information on the factory parts ID sticker and the marking on the components. The bag will be re-sealed 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, and the physical description from the Purchase Order, with the inspection lot size determined by the Dodge and 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 and 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 and forward the packing slip to the Accounting Dept if all criteria are met. If deficiencies are found, the parts will be labeled with a Rejection tag and placed in the Reject Material cabinet.
Note: Multiple reels of like items will additionally receive a letter suffix to differentiate each reel. Example: Three reels are received & the 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, and 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 QC16, 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 and 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 and the lead person will be notified. A rejected lot may be 100% inspected (if directed by a supervisor) and 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.

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 and defects will be entered into ERP or fill an Inspection Report (Form QC 14). 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 and, 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 QC16, 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 and repair will conform to ANSI/IPC-A-610 (latest rev), and/or customer requirements and specifications, and will be re-tested (if applicable).

10.1.23. All rework and repair of the printed circuit boards will conform to **IPC-7711/772**1) Rework/repair of electronic assemblies) and/or customer requirements and specifications and 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. 10.1.24. 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 and included with the shipment.

ROVING INSPECTION

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

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 and ready for shipment will be forwarded to QC personnel (along with a First Article Inspection form, Form QC17b) who will inspect the assembly per the sections for Visual Inspection and Final Inspection. If the lot is acceptable, it will be shipped to the customer along with Form QC17b. **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:
QC35, Certificate of Conformance
QC6, Equivalent Item Authorization of Electronic Assemblies
QC 6, Corrective Action Response
QC17b, First Article Inspection
QC22, Shipping Information
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, QC14d Technician Report 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 and 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 and maintains specific methods to control, calibrate, and maintain inspection, measuring, and test equipment. These methods are described in the Calibration Control Procedure (Section 11.1). Records of calibration are kept per Section 16.

2. Test software or hardware that is used as suitable forms of inspection shall be included as part of the calibration procedure.

3. When required by contract, technical data pertaining to measurement equipment shall be made available to the customer.

4. Where a Gage R & R is required, the acceptable gage R & R error shall be less than 10%.

SECTION 11.1
CALIBRATION CONTROL PROCEDURE

11.1.1. When Siemens specified testing or calibration is required, the Quality System Manager, Engineering Dept, and/or the Senior Technician will determine the measurements to be made and the accuracy required, and then select equipment that is capable of the necessary accuracy and precision. The measurement and 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 and the accuracy required. The Quality System Manager, Engineering Dept, and/or the Senior Technician will then select the appropriate equipment that is capable of the necessary accuracy and precision. The measurement requirements will be recorded on the customer supplied test procedure.

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

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

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

calibration history of the equipment in question.

11.1.6. The Quality System Manager or the Engineering Manager will determine whether a given piece of inspection, measuring, or test equipment is to be calibrated in-house or sent out to a calibration lab. This information will be recorded on Calibration Recall program (computer program on PC). 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, and test equipment requiring calibration will be calibrated against certified equipment having a known valid relationship to nationally or internationally recognized standards. Where no such standard exists, the basis used for calibration will be documented.

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

11.1.9. Upon completion of an in-house calibration, the person performing the calibration will fill out and affix to the calibrated equipment a Calibration/verification Certification label which shall show as a minimum the person performing the calibration/verification and the calibration/verification due date, record the calibration results onto the Calibration Record (Form QC7b), and forward the Calibration Record to the Quality System Manager for traceability. The Calibration certification label 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) and approved (by a review of the Quality System Manual of the calibration facility) calibration laboratory. Calibration must be performed to manufacturer specifications in accordance with 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 and due date) affixed to it, and the results of the calibration will be recorded on a Certificate of Calibration which will be forwarded to the Quality System Manager for traceability.

11.1.13. The Quality System Manager and/or the Engineering Dept will review all calibration records and assess and document (Form QC7a) the validity of previous inspection and test results when inspection, measuring, or test equipment is found to be out of calibration.

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

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

RECORDS: QC7a, Calibration Evaluation
QC7b, Calibration Record

SECTION 12
INSPECTION & TEST STATUS

1. Siemens Mfg. Co., Inc. has established and maintains specific methods to indicate the inspection and test status of conforming and nonconforming product. These methods are described in the Procedure for the Indication of Inspection and Test Status, Section 12.1.

2. The Quality System Manager will make certain that items will retain an indication of their inspection and test status at all times. This is accomplished through the use of the Job traveler, red "Reject" tags (Form QC13C), and/or individual inspection and test stamp(s)/label(s) when required by the customer.

3. The identification of inspection and test status will be maintained throughout production, installation, and servicing of the product to ensure that only product that has passed the required tests and inspections is released for further processing or use.

4. Records of inspection and test status are kept per Section 16.

SECTION 12.1
PROCEDURE FOR INSPECTION & TEST STATUS

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

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

12.1.3. Additional label configuration (if used) is shown below:
Cal = 1st Calibration: The item has passed an electrical test prior to shipping or, if required, burn-in.

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

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

ICT = In circuit test (Agilent 3070)

RECORDS: Assembly transfer history in EPICOR

SECTION 13
CONTROL OF NONCONFORMING PRODUCT

1. Siemens Mfg. Co., Inc. has established and maintains specific methods to ensure that product that does not conform to specific requirements is prevented from unintended use or installation.

2. These methods, which are described in the Procedure for Control of Nonconforming Product (Section 13.1), provide for identification, documentation, evaluation, segregation (as practical), disposition of nonconforming product, and for notification to the functions concerned.

3. Records of nonconforming product are kept per Section 16.

SECTION 13.1
PROCEDURE FOR CONTROL OF NONCONFORMING PRODUCT

13.1.1. When nonconforming items are found during receiving inspection, the Incoming Inspector will note the defect(s) on the Rejection Report-Log ("QC Parts" database on computer). If there are enough defects to cause the lot to be rejected, the inspector will identify the lot as nonconforming with a red reject tag and place the lot in a nonconforming area. If there are not enough defects to reject the lot, the nonconforming items will be identified red reject and placed in a nonconforming area. It is the responsibility of the Incoming Inspector to fill out all sections of the "Reject" form, with the exception of "Disposition", which will be determined at the weekly purchasing meeting. A rejected lot may be 100% inspected (if so, directed by a supervisor) and then only the defective product (rather than the entire lot) will be rejected and placed in the nonconforming area for disposition.

13.1.2. When the disposition of the rejected material is determined, the action taken will be recorded on the Rejected Material Report, and the "Reject" report will be forwarded to Incoming Inspection to be recorded on the QC Parts database. The Reject Report will then be disposed of.

13.1.3. If, during production, customer supplied electronic components are lost or damaged the lead person for that job will fill out a Purchase Requisition (Form QC40) and forward the requisition (along with all damaged parts) to the Inventory Clerk who will record the shortage on PC (Personal computer, Database program). Siemens purchased components that were damaged during production will be dispositioned by the lead person and replaced at Siemens expense. Siemens purchased components that were received damaged will be returned to the supplier for replacement using the Floor Reject process. Customer supplied components that were received damaged will be returned to the customer and 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 and quantity of defect found, the job number, the date, and the Inspectors initials. The Inspector will then, if possible, rework the defective product. If rework is not possible at this time, the Inspector will place the product in a hold area with a traveler and a red toe tag (blank red tag), and notify the Lead Person for the product placed on hold. When the disposition of In-House rejects has been determined, the product will be forwarded to the appropriate department for disposition, and the red toe tag will be disposed of once rework has been completed. If product is damaged beyond normal rework criteria (damaged board, excessive cost, etc.), the Lead Person will fill out a red "Rejected" tag, then notify the Supervisor for that product line and/or the Quality System Manager who will either contact the customer for disposition, or scrap the assembly. The Lead Person will forward the assembly, along with the completed "reject" tag to the Documentation Specialist who will fill out the Reject Material Report. The Supervisor, Customer Service, or the Quality System Manager will notify the customer if it has been determined that defective material has been shipped.

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

13.1.6. If the discrepancy is attributed to a supplier, expedient action will be taken by the Purchasing Manager 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 and 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 Quality System Manager Documentation for final resolution. The Customer Service representative or the Quality Control manager will notify the customer (if applicable).

13.1.8. Repaired and/or reworked product shall conform to **IPC-7711/772**1 (Rework/repair of electronic assemblies) as well as IPC 610 current rev, and/or customer requirements and specifications, and be re-inspected for conformance to requirements (ref: QC Manual, section 10: inspection and testing). When the proposed use or repair does not conform to specific requirements, the Quality System Manager or Customer Service shall notify the customer and 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, or Documentation personnel of the need to return material to Siemens. The representative shall issue an RMA (Return Material Authorization) number to the customer authorizing product return. The representative will log the RMA number onto the Siemens job list (computer entry EPICOR).
- **B.** Once received, the Documentation personnel shall count and verify the product returned, start a repair folder, start a tech report (Form QC14d), and enter the sales order and work order into EPICOR. The Documentation personnel shall forward a copy of the RMA paperwork to the Quality System Manager.
- **C.** If there are any discrepancies, the Documentation personnel will immediately notify a Customer Service/support member as well as the Quality System Manager of the nature and extent of the discrepancies, and place the returned materials, with a Tech report (Form QC14d), in the Hold area until the discrepancies are resolved by the Quality System Manager.
- **D.** **D**. All steps taken to repair the product, (parts replaced, recalibration, etc.), shall be recorded on the technical report (Form QC14d), for traceability.
- **E.** All product shall be tested when received (to verify the customer complaint) and retested (if required) after all repairs are completed. Retested units will receive a “CAL 1 RMA” label (if there is room for the label). Units that pass test as received get an “RMA 6” label.
- **F.** The technician performing product repairs will inspect their work to ensure that all repairs conform to applicable standards (**IPC-7711/772**1 Rework/repair of electronic assemblies, etc.), drawings and/or purchase order requirements (ref also: Siemens QC Manual, section 13.1, Nonconforming Product).
- **G.** All boards will be packaged properly and returned to the customer (ref: Siemens QC Manual, Section 15.1. Packaging.1).
- **H.** The technician will forward one copy of the technician report (Form QC14d) to the Shipping supervisor who will place them in the “Outgoing RMA” folder and forward the “Outgoing RMA” folder to the Quality System Manager for data entry (computer program; Nonconformance Tracking System). When data entry is complete, the Quality System Manager will return the “Outgoing RMA” folder to the Documentation personnel who will forward the technician report to the office for billing purposes, (this copy will be filed in the job folder, for traceability).
- **I.** If the disposition of returned material is “scrap”, then a copy of the Scrap report will be forwarded to the Customer service rep and the Accounts receivable rep for that customer.

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: AOI printout, QC14 Inspection Report, QC14d Technician Report form QC14e Repair Report, QC14f Test Report.

REFERENCE: **IPC-7711/772**1 Rework/repair of electronic assemblies
ANSI/IPC-A-610 (latest rev), Acceptability of Electronic Assemblies

SECTION 14
CORRECTIVE ACTION/CONTINUAL IMPROVEMENT

1. Siemens Mfg. Co., Inc. has established and 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, and applying controls to ensure that corrective action is taken and 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 and 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, include with the Corrective action a document (excel, word, power point, etc.) noting how the verification of Corrective Action was determined.

SECTION 14.1
CORRECTIVE ACTION PROCEDURE

Corrective action:

14.1.1. The Quality System Manager will analyze the data from appropriate sources (Quality Control Reports (Form QC14a), Inspection Reports (Form QC14), Technician Reports (Form QC14E & F), Customer Complaints to identify problem areas, etc.). The Quality System manager will, if necessary, work with the Production Supervisors to determine what modifications need to be made to the processes and/or work instructions which affect conformity to product requirements to achieve a reduction in future nonconformities.

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

that corrective action is taken and that it is effective.

14.1.3. Root Cause evaluation (and corrective action) will also be performed by determining the leading contributor to product quality (by Pareto for a single part number at a time). If a process changes to a given product is necessary, then it will be noted by the Lead Person on the process sheet. If a change to the Quality System is necessary, then the Corrective Action Request form will be reviewed during the next management meeting to determine the most appropriate method for implementation (ref. Section 5.1. Quality System Manual Change Procedure). The results of the management review will be recorded and will be filed on PC. The Production Supervisor or an Internal Auditor will also follow up on the corrective action to verify that the actions taken were effective. Once completed, the Corrective Action Request results will be maintained on-line.

14.1.4 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 the Engineering manager or a production Supervisor. 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). The results of the CAR shall be reported as a part on the Management meeting.

Continual Improvement Procedure

14.1.5 The Leadership Team of Siemens Manufacturing shall establish and 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 and 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 and 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

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

Assembly transfer history in EPICOR

REFERENCE: **IPC-610 (current rev)**, Requirements for Soldered Electrical and Electronic Assemblies
IPC-7711/7721 Rework/repair of electronic assemblies
IPC/WHMA-A-620 Requirements and acceptance for cable & wire harness assemblies

SECTION 15

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

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

HANDLING:

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

15.1.2. Assemblies in cases may be transported in any container appropriate for the size and 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. Software media will be stored in a climate-controlled area.

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 demand. Customer supplied parts will be accepted if there is a packing slip and 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 or Customer Service will release the kit to production.

15.1.13. Components released as replacement for shortages will be issued to production with a Shortage Requisition (Form QC43.7), which will be signed by the lead person requesting the component, forwarded to the stock room, and discarded when filled.

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

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

- **A.** Check the parts in using the purchase order (for Siemens purchased material) or the packing slip (for customer supplied material) to verify that the proper part and quantity of parts was received and verify current demand. All cartons will be inspected for physical damage at this time. Any damage will be noted and reported to the supervisor responsible for that product line. Rejected product will be handled per Section 13.1, Control of Nonconforming Product.
- **B.** Customer Supplied stickers (Form QC19A) will be applied when a skid is broken down.

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

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

15.1.18. If electronic components are needed to complete a job because they were lost or damaged (ref. also Section 13.1: Nonconforming Product), then the lead person requiring the component will fill out a Purchase Requisition (Form QC40) and send it to the Inventory Clerk. If the Inventory Clerk has the parts in stock, then the parts will be issued. The requisition will be marked “filled” and filed for reference. If the Inventory clerk does not have the part or if the part issued is taken from another kit, then the requisition will be forwarded to a Purchasing team, who will then order the parts.

15.1.19. If electronic components are needed to repair printed circuit assemblies, the technician will fill out a Purchase Requisition and forward the requisition to Inventory or Engineering Dept. If the parts are in stock, then the parts will be issued. If the parts are not in stock, the Inventory personnel will forward the purchase requisition to a Purchasing team, who will then order the parts.

15.1.20. Control of materials (i.e. chemicals) with a specified shelf life shall be accomplished in the following manner:

- **A.** The receiving Inspector will affix to the container a sticker indicating the shelf-life expiration date **ONLY** if the expiration is not already printed on each individual container. The label will have the date of receipt, the expiration date, and the Inspectors stamp or initials.
- **B.** A monthly audit of storage areas will be conducted by the QC Manager.
- **C.** Chemicals that are found to have an expired shelf life will be disposed of according to OSHA and EPA approved methods.
- **D.** Solder pastes logs and 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 / Shipping and Receiving Supervisor will work with Customer Service to determine the extent of packaging necessary to protect the product during shipment. The SIEMENS developed packaging requirements will be recorded on the Process sheet, or on PC as applicable which will be reviewed/approved by the Production Supervisor or the Quality System Manager, and kept in their respective packaging area.

15.1.22. The GREEN quantity on the EPICOR shipping screen authorizes product shipment.

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

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

PRESERVATION/SEGREGATION:

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

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

15.1.25. Product that is awaiting disposition (whether to accept, reject, scrap, awaiting shortages, etc.) will be kept in a Materials Hold area and will be identified with a traveler and a red toe tag.

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

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

15.1.28. Product storage:

- **A.** Siemens Mfg. is committed to achieving 100% on-time delivery.
- **B.** Finished product is shipped based on a Siemens order driven process.
- **C.** Therefore, finished product storage is kept to a minimum.

DELIVERY:

15.1.29 Where contractually required, the protection of the product shall be extended to include delivery to its final destination. Any additional packing requirements will then be recorded on the Process Sheet, or PC as applicable.

REFERENCE:

SECTION 16
QUALITY RECORDS

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

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

SECTION 16.1
PROCEDURES FOR CONTROL OF QUALITY RECORDS

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

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

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

- **A.** Certifications and test reports for purchased materials (if required by contract).
- **B.** Completed in-process checklist (as required). Ref. Section 10.1
- **C.** Copies of all shippers. Ref. Sections 7.1, 10.1, 15.1
- **D.** Purchase orders. Ref. Section 6.1
- **E.** Data from Inspection Reports. Ref. Section 10.1
- **F.** Data from Test/technician (Quality Control) reports. Ref. Sections 10.0 & 11.1
- **G.** Copies of "Certificates of Conformance" issued (Cs of C computer generated for shipping do not need copies maintained. Ref. Section 10.1
- **H.** Inspection and test equipment calibration records (on PC). Ref. Section 11.1
- **I.** Personnel training. Ref. Section 18.1
- **J.** Records of any other related documents pertaining to the quality system and purchase order and/or contractual requirements.
- **K.** Audit reports. Ref section 17.1
- **L.** Management review reports. Ref. Section 1.1
    1. Supplier records. Ref. Section 6.1
    2. Subcontractor records. Ref. Section 6.1
    3. RMA's (Data from technician reports). Ref. Section 13.1
- **M.** Corrective action reports. Ref. Section 14.1
- **N.** Quotes. Ref. Section 3.1
- **O.** Contract Review Problem form. Ref. Section 3.1

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

16.1.5. 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 and contain, as a minimum, the Siemens Job number and/or part number.

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

TABLE 1

QUALITY SYSTEM MANUAL SECTION #	SIEMENS FORM #	RESPONSIBILITY	FILE LOCATION
16.1.3.a	Not Applicable	QC MANAGER	QC FILE
16.1.3.b	N/A	QC Mgr	As required by customer
16.1.3.c	QC 22	VICE PRESIDENT	Thrown away when product is shipped
16.1.3.d	Not Applicable	PURCHASING AGENT	PURCHASING FILE
16.1.3.e	QC 14	QC MANAGER	PC
16.1.3.f	QC14a	QC MANAGER	PC
16.1.3.g	QC 35	QC Mgr	QC Master Folder (BY Job Name)
16.1.3.h	Not Applicable	QC MANAGER	PC
16.1.3.i	N/A	QC Mgr	PC
16.1.3.j	Computer file	QC Mgr	PC
16.1.3.k	As applicable (QC 29 & 29a)	QC MANAGER	QC OFFICE
16.1.3.l	Mgt report	QC MANAGER	PC
161.3.m	QC 16 (ref section 14.1.3)	QC MANAGER	PC
16.1.3.n	N/A	Quotations Mgr	QUOTE OFFICE
16.1.3.o	QC 33	QC Mgr	Documentation office

SECTION 17
INTERNAL QUALITY AUDIT

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

2. Records of Quality Audits, as well as the results of the audits, shall be maintained per section 16.

SECTION 17.1
INTERNAL QUALITY AUDIT PROCEDURE

17.1.1. Quality System Manager or certified Lead Auditor is responsible for planning and implementing internal quality audits, and 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 and the importance of the area being audited as well as the results of previous audits.

17.1.2. Qualified auditors will audit all in-house Quality System policies and procedures (exception: auditors will **not** audit their own work). The auditor will be trained (Certified by a 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. Auditors will be selected (if not already certified) by an interview process using criteria listed on the Auditor Job posting. Successful candidates will then be sent to a 3rd party for training /certification. As an interim action, auditor training can be provided by a certified Lead Auditor which will allow, upon successful completion, that person to conduct internal audits until 3rd party training can be scheduled (within the next 12 months).

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 QC29 for a compliance audit or Form QC29a for a process audit, the results of which will be forwarded to the Supervisor responsible for the area being audited for review. The Supervisor responsible for the area audited shall take corrective action (Form QC16, or equivalent) within 90 days on Minor deficiencies found during the audit. The Supervisor responsible for the area audited shall take corrective action (Form QC16, 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 QC16 will be filed with the Quality System Manager for follow-up purposes.

17.1.7. A follow-up audit will verify and record (Form QC16) the implementation and effectiveness of the corrective action taken. A follow up audit will be conducted within 90 days for Minor findings, and within 30 days for Major findings. The follow-up audit will also record unresolved deficiencies.

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

RECORDS: Management Review
QC16, Corrective Action
QC29, Audit Checklist, QC29a Process audit form

SECTION 18
PERSONNEL TRAINING

1. Siemens Mfg. Co., Inc. has established and maintains specific methods for determining training needs and provide for the training of all personnel performing tasks affecting conformity to product requirements.

2. Personnel performing specific assigned tasks shall be qualified on the basis of education, training and/or experience, as required.

3. Quality System Manager is responsible through training and monitoring for having personnel correctly and consistently use various forms, cross-referenced in this manual. This will assure traceability through documentation, from the beginning of the contract to the shipping of product. The Quality System Manager is also responsible for submitting copies of the Quality System Manual to designated personnel to ensure proper preparation and training in all applicable facets of this quality system and will ensure that training is provided by qualified personnel.

4. It is the responsibility of the Supervisor in charge of a given department to determine training needs and ensure that all personnel in their department that require training, are trained and competent.
5. Records of personnel training are kept as stated in Section 16.

SECTION 18.1
PERSONNEL TRAINING

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

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

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

18.1.4. Technicians (who troubleshoot defective product) will have the technician test evaluated in conjunction with relevant work experience. Other jobs at Siemens have no minimal requirements; however, related experience is beneficial.

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

18.1.5 As competency needs evolve (new skills needed, new equipment is added, etc.), Siemens Mfg. Co, will determine the training needs and 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
SERVICING

1. If required by contract, servicing can be implemented and a plan for implementation will be developed

as part of Quality Planning (ref: SECTION 2).

2. The Quality Plan will address the issues of establishing and maintaining documented procedures for performing, verifying, and reporting that the servicing meets the specified requirements.

SECTION 20
STATISTICAL TECHNIQUES

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

SECTION 20.1
STATISTICAL TECHNIQUES

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

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

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

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

20.1.5. Ionic Residue limits are outlined in the Joint Industry Standard ANSI/J-STD-001, 2005 ver., Section 8.3.6.1.

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 QC Manager	Was “Shipping Clerk”. Changed to “Order Entry Clerk”
5.1.16 Page 15	21 Sept 96	Perry Danford QC Manager	Now reads “temporary changes **to SIEMENS controlled documents**”
3.1.8 line 9 Page 9	11 Nov 96	Perry Danford QC Manager	Was “will dispose of” Is “will file for reference”
3.1.6.A Page 8	1 Apr 97	Perry Danford QC Manager	defined database program as “Access”
3.1.6a Page 8	1 Apr 97	Perry Danford QC Manager	Was “forward to John III” Is “forward to an operations Committee member”
3.1.8 line 9 Page 9	1 Apr 97	Perry Danford QC Manager	Was “Materials Control Manager will transcribe” Is “the Purchasing Agent will transcribe”
3.1.8a,9,12 Page 10	1 Apr 97	Perry Danford QC Manager	Replaced “John III” with “an operations Committee member”

3.1.16 line 4 Page 11	1 Apr 97	Perry Danford QC Manager	The 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 QC Manager	Was “Dispose of obsolete documents” Is “Stamp obsolete documents ... file for reference”
6.1.1H Page 19	1 Apr 97	Perry Danford QC Manager	Replaced “John III” with “an operations Committee member”
6.1.8.D Page 20	1 Apr 97	Perry Danford QC Manager	Replaced “John III” with “an operations Committee member”
10.1.4 Page 31	1 Apr 97	Perry Danford QC Manager	Added “(if required by the Siemens Process Sheet; Form QC 8)”
14.1.2 line 5 Page 44	1 Apr 97	Perry Danford QC Manager	Added “Exception:”
15.1.12 line 6 Page 47	1 Apr 97	Perry Danford QC Manager	Added “SMD parts that were received with a desiccant...”
1.7 line 1 Page 5	26 Nov 97	Perry Danford QC Manager	Was: Every three months... Is: Every twelve months...
3.1.6a lines 4 & 5 Page 8	26 Nov 97	Perry Danford QC Manager	Was: ...the Sales Manager... Is: ...the Sales Manager/Customer Service ...
3.1.7 lines 1, 2, & 4 Page 9	26 Nov 97	Perry Danford QC Manager	Was: ... the Sales Manager... Is: ...the Sales Manager/Customer Service ...
3.1.7a lines 2 & 4 Page 9	26 Nov 97	Perry Danford QC Manager	Was: ... the Sales Manager... Is: ...the Sales Manager/Customer Service ...
3.1.12 line 4 Page 10	26 Nov 97	Perry Danford QC Manager	Was: ... the Sales Manager... Is: ...the Sales Manager/Customer Service ...
5.1.4.D Page 13	26 Nov 97	Perry Danford QC Manager	Was: ...the senior technician. Is: ...the senior/lead technician.
5.1.8 Page 14	26 Nov 97	Perry Danford QC Manager	Was: Only technicians... Is: ... the lead tech., senior tech, Tech. Coordinator...
5.1.10 Page 17	26 Nov 97	Perry Danford QC Manager	Was: ...Production Supervisor... Is: ...Production Supervisor (or his designee) ...
6.1.7.D Page 20	26 Nov 97	Perry Danford QC Manager	Was: ... the Sales Manager... Is: ...the Sales Manager/Customer Service ...
7.1.6 line 1 Page 22	26 Nov 97	Perry Danford QC Manager	Was: ...the Production Supervisor... Is: ... Supervisor or the Quality System Manager...
7.1.9 line 2 Page 23	26 Nov 97	Perry Danford QC Manager	Was: ...shelves by job name... Is: ...shelves by customer/job name...
7.1.9 line 2 Page 23	26 Nov 97	Perry Danford QC Manager	Was: ...if required by contract... Is: ...after contacting the customer...
10.1.1 line 5 Page 28	26 Nov 97	Perry Danford QC Manager	Was: ...until it has been inspected... Is: ...until the lot has been inspected...
10.1.4.E, F, I &J Page 29	26 Nov 97	Perry Danford QC Manager	Deleted: (Siemens part #, first two digits ...)
5.1.16.c . Note Page 15	16 July 98	Perry Danford QC Manager	Modified note to require Mallinckrodt approval on documents & processes prior to implementation.
18.1.4 & 7 Page 53	16 July 98	Perry Danford QC Manager	Combined & clarified lines 4 & 7
Section 10 Page 36	9/3/99	Perry Danford QC Manager	Added First Article (Customer Approval)

Section 16 Page 51	9/3/99	Perry Danford QC Manager	Form QC 28 is responsibility of the Training Specialist
Section 18 Page 53	9/3/99	Perry Danford QC Manager	Form QC 28 deleted
Section 5.1.D Page 18	10/1/99	Perry Danford QC Manager	was: ...update QC master list is: update ... (local PC: QCMAN1.wpd).
Section 5.1.E Page 18	10/1/99	Perry Danford QC Manager	was: update unissued Quality System manuals is: update ... (network file QCMAN1.pdf).
Section 8.1.2 Page 24	02/03/00	Perry Danford QC Manager	Added note: 8.1.2 "...does not apply to transformer components".
Section 15.1.14 Page 48	02/10/00	Perry Danford QC Manager	Added a list of materials that would be tracked.
RE-INDEX ALL	2/23/00	Perry Danford QC Manager	Eliminated repeating paragraph numbers within a section. Went to sequential paragraph numbering.
Section 10.1.6.B Page 30	6/6/00	Perry Danford QC Manager	Added: "Note: Multiple reels of like items...".
Section 15.1.25 Page 50	7/11/00	Perry Danford QC Manager	Added: "Finished units that are shipped more than 30 days..."
Section 5.1.4 Page 13	8/30/00	Perry Danford QC Manager	Added Table B for routing document Rev changes.
Section 3.1	3/1/01	Perry Danford QC Manager	Changed responsibilities from "Order Entry" to "Customer Service"
Section 10.1.25 Page 34	8/3/01	Perry Danford QC Manager	Added "If additional tests are required by the customer, ...".
Section 10.1.1 Page 30	8/3/01	Perry Danford QC Manager	Was "Inspection personnel shall transcribe..." Now is "Data entry personnel shall transcribe..."
Section 3.1.4 Page 7	10/31/01	Perry Danford QC Manager	Was "clerical personnel shall assign a quote number" Now is "quote estimator assigns the quote number"
Section 3.1.6.C Page 8	10/31/01	Perry Danford QC Manager	Was "... stamp P.O ACCEPTED..." Now is "...stamp the P.O. ENTERED and DATED"
Section 3.1.6b Page 8	10/31/01	Perry Danford QC Manager	Was "...fill out form QC 18..." Now is "update the Sales Order computer..."
Section 3.1.8 Page 9	10/31/01	Perry Danford QC Manager	Added "forwarded to the documentation department for verification."
Section 3.1.8 Page 9	10/31/01	Perry Danford QC Manager	Added "QC 17 to be used on formal rev changes"
Section 3.1.8a Page 9	10/31/01	Perry Danford QC Manager	Added "forwarded to the document department for verification"
Section 6.1.1 Page 19	10/31/01	Perry Danford QC Manager	Was "... form QC 18" Now is "... purchase order"
Form QC 2	12 19/01	Perry Danford QC Manager	Modified organizational chart to reflect changes within the purchasing dept.
Section 18.1.2 Page 53	1/31/02	Perry Danford	Was "Training Specialist responsibility" Now is "QC Manager responsibility".
Section 18.1.3 Page 53	2/13/02	Perry Danford	added training checklist

Section 10.1.16 Page 32	3/5/02	Perry Danford	Added 10.1.16.F
Section 10.1 41 Page 36	3/6/02	Perry Danford	Added “sign the In Process Checklist...”
Section 5.1 7 Page 14	8/22/02	Perry Danford	Added “...personnel who perform incoming inspection...” to access the QC master file.
Section 7.1.1 Page 22	9/04/02	Perry Danford	Added “...Blue paint to indicate Customer Supplied.”
Section 7.1.2 Page 22	12/5/02	Perry Danford	Deleted form QC 24
Section 71.3 Page 22	12/5/02	Perry Danford	Kits are no longer double checked
Section 9.1 5 Page 25	12/5/02	Perry Danford	Added Table C
Section 5.1.19 Page14	5/9/02	Perry Danford	Added “... and remain legible & readily identifiable.”
Section 2	12/9/02	Perry Danford	Deleted form QC 5
Section 6 pages 19 & 20	12/10/02	Perry Danford	Updated section per minutes from November management meeting.
Index	1/14/03	Perry Danford	Added Form QC 20 Customer Satisfaction survey
Various	1/17/03	Perry Danford	Changed Q9000, 1994 to ISO 9001: 2000
Various	5/22/03	Perry Danford	Deleted Form QC 17a
Section 8.1.3 Page 22	9/23/03	Perry Danford	Added “...Computer generated Traveler can be used instead of Form 8a.
Various	2/19/04	Perry Danford	Added Form QC 41
Various	5/3/04	Perry Danford	Rev A of Form QC 8a (In-Process Checklist)
12.1.2	6/21/04	Perry Danford	Eliminated requirement for many stamps, and added the requirement for a single label (date & work order number).
11.1.11 Pg 32	7/26/04	Perry Danford	Added requirements for selection of a calibration facility
15.1.20	8/9/04	Perry Danford	added Humiseal 1B73 to shelf-life materials
13.1.9.B Pg 37	10/18/04	Perry Danford	replaced “shipping clerk” with RMA specialist”.
5.1.18 Pg 14	10/20/04	Perry Danford	Added an expiration date to uncontrolled documents.
14.1.3 Pg 38	11/30/04	Perry Danford	Added “... or customer specified format”
Misc	1/12/06	Perry Danford	Was...2 production folders Is... one production folder
5.1.5 Pg	1/12/06	Perry Danford	Added the requirement for GREEN paper or highlights for the process sheet and the In-Process checklist for RoHS compliant units.
10.1.7 & 10.1.8	8/4/06	Perry Danford	Changed re-inspection of 1st article to re-inspect 100% for the reject MODE rather than just verifying that the rejected component was corrected

10.1.26	10/18/06	Perry Danford	added "...RoHS compliant boards will be 100% checked for..."
Various	4/18/07	Perry Danford	Deleted form QC 14a, replaced with QC 14 e & 14 f
15.1.20	9/23/07	Perry Danford	Was... Loctite 348 Is... all Loctite products
15.1.20.B	9/24/07	Perry Danford	Added SOP-15-1 shelf-life procedure
Various	1/11/08	Perry Danford	Deleted Form QC 39
18.1.1	5/25/08	Perry Danford	Added the person doing the training...
5.1.14	8/8/08	Perry Danford	Added QOP-5-1 ...work instructions...stored in an electronic format
17.1.1	7/1/09	Perry Danford	Added "two process audits and one compliance audit per year"
14.1.3	7/1/09	Perry Danford	Was "...maintain corrective action results in New Athens..." Is "...Maintain corrective action results on line".
17.1.3	7/2/09	Perry Danford	Added Auditor selection criteria
Various	7/20/09	Perry Danford	Changed ISO 9001: 2000 to ISO 9001: 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, and 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 1st 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, and 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	2/1/10	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 and 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 and 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 and 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, and programmed parts.
3.1.1-3.1.5	9/22/20201	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, and 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	Sections 1 thru 10 updated for clarity. See color coded manual for changes.