EST4 Quality Plan

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Content

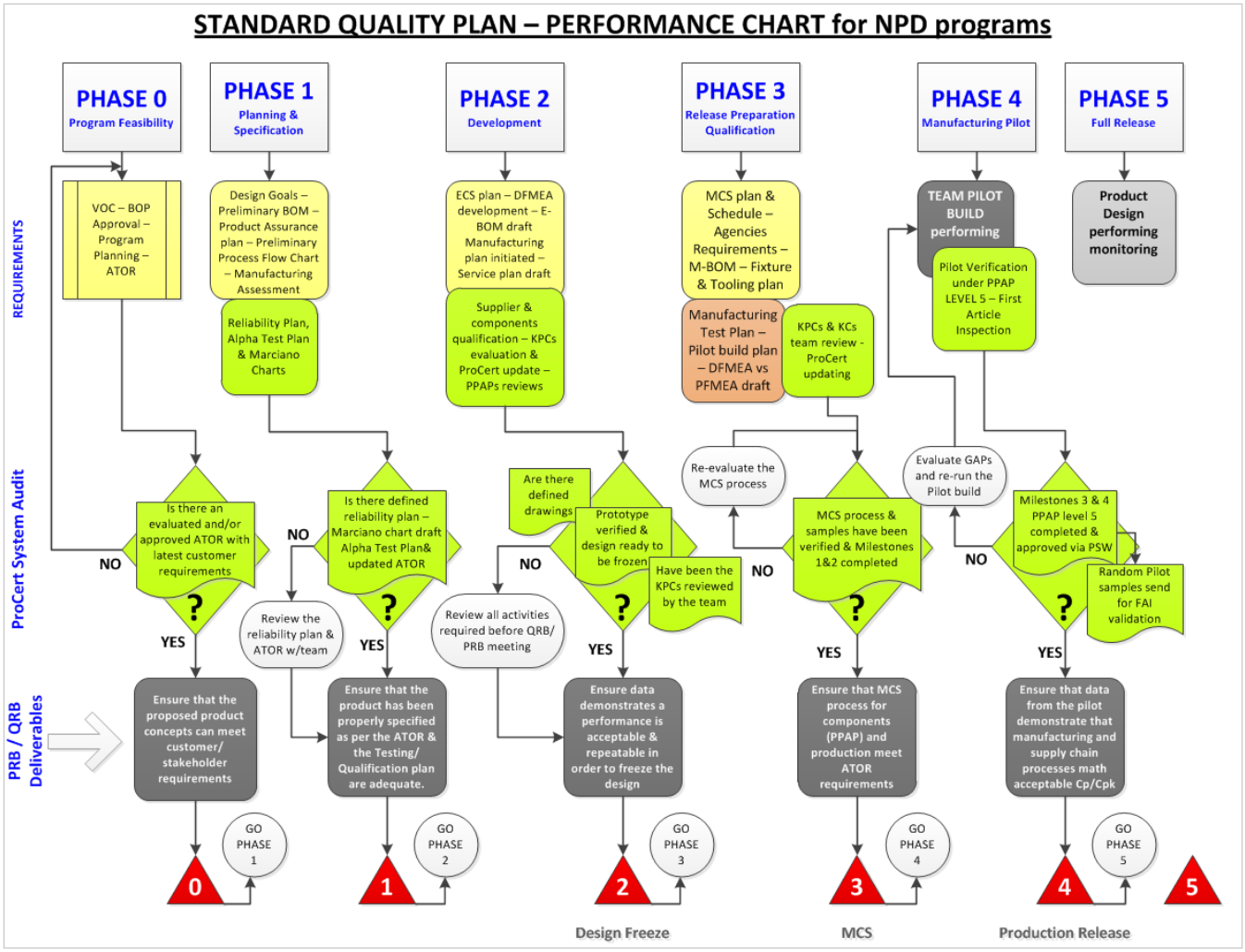
Important information

Foreword

This document is the “total quality plan” created during the design, manufacture, reliability assurance, and customer quality support phases of the project to develop EST4.

This quality plan conforms to and exceeds the requirements of the Carrier Excellence (Cx) standard as well as the requirements of UL, ULC, and other regulatory agencies. This plan and subsequent updates to the plan demonstrate a continuing resolve to make products as reliable and consistent as one would expect for life safety system operation. In all cases, ensurances are put in place for the system to operate reliably without compromising the life safety aspect of operation. The Quality Plan, in general, verifies that all stages of the NPD (New Product Development) process are completed according to the standards; this process is shown in the Standard Quality Plan (Figure 1 below).

Figure 1: Standard Quality Plan flowchart



Limitation of liability

To the maximum extent permitted by applicable law, in no event will Carrier be liable for any lost profits or business opportunities, loss of use, business interruption, loss of data, or any other indirect, special, incidental, or consequential damages under any theory of liability, whether based in contract, tort, negligence, product liability, or otherwise. Because some jurisdictions do not allow the exclusion or limitation of liability for consequential or incidental damages the preceding limitation may not apply to you. In any event the total liability of Carrier shall not exceed the purchase price of the product. The foregoing limitation will apply to the maximum extent permitted by applicable law, regardless of whether Carrier has been advised of the possibility of such damages and regardless of whether any remedy fails of its essential purpose.

Accordance with this manual, applicable codes, and the instructions of the authority having jurisdiction is mandatory.

While every precaution has been taken during the preparation of this manual to ensure the accuracy of its contents, Carrier assumes no responsibility for errors or omissions.

Chapter 1
Introduction

Content

Introduction

This plan defines activities carried out to ensure the product line meets all required functional performance specifications and reliability criteria. The approach is error prevention and the purpose, in the long term, is to balance cost and required quality while performing proactive efforts to eliminate the sources of potential errors and failures. This quality plan aims to prevent errors and provides feedback mechanisms for corrective and preventive actions. This also helps to lessen any chances of unforeseen errors.

This document applies to the Edwards EST4 system. The emphasis is on the chapters on design assurance, manufacturing processes, reliability practices, and customer quality support. There are other corresponding aspects of this document to cover the entire project, from the planning stage to obsolescence.

Our quality management system is based on the Carrier Quality Tools standard. This is reflected in a *Quality System Management Manual* (QSMM) with all applicable documents listed. The eight main components are:

1. Scope
2. Normative reference
3. Terms and definitions
4. Quality management system
5. Management responsibility
6. Resource management
7. Product realization
8. Measurement, analysis, and improvement

The Quality Assurance (QA) program applies to:

- Product planning
- Process planning
- Supplier quality
- Processes and resources
- Documentation and training
- Customer support and service
- Feedback and measurements

Revision and approval

The quality plan for the EST4 project is updated and controlled by the Quality Assurance group of Edwards as needed. This also helps to lessen any chances of unforeseen errors.

Chapter 2
Design assurance

Content

Design approach

The EST4 fire alarm control panel assemblies are designed using the guidelines of the Carrier design control management process called Passport.

Electrical, mechanical, and firmware designs are subjected to a series of engineering design reviews. Product design reviews are held with members from Marketing, Engineering, Compliance, Testing, Reliability, Sourcing, Advanced Manufacturing, and Quality Assurance to assure a high level of quality is maintained before releasing any product or revision to manufacturing. Manufacturing is involved in all applicable areas early in the process.

Design development planning

Design development begins by planning and developing the customer voice using the *Agreed Terms of Reference* (ATOR). A project plan, detailed architectural and functional specification, and verification / validation test methodology are then employed. The project schedule is developed and followed by the team and includes all activities that affect project delivery such as design validation, compliance testing, design verification, qualification, etc.

Electrical and mechanical engineering

Schematics, purchased part specifications (PPS), bills of material (BOM), and system hardware specifications are controlled by the Engineering Change system to meet the requirements of the ATOR. The system hardware specification describes the module breakouts, electrical interfaces, system application, system power requirements, system expansion plan, system test plan, and prototype requirements. Board-level specifications for each printed circuit board assembly include information on the sequence of operation, a block diagram, physical constraints, software requirements, module test plans, and the target cost.

Mechanical design specifications cover mechanical parts, enclosures, and metal work. All design documentation and printed circuit board constraints are reviewed by Engineering. The schematic and printed circuit board layout are reviewed by Advanced Manufacturing for testability and manufacturability considerations.

Engineering uses the requirements to do the design verification / validation planning and testing.

Software and firmware engineering

The *System Design Document* (SDD) and *Detailed Software Document* (DSD) are created based on the ATOR. The senior design team reviews the documents. The software and firmware are then coded and reviewed. All code generated is entered into a defined version control system for tracking and revision control. All modules are black box and white box tested. The modules are put together according to the SDD or DSD and each build is tested.

Before release to validation testing, the software and/or firmware is fully integrated with the target hardware and fully system tested as specified in the *EST4 Test Plan* or *ATLAS Power Supply Test Plan*. All quality records for the design process are stored in the project file.

Agency requirements

In addition to normal functional design verification, the designs will be compared to the standards shown in Table 1 below.

Table 1: Listing matrix for all marketplaces

Agency/Listing	Americas	Europe	China
UL 864/ULC-S527			
UOJZ/7/C	Y	N	N
UUKL/7/C	Y	N	N
UOXX/7/C	Y	N	N
SYZV/7/C	Y	N	N
UOQY	Y	N	N
UL 2572	Y	N	N
ULC-S527-99	Y	N	N
ORD-C1076	Y	N	N
UL 1076	Y	N	N
UL 1610	Y	N	N
UL 1635	Y	N	N
UL 2017	Y	N	N
UL 2043	Y	N	N
UL 2572	Y	N	N
UL 294	Y	N	N
UL 365	Y	N	N
UL 464	Y	N	N
UL 609	Y	N	N
UL 636	Y	N	N
UL 639	Y	N	N
ULC-S303	Y	N	N
ULC-S524	Y	N	N
ULC-S525	Y	N	N
ULC-S559	Y	N	N
ULC-S576	Y	N	N
FM 3010	Y	N	N
CSFM 6911	Y	N	N
CSFM 7120	Y	N	N

Agency/Listing	Americas	Europe	China
CSFM 7165	Y	N	N
CSFM 7300	Y	N	N
ICC-ES AC 156 (OSHPD)	Y	N	N
MEA (New York)	Y	N	N
CFR 47, Part 15 (FCC)	Y	N	N
ICES-003	Y	N	N
NOM-016-SCFI (Mexico)	Y	N	N
City of Chicago High-Rise	Y	N	N
City of Chicago Class I	Y	N	N
City of Chicago Class II	Y	N	N
IRAM 3551 (Argentina)	Y	N	N
EC1907/2006 (REACh)	Y	Y	Y
EN/IEC62368-1	N	Y	N
EN 50130-4 2011	N	Y	N
EN 54-2	N	Y	N
EN 54-4	N	Y	N
EN 54-13	N	Y	N
EN 54-16	N	Y	N
EN 54-17	N	Y	N
EN 54-21	N	Y	N
EN 55022/CISPR 22	N	Y	N
EN 55024	N	Y	N
EN 60001-4-2	N	Y	N
EN 60529	N	Y	N
EN 61000-3-2	N	Y	N
EN 61000-3-3	N	Y	N
EN 61000-6-3	N	Y	N
2015/863/EU (RoHS)	Y	Y	Y
2012/19/EU (WEEE)	Y	Y	Y

Agency/Listing	Americas	Europe	China
2015/720/EU	Y	Y	Y
2013/56/EC (Battery)	N	Y	N
PN 100/5 (LPCB/BRE)	N	Y	N
CNBOP (Poland)	N	Y	N
EAC (Russia)	N	Y	N
TSE (Turkey)	N	Y	N
Conflict Minerals (EU)	N	Y	N

Agency/Listing	Americas	Europe	China
PSB (Singapore)	N	Y	N
CCCF GB 4717-2005 **(See Appendix B)**	Y	N	Y
CCCF GB 16806-2006/XG1-2016	N	N	Y

Notes
- Security listings with the 3-SAC etc. will not be required.
- SYZV: Control Units Releasing Devices
- UOQY: Emergency Communication and Relocation Equipment

Reliability

During the new product development stage, the SDD is developed by Engineering and reviewed by assigned members for the design specification review process. This provides assurance that new products meet the goals of the quality assurance program and do not violate requirements of the relevant regulatory agencies. Component Engineering determines if the reliability of each design is sound by doing the calculation of Mean Time Between Failure (MTBF) rates of the electrical designs based on MIL-HDBK-217. During the early stages of design, an Alpha Test Plan is developed with a minimum MTBF goal of 1,000,000 unit/hours operation for the panel (an accumulation of all assemblies involved) prior to final release.

Once the product is released, product Quality tracks the actual MTBF for each major component of the system. The MTBF data is reviewed and acted upon as needed.

Release to manufacturing

After completion of design validation testing, Engineering releases the product and creates an engineering change notice (ECN). The ECN is used for approving and releasing the new product to manufacturing. Quality Assurance verifies that applicable requirements are met and signs the ECN. The ECN package includes engineering drawings and BOM or schematics. The firmware is released using the applicable controlled design tool along with pertinent version information and final checksums (if applicable). The software engineer, or delegate, creates product release files in the Software Control System for Manufacturing. Duplicated firmware ID is labeled with the part number, version, and checksum (if applicable). The associated ECN is given to Manufacturing and maintained by the designated liaison within Edwards. Quality Assurance uses this information while configuring and conducting audits on the EST4 product line.

In the case of changes to products certified under CPR rules (EN 54-x), the Notified Body shall be informed of said changes. All changes shall be applied only after the Notified Body has approved the changes.

Qualification/first article testing

The object of the qualification testing is to closely simulate what a customer would experience in actual field installations with alarms, audible, visible, and switch operations included. Any discrepancies are documented and reviewed by quality and design teams for agreed-upon actions before allowing shipments to begin. Quality Assurance orders all new assemblies (see “Table 3: High-Level Electronic Assemblies” on page 28”) and develops a test plan based on the applicable specifications and complexity of the system. The associated documentation released via the ECN system is used during this process. This includes schematics, assembly drawings, BOMs, and technical documentation. The first step is a visual inspection of the packaging and the drawings to ensure proper labeling, operating firmware versions, hardware revisions, and applicable agency marks. The test plan is then executed, and normal system operation is obtained according to the test plan. First article testing is performed at the manufacturing facility by the Quality Assurance Team. This ensures the first pieces off the assembly line meet the same requirements as above. A flow diagram of the FAI audit process can be seen in Figure 2 on page 27.

Alpha site testing

Due to the life safety aspect of these products, an in-depth alpha test program is performed. This includes requirements for minimum number run-time hours with no significant defects allowed. The senior management team comprised of staff from the Quality Assurance, Product Management, Engineering, and Manufacturing departments review results and any noted concerns before allowing release to customers. Panels are run in different configurations and test plans to best capture all intended operations. Weekly reviews are held to discuss all issues until release.

Chapter 3
Manufacturing

Content

Introduction

The Manufacturing group builds all assemblies used in this project. The whole process involves purchasing materials according to the Edwards PPS and sourcing process. All necessary tests and inspections such as in-circuit testing (ICT), functional test (FCT), reliability test, and packaging/shipping are completed according to specifications. The facility where EST4 products are manufactured is registered to ISO 9001 or other approvals as needed to meet requirements of this document to build EST4 board assemblies. This involves site visits and approvals conducted by Quality Assurance department staff, where needed.

This chapter defines the manufacturing activities necessary to ensure the product line meets required functional performance specifications and reliability criteria. The approach is error prevention. The plan defined in this chapter aims to prevent errors and provide feedback mechanisms and corrective and preventive actions for unforeseen errors.

The program applies to:

- Product planning
- Process planning
- Supplier quality
- Processes and resources
- Documentation and training
- Customer support and service
- Feedback and measurements

Product and process planning

Product evaluation and samples

Edwards design supplies all necessary engineering drawings, documentation, and specifications to describe the parts and construction of the product for test requirements to make sure the product can perform its designed function. The product is built and inspected according to IPC requirements. Sample lots are built and sent to Edwards for qualification and approval. Please see Appendix A “Qualification process in the U.S.” on page 25 for further details. Regardless of the type of component, all customized parts are evaluated and approved by the Production Part Approval Process (PPAP) level 3.

Process planning

Process planning includes selecting the right equipment, developing the tooling and fixtures, providing complete work instructions, test methods, and using the proper process control to comply with all requirements specified in the Carrier quality operating system. The Manufacturing group, under guidance from Edwards product management and design, completes this aspect.

Purchased material quality assurance

Supplier selection and approval

Quality Assurance is responsible for assessing all potential new suppliers. QA audits typically include reviews of the supplier's quality control structure and their manufacturing and engineering capabilities, which may include on-site visits to suppliers of critical components and assemblies or subcontractor facilities. All assessments are carried out following established quality operation procedures for vendor survey and control.

A supplier must receive approval by QA before being added to the *Approved Vendor List*. Edwards controls the materials used in the manufacture of this product, and the Manufacturing group is required to follow the Edwards list of approved parts. The Manufacturing group uses the Edwards part number system to identify Edwards-controlled parts. The Manufacturing group closely consults the Edwards Quality Assurance department during the supplier approval process.

Incoming inspection and test planning

The Quality Assurance department is responsible for documenting the appropriate incoming inspection, test plans, and test procedures for all purchased items. The test plan is based on the applicable component specification sheet, or on the parts drawing, and is designed to ensure all components and assemblies released to the stocking locations meet any documented requirements.

Planned tests for electronic components

Industry standard integrated circuits are visually inspected to ensure the correct component has been supplied. Devices with a history of solid long-term quality performance may be qualified to be ship-to-stock using established guidelines. Emphasis is placed on component selection by Component Engineering of Edwards to assure use of reliable components.

Industry standard ICs are generally not tested at incoming inspection due to their complexity and the investment necessary for test equipment to conduct meaningful tests. Suppliers of these items are qualified by QA to ensure product quality. Ultimately, the devices are tested when the product is tested during functional performance.

Planned inspection and test for other parts

Every component, in general, is inspected according to an established plan, evaluated, approved, and documented in the control plan that is part of the PPAP. Other parts (for example solder paste, adhesives and epoxies, potting compound, conformal coating, etc.) are also inspected and shelf-life control is established according to the product's specifications and the procedures set forth by the Manufacturing group.

Nonconforming material control and corrective or preventive actions

Nonconforming materials are handled at incoming inspection per established quality procedures, which includes review, verification, and feedback to suppliers. Nonconformities are addressed using the 8D process. The goal is prevention of problems.

Supplier quality inspection tracking

Only when required by one or more of the 10 Alternate Means of Control (AMC) requirements or the inspection of a safety Key Product Characteristic (KPC), the product, reports, and certificates are audited upon receipt. Under normal circumstances, the reception of parts from authorized suppliers (standard or customized) must be properly documented according to what is specified in the Supplier Quality Manual (see the link following this paragraph). Rejections found at incoming inspection are documented according to the supplier quality manual, which specifies what to do in these cases. Quality control is responsible for generating a quarterly supplier quality profile for the main suppliers, which is sent to the Management and Purchasing groups for review before sending it to the supplier. Edwards is kept informed of a supplier's critical problems.

https://www.corporate.carrier.com/suppliers/

First article inspection

Any revision changes to the product must be reviewed by Quality Assurance for determining first article inspection requirements. These requirements are typically listed in the ECN package given to Manufacturing but could come out of any regularly scheduled reviews of new or legacy products. The first article inspection is intended to ensure the design intent is met, and any findings are handled by corrective action. Appendix A shows the list of the assembled SKUs (Tables 3-8).

Process assurance

The Quality Assurance (QA) group includes representation by the Manufacturing, Engineering, Quality Assurance, Production, and Training departments. The entire group operates under a set of quality and engineering procedures designed to satisfy or exceed ISO 9001 requirements.

QA evaluates all design, process, and sample manufacturing procedures. Required skills, equipment, and tooling for operators are evaluated.

Procedural documentation is produced for all manufacturing processes to be used by operators, inspectors, and technicians and for training materials. Production staff is trained and certified using established procedures.

The online audit inspector audits proper ESD controls, material handling, and production processes. Audit results are documented and entered into the Quality Assurance database daily for periodic analysis, reporting by Engineering, and Management review. Corrective or preventive actions are initiated if required.

Corrective action is taken immediately if a discrepancy is found.

As part of the NPD process, the production processes are evaluated by the Process Certification procedure known as ProCert, which is divided into four stages, with tollgates known as milestones, that start after the design is frozen.

Manufacturing flow – all versions of PC boards

The boards comprise all model numbers built.

All PC board assemblies use BGA, through hole, and surface mount technology. All assemblies are either single- or double-sided. The surface mount process uses pick and place equipment and reflow ovens. This is followed by through hole component assembly and wave solder. All PC board assemblies perform different functions in the product family, but manufacturing processes for them are effectively the same. All versions are tested with different in-circuit test and functional test programs according to the characteristics of each product. Some heat or solvent sensitive components are hand soldered with no-clean solder wire. Figure 3 on page 34 shows the manufacturing steps and controls in this process.

Note: All manufacturing workstations are subject to QA audit. Problems are corrected immediately while emphasizing, “Do it right the first time.” SPC is applied on the wave soldering process and the defective rate is monitored.

Process assurance and trend analysis

Quality Assurance and Manufacturing are informed of any deviation from quality requirements for immediate corrective action.

Regular quality meetings are conducted to review all quality reports and define action items if required.

Nonconforming material and corrective / preventive action request

Whenever nonconforming material is found in quantities that exceed predefined limits, a defective material report is generated by production.

Quality Assurance works with Manufacturing as a team to define the root cause and generate a corrective action, which is then submitted to the material review board for review and approval. After the action is taken, Quality Assurance verifies whether the action has been effective.

If any of the following problems are found, QA generates a corrective and preventive action request.

- Discrepancy is found on a finished goods and reliability audit
- Edwards returned material analysis and findings
- Process assurance or trend analysis indicates an unexpected rate of defects
- Failure in production is higher than expected
- MRB recommendation

Training

The Manufacturing group is responsible for maintaining and implementing a comprehensive training system. All production and special process operators are trained and certified before beginning work. All process techniques are documented with a written manufacturing procedure used as a reference for training and as a guideline for the process. All personnel working in PCB assembly and material handling are trained for ESD procedures. All personnel working in soldering and inspection processes are trained for IPC soldering technology requirements. The criteria for certification are defined. The Manufacturing group trains inspectors, leaders, and engineers for workmanship requirements based on IPC standards.

Product assurance

The Advanced Manufacturing and Test group develops test plans according to customer requirements. The entire test process for the EST4 panel product is shown in Figure 3 on page 34. The following describes the major test steps, which assure the EST4 panel product family meets the requirements defined by Edwards.

Manufacturing process verifications

Solder Paste Inspection (SPI)

PCBs are inspected either offline as an audit or online as part of the surface mount process to verify the coverage of the solder paste using automated equipment.

Automated Optical Inspection (AOI)

Surface mount components are inspected using an AOI to check for catastrophic failures or quality defects during the surface mount process.

Assembly tests

The assembly tests used for the EST4 are listed in Table 2 below.

Table 2: Assembly tests per EST4 SKU or Assembly

Catalog Number (* includes all with the same base number)	Description	Dielectric	ICT	FCT	Burn-In	Final Test	Quality Audit
		PCBA Level SMT Area	PCBA Level SMT Area	PCBA Level Assembly Area	SKU Level Assembly Area	SKU Level Assembly Area	SKU Level Packing Area
4-24L*	Display Module, 24 LED		X				X
4-24L12S*	Control Display Module, 24 LED/12 Switches		X				X
4-24L18S*	Control Display Module, 24 LED/ 18 Switches		X				X
4-24L24S*	Control Display Module, 24 LED/ 24 Switches		X				X
4-3LCD*	Display, LCD, EST3 Upgrade		X	X			X
4-ANNAUDTEL	Annunciator, Audio and Telephone		X				X
4-ANNCPU*	Annunciator, Central Processor		X	X			X
4-AUDTELS*	Audio and Telephone Interface/Riser		X				X
4-COMREL	Common Relay Module		X				
4-CPU*	Central Processor Module		X	X			X
4-CPUGRPH*	Graphic Annunciator, Central Processor		X	X			

Catalog Number (* includes all with the same base number)	Description	Dielectric	ICT	FCT	Burn-In	Final Test	Quality Audit
		PCBA Level SMT Area	PCBA Level SMT Area	PCBA Level Assembly Area	SKU Level Assembly Area	SKU Level Assembly Area	SKU Level Packing Area
4-FT	Firefighter Master Handset		X				X
4-FWAL1*	Firewall Module		X	X			X
4-FWAL2*	Firewall Module with DACT		X	X			X
4-FWAL3*	Firewall Module with Email		X	X			X
4-FWAL4*	Firewall Module with DAC, Email		X	X			X
4-MIC*	Paging Microphone		X				X
4-NET-AD*	Network Adder Module		X	X			X
4-USBHUB	Multiport USB Hub Module		X	X			
4-LCDAUDTEL	LCD Module for Audio/Telephone Control		X				X
4-LCD*	Main LCD Module		X				X
UI RAIL	UI Rail PCB Assembly		X				
4-NET-TP	SFP Network Controller, 2Mbps			X			
4-NET-TP-HC	SFP Network Controller, 0.3Mbps			X			
4-NET-XT	Network Extender Module				X		
4-PPS/M*	Power Supply with Monitor	X	X	X	X	X	X
4-FERKIT5	Ferrite Mounting Kit			X			
Buzzer Board	Buzzer Board PCB Assembly			X			
Filter Board	Common Mode Filter PCB Assembly		X				

Printed circuit board assembly tests

Dielectric test (Hi-Pot)

All EST4 panel PCBs with high voltage as defined by agency requirements are required to complete dielectric testing, also known as hi-pot. High voltages are applied between the AC input and earth ground and between the high and low voltage areas to ensure sufficient separation between the lines. Dielectric testing is performed with an enclosed bed of nails fixture, which allows access to all terminals for applying the high voltage. Dielectric test equipment is utilized to generate the high voltage and measure the current. This test is performed on 100% of applicable EST4 PCBAs.

In-Circuit Test (ICT)

All EST4 panel PCBAs are required to have sufficient nodal access to support 100% functional testing. This means that comprehensive and effective in-circuit and functional tests are generated to ensure that no defects are present on the PCBA. The test platform is capable of performing functional and in-circuit testing. In-circuit testing is performed with a bed of nails fixture, which allows access to all components on the board. A test program is designed to perform the following test functions:

- Shorts and continuity
- Version tests
- Analog component value tests
- Digital tests
- Functionality tests

Shorts and continuity: Performed on 100% of EST4 PCBAs. Tests all nodes on the circuitry for short-circuit and continuity to make sure the component is populated and soldered correctly.

Version tests: Performed on 100% of EST4 PCBAs. The test program will test components using the latest code revision in production. Some programmable chips (such as those for audio boards) are bought preprogrammed and are tested at the appropriate point in the process.

Analog component value tests: Performed on 100% of EST4 PCBAs. The program tests all non-digital components R, L, C, diode, FET, transistor, zener diode, etc. on the board.

Digital tests: Performed on 100% of EST4 PCBAs that include digital components. The program tests all accessible operational features of the digital component.

Functionality tests: Performed on 100% of EST4 PCBAs with a low complexity that do not require an additional PCBA Functional Test. The program exercises the basic functionality of each circuit of the assembly.

PCBA Functional Test (FCT)

Performed on EST4 PCBAs. The tests include but are not limited to:

1. Power startup test
2. Verify voltage outputs
3. Verify voltage inputs
4. Verify the current drawn is within design limits
5. In circuit power and functionality testing
6. Unit configuration
7. Power on and test in-system and simulate CPU functions. This tests the unit in a power-up condition to mimick operation in the field
8. Any assembly that fails will be tracked by online download of test data and followed up by real time corrections to processes or procedures

Burn-in test

This is a required system test for those SKUs with a high-power circuitry, such as amplifiers and power supplies, to weed out infant mortality. Burn-in tests are performed for an extended period while the assembly is operating and being monitored by an EST panel for faults. The burn-in fixture also monitors for constant voltage output at regular intervals.

Final test

This is a 100% required functional test for those SKUs that include multiple mid-assemblies, are considered an assembly of a considerable level of complexity or require further verification.

Rejected parts in this test are reported with a printed ticket report that facilitates determining the root cause and the failure mode. With this report the technician can fix the problem accurately and retest it.

Quality audit

The Manufacturing group uses test procedures and fixtures written and designed by Edwards for all outgoing quality audits carried out on a consistent basis. Details of this process are described in Chapter 4 “Reliability audit and customer quality support” on page 21.

Quality information collection and feedback

Data from quality, testing, and online audits is generated throughout the manufacturing cycle. The following paragraphs list the data sources and reports generated for management review.

Purchased material quality data

Incoming material inspection data is manually collected, analyzed, and reported. Four procedures govern QA for purchased material, as defined in these documents:

- *Supplier Qualification Process*
- *Supplier Excellence Playbook*
- *Supplier Corrective Action Reports*
- *Control of Non-Conforming Material*

Manufacturing test data collection

Data is collected from all test stations. The data is analyzed to detect problems and corrective action is taken (see Figure 3 on page 34). EN54-approved products are audited at predetermined intervals with evidence of those audits retained for a period of 3 years.

Customer corrective action

Quality Assurance ensures prompt corrective action on customer reports through the Technical Support department’s Case Ease system interfacing with Sales, Product Management, and Engineering. Current database tools are used, and reports analyzed for metrics reporting and escalation.

Process assurance

Inspection, rework, and online auditor inspection records help focus on corrective actions and operator performance. In accordance with Regulation (EU) No. 305/2011, the follow record keeping periods are observed:

- Production results for a period of 10 years
- This quality plan for a period of at least 10 years
- Calibration certificates of measurement equipment for a period of 5 years
- Production machinery/equipment maintenance records for a period of 2 years

Final inspection

A product audit report shows the weekly audit inspection and test results for every lot, the lot acceptance by part number and production line, the acceptance rate, and defects found if the product is rejected at inspection. It also shows the monthly acceptance rate by part number for all shipped products.

The report is based on audit inspection and testing results for the previous six months. Cumulative results can be selected for analysis of a specific period of time to determine the cumulative PPM of shipped product.

Customer data tracking

The Quality Assurance group collects customer data and tracks quality performance. Data is provided from the following sources:

- Returned material data
- Quality Issue Tracker (QIT)

Final assembly

Manufacture and configure flow

The final configuration of the product takes place at the manufacturing facility. At this location, assembly includes generic stock electronics. The final configuration process picks the parts and package to order as shown in Figure 3 on page 34.

Chapter 4
Reliability audit and customer quality support

Content

Introduction

The reliability audit activity is divided between the manufacturing location and Edwards headquarters in Bradenton.

On-site reliability audits

This section describes the reliability audit requirements for EST4 products carried out at Edwards after products are manufactured.

Reliability test audits are conducted at predetermined intervals as specified in established audit plans. The environmental parameters are based on the design and test specifications in UL 864. Worst-case field use conditions of the product are simulated in a fully monitored test system during the audit.

Reliability audits align to the requirements of each agency including, but not limited to:

- Document revisions
- Critical components
- EMC testing
- ESD testing
- Functionality testing

Note: Audits and audit plans are continually reviewed and revised as necessary based on field findings and customer inputs.

Field data tracking

Field performance data is tracked using one of several methods:

- Returned material data
- Service information
- Marketing feedback analysis (MFA) surveys
- Mean Time Between Failures (MTBF); values are calculated quarterly, based on field performance
- Technical Support activity log review
- Sales data

Customer quality support

The primary focus of customer support is to quickly identify and resolve customer complaints.

These may come from various sources:

- Customer calls, MFA surveys, and MFA meetings
- Sales
- Technical Support
- Engineering
- Marketing

End-user customers, OEMs, Sales, or Technical Support staff can contact the Customer Quality Support group. Additionally, QA may visit the customer's site to address and resolve specific issues. Customer Quality Support also performs the following activities:

- Maintain customer contact database via phone
- Measure and monitor field return rates
- Conduct MFA surveys
- Monitor mean time between failures
- Conduct meetings to address customer issues
- Provide root cause analysis and feedback to customers

Failure analysis / corrective and preventative actions

An end-user, OEM, Technical Support, or Sales office can request a detailed analysis on modules or panels being returned.

The analysis report will contain the following information, based on the Carrier Quality tool, Define, Investigate, Verify, and Ensure (DIVE) format:

- **Define**: What the customer reported
- **Investigate**: Visual and electrical test results
- **Verify**: Details of the probable root cause for the failure
- **Ensure**: Recommended corrective and preventive action required by Edwards and/or the customer.

Failure analysis data is used internally to identify process-related, manufacturing assembly, and component reliability issues. Changes or corrections are implemented as necessary when identified. The Manufacturing group's help is solicited as needed during the analysis.

Returned material support

In the case of EST4, returned materials are handled like all other Edwards products. The Manufacturing group is involved as required to ensure corrective and preventive actions and supply replacements if needed. The RMA group collects returns and forwards them to Edwards Quality for analysis and action.

Appendix A
Qualification process in the U.S.

Content

Qualification process

This is a three-part qualification process:

- Overall design performance and manufacturing process where built
- Qualification process where designed
- Customer configuration

The details of these three categories are given below.

Overall design performance and manufacturing process where built

The overall design performance and manufacturing build qualification verifies nothing was missed during the internal checks and balances of the design process and the product was manufactured according to the design intent. This electrically verifies operation as well as mechanically checks out form, fit, and function. This also verifies the product meets the requirements of applicable agencies. This is done by visual inspection, build vs. drawings comparison, and electrical testing against specifications released by Edwards's Advanced Manufacturing group. Quality Assurance decides how many units of each assembly is to be qualified. Quality Assurance works with Purchasing and Advanced Manufacturing to complete this step.

Qualification process where designed

Units are qualified by placing an order with Customer Service to verify correct catalog numbers and the process of relaying orders to Manufacturing. Once the orders are received, the proper processes and procedures are verified to be in place through visual inspection, build vs. drawings, BOM comparison to the enterprise resource planning (ERP) system, and the verification of adequate packaging of the shipped system. Where applicable, this includes configuring and operating the system in a customer configuration to verify usability.

Customer configuration

Quality Assurance sets up a customer configuration to qualify the correct system operation and design intent.

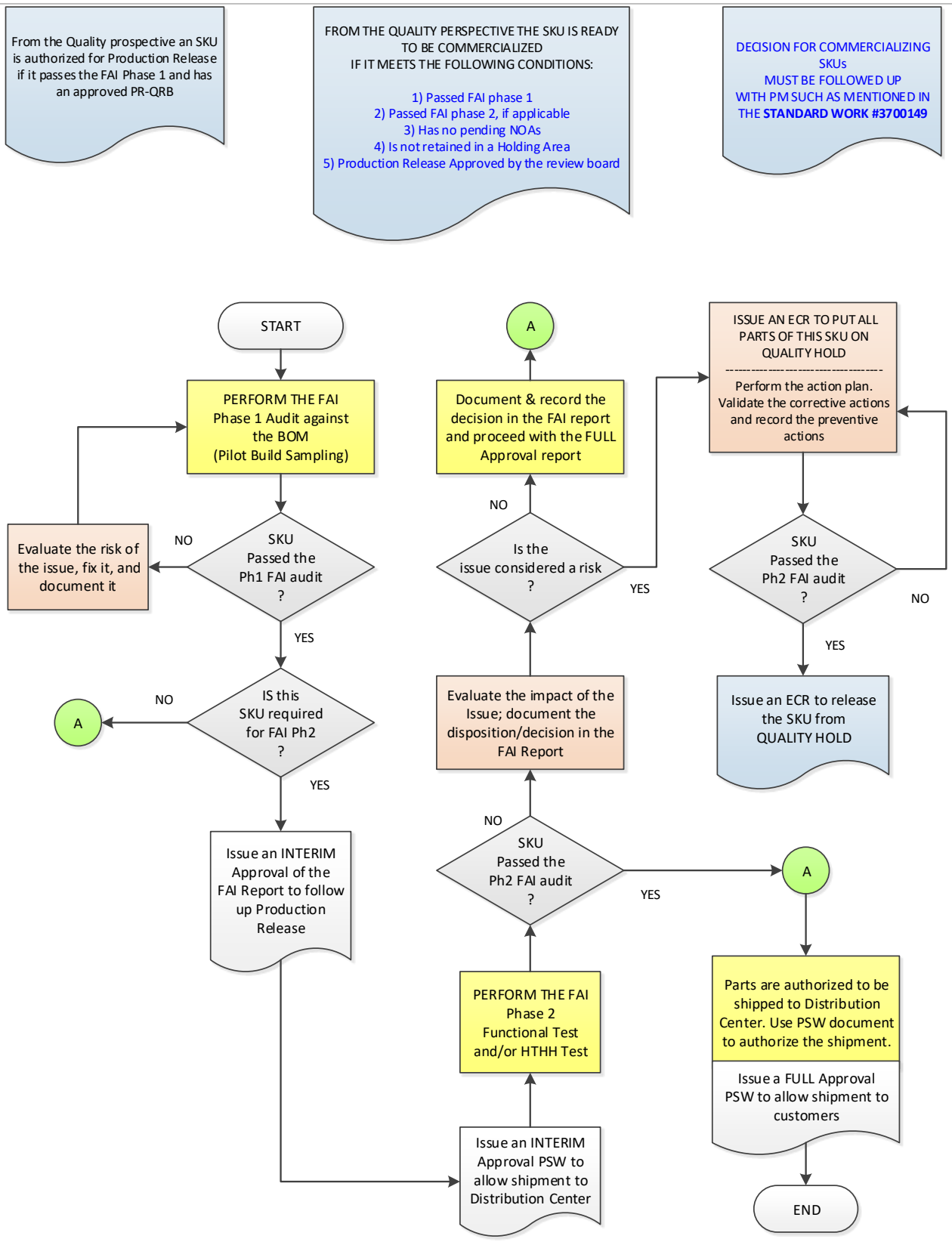
Equipment list:

- Temperature chamber
- Test jig
- DC voltage source
- Multimeter
- Oscilloscope
- Electronic and device loads
- IDC and NAC devices

Upon successful completion of the above three parts, Quality Assurance gives approval for shipments.

FAI audit flow diagram process

Figure 2: First Article Inspection audit – flowchart



EST4 SKUs – FAI audit process requirements

Table 3: High-Level Electronic Assemblies

ITEM	Catalog	Final/Pilot ECN	DATA Rev.	PHASE 1			PHASE 2	
				Labels	Inst. Sheets	Bag Assy	Quantity Required for Functional Test	QTY Required for Environmt. (HTHH)
1	**4-24L**	19-02243	004	X	X	X	12	1
2	**4-24L12S**	19-02243	004	X	X	X	12	1
3	**4-24L18S**	19-02243	004	X	X	X	8	1
4	**4-24L24S**	19-02243	004	X	X	X	12	1
5	**4-3LCD**	19-02269	004	X	X	X	8	1
6	**4-ANNAUDTEL**	19-02243	006	X	X	X	8	1
7	**4-ANNCPU**	19-02269	003	X			8	1
8	**4-AUDTELS**	19-02280	004	X	X	X	8	1
9	**4-COMREL**	19-02243	005	X	X	X	8	1
10	**4-CPU**	19-02280	004	X	X	X	19	1
11	**4-CPUGRPH**	19-02269	004	X	X		8	1
12	**4-FT**	19-02243	004	X	X	X	8	1
13	**4-FWAL1**	19-02280	004	X	X	X	3	1
14	**4-FWAL2**	19-02280	004	X	X	X	8	1
15	**4-FWAL3**	19-02280	004	X	X	X	5	1
16	**4-FWAL4**	19-02280	004	X	X	X	8	1
17	**4-MIC**	19-02243	004	X	X	X	12	1
18	**4-NET-AD**	19-02269	004	X	X	X	6	1
19	**4-TAMP**	19-02243	003	X	X	X	1	1
20	**4-USBHUB**	19-02243	004	X	X	X	7	1
21	**4-CABLUSBSM**	19-02243	004	X			1	1
22	**4-CABL0541**	19-02269	004	X			1	1
23	**4-LCDAUDTEL**	19-02269	004	X	X	X	1	1
24	**4-LCD**	19-02269	004	X	X	X	12	1
25	**4-PPS/M**	21-03494	002	X	X	X	5	N/A
26	**4-PPS/M-E**	23-04838	003	X	X	X	N/A	N/A
27	**4-3LCD-E**	23-04751	002	X	X	X	N/A	N/A
28	**4-CPU-E**	23-04751	003	X	X	X	2	N/A
29	**4-ANNCPU-E**	23-04751	002	X			2	N/A
30	**4-NET-AD-E**	23-04751	002	X	X	X	N/A	N/A
31	**4-FWAL1-E**	23-04751	002	X	X	X	N/A	N/A
32	**4-FWAL2-E**	23-04751	002	X	X	X	N/A	N/A
33	**4-FWAL3-E**	23-04751	002	X	X	X	N/A	N/A
34	**4-FWAL4-E**	23-04751	002	X	X	X	N/A	N/A

ITEM	Catalog	Final/Pilot ECN	DATA Rev.	PHASE 1			PHASE 2	
				Labels	Inst. Sheets	Bag Assy	Quantity Required for Functional Test	QTY Required for Environmt. (HTHH)
35	**4-24L-E**	23-04751	002	X	X	X	N/A	N/A
36	**4-24L12S-E**	23-04751	002	X	X	X	N/A	N/A
37	**4-24L18S-E**	23-04751	002	X	X	X	N/A	N/A
38	**4-24L24S-E**	23-04751	002	X	X	X	2	N/A
39	**4-MIC-E**	23-04751	002	X	X	X	2	N/A
40	**4-PPS/M-C**	22-04645	003	X	X	X	2	N/A
41	**4-CPU-C**	22-04645	003	X	X	X	N/A	N/A
42	**4-ANNCPU-C**	22-04230	001	X			N/A	N/A
43	**4-NET-AD-C**	23-04889	002	X	X	X	N/A	N/A
44	**4-FWAL1-C**	22-04645	002	X	X	X	N/A	N/A
45	**4-FWAL2-C**	22-04645	002	X	X	X	N/A	N/A
46	**4-FWAL3-C**	22-04645	002	X	X	X	N/A	N/A
47	**4-FWAL4-C**	22-04645	002	X	X	X	N/A	N/A
48	**4-24L-C**	23-04839	002	X	X	X	N/A	N/A
49	**4-24L12S-C**	23-04839	002	X	X	X	N/A	N/A
50	**4-24L18S-C**	23-04839	002	X	X	X	N/A	N/A
51	**4-24L24S-C**	23-04839	002	X	X	X	N/A	N/A
52	**4-AUDTELS-E**	23-04751	002	X	X	X	N/A	N/A

Table 4: Large Low-Level Mechanical Assemblies

ITEM	Catalog	Final/Pilot ECN	DATA Rev.	PHASE 1			PHASE 2	
				Labels	Inst. Sheet	Bag Assy	Quantity Required for Functional Test	QTY Required for Environmt. (HTHH)
1	**4-16ANNMT**	19-02244	004	X	X		N/A	N/A
2	**4-24ANNMT**	19-02244	004	X	X		N/A	N/A
3	**4-8ANNMT**	19-02244	004	X	X		N/A	N/A
4	**4-CAB16D**	19-02256	005	X	X	X	N/A	N/A
5	**4-CAB16DR**	19-02256	005	X	X	X	N/A	N/A
6	**4-CAB24D**	19-02256	005	X	X	X	N/A	N/A
7	**4-CAB24DL**	19-02256	004	X	X	X	N/A	N/A
8	**4-CAB24DR**	19-02256	005	X	X	X	N/A	N/A
9	**4-CAB24DRL**	19-02256	004	X	X	X	N/A	N/A
10	**3-CAB5B**	19-02244	003	X	X	X	N/A	N/A
12	**4-CAB8D**	19-02256	004	X	X	X	N/A	N/A
13	**4-CAB8DR**	19-02256	003	X	X	X	N/A	N/A
14	**4-CABL0542**	19-02267	004	X	X		N/A	N/A
15	**4-PL0457**	19-02244	001	X			N/A	N/A

ITEM	Catalog	Final/Pilot ECN	DATA Rev.	PHASE 1			PHASE 2	
				Labels	Inst. Sheet	Bag Assy	Quantity Required for Functional Test	QTY Required for Environmt. (HTHH)
16	**4-HNG714**	19-02244	004	X			N/A	N/A
17	**4-HNG21**	19-02244	004	X			N/A	N/A
18	**4-LOCK2KEY**	19-02244	004	X			N/A	N/A
19	**4-CABL0505**	19-02256	004	X		X	N/A	N/A
20	**4-CABL0507**	19-02256	004	X		X	N/A	N/A
21	**3-CHAS7-I**	23-04839	004	X	X	X	1	N/A
22	**4-CAB16D-E**	23-04762	002	X	X	X	N/A	N/A
23	**4-CAB16DR-E**	23-04762	002	X	X	X	N/A	N/A
24	**4-CAB24D-E**	23-04762	002	X	X	X	N/A	N/A
25	**4-CAB24DR-E**	23-04762	002	X	X	X	N/A	N/A
26	**4-CAB24DL-E**	23-04762	002	X	X	X	N/A	N/A
27	**4-CAB24DLR-E**	23-04762	002	X	X	X	N/A	N/A
28	**4-CBA48D**	22-04570	001	X	X	X	N/A	N/A
29	**4-CBA72D**	22-04570	001	X	X	X	N/A	N/A
30	**4-CBA48ID**	22-04570	001	X	X	X	N/A	N/A
31	**4-CBA72ID**	22-04570	001	X	X	X	N/A	N/A
32	**4-CBABIN**	22-04570	001	X	X	X	N/A	N/A
33	**4-CBABATS**	22-04570	001	X	X	X	N/A	N/A

Table 5: Small Low-Level Mechanical Assemblies

ITEM	Catalog	Final/Pilot ECN	DATA Rev.	PHASE 1			PHASE 2	
				Labels	Inst. Sheet	Bag Assy	Quantity Required for Functional Test	QTY Required for Environmt. (HTHH)
1	**4-BRKT-CB**	19-02246	004	X	X	X	N/A	1
2	**4-BRKT-CS**	19-02246	003	X	X	X	N/A	1
3	**4-MPLT**	19-02246	003	X	X	X	N/A	1
4	**4-2ANND**	19-02246	005	X	X	X	N/A	1
5	**4-4ANND**	19-02246	004	X	X	X	N/A	1
6	**4-6ANND**	19-02246	004	X	X	X	N/A	1
7	**4-2ANNMT**	19-02246	004	X	X	X	N/A	1
8	**4-4ANNMT**	19-02246	004	X	X	X	N/A	1
9	**4-6ANNMT**	19-02246	004	X	X	X	N/A	1
10	**4-ANNSK**	19-02246	003	X		X	N/A	1
11	**4-FERKIT1**	22-04645	002	X		X	N/A	N/A
12	**4-FERKIT5**	22-04645	002	X	X	X	2	N/A
13	**4-2ANND-E**	22-04729	002	X	X	X	N/A	N/A
14	**4-4ANND-E**	22-04729	002	X	X	X	N/A	N/A

ITEM	Catalog	Final/Pilot ECN	DATA Rev.	PHASE 1			PHASE 2	
				Labels	Inst. Sheet	Bag Assy	Quantity Required for Functional Test	QTY Required for Environmt. (HTHH)
15	**4-6ANND-E**	22-04729	002	X	X	X	N/A	N/A
16	**4-FERKIT2S**	23-04751	002	X	X	X	N/A	N/A
17	**4-FERKIT2L**	23-04751	003	X	X	X	N/A	N/A

Table 6: Warehouse Configured and Kitted Assemblies

ITEM	Catalog	Final/Pilot ECN	DATA Rev.	PHASE 1			PHASE 2	
				Labels	Inst. Sheet	Bag Assy	Quantity Required for Functional Test	QTY Required for Environmt. (HTHH)
1	**4-2ANN**	19-02281	003	X	X	X	N/A	N/A
2	**4-4ANN**	19-02281	003	X	X	X	N/A	N/A
3	**4-6ANN**	19-02281	003	X	X	X	N/A	N/A
4	**4-8ANN**	19-02281	003	X	X	X	N/A	N/A
5	**4-16ANN**	19-02281	003	X	X	X	N/A	N/A
6	**4-24ANN**	19-02281	003	X	X	X	N/A	N/A
7	**4-LCDANN**	19-02281	003	X	X	X	N/A	N/A
8	**4-LCDAUDTELCAB-CB**	19-02281	003	X	X	X	N/A	N/A
9	**4-LCDAUDTELCAB-MPLT**	19-02281	003	X	X	X	N/A	N/A
10	**4-LCDAUDTELANN**	19-02281	003	X	X	X	N/A	N/A
11	**4-ANNCPU**	19-02281	003	X	X	X	N/A	N/A
12	**4-LCDLE**	19-02281	003	X		X	N/A	N/A
13	**4-2ANN-E**	22-04300	001	X	X	X	N/A	N/A
14	**4-4ANN-E**	22-04300	001	X	X	X	N/A	N/A
15	**4-6ANN-E**	22-04300	001	X	X	X	N/A	N/A
16	**4-16ANN-E**	22-04300	001	X	X	X	N/A	N/A
17	**4-24ANN-E**	22-04300	001	X	X	X	N/A	N/A
18	**4-PWRDIST**	23-04751	002	X	X	X	2	N/A
19	**4-PPSKIT**	23-04751	002	X	X	X	N/A	N/A
20	**4-2ANN-C**	22-04290	001	X	X	X	N/A	N/A
21	**4-4ANN-C**	22-04290	001	X	X	X	N/A	N/A
22	**4-6ANN-C**	22-04290	001	X	X	X	N/A	N/A
23	**4-8ANN-C**	22-04290	001	X	X	X	N/A	N/A
24	**4-16ANN-C**	22-04290	001	X	X	X	N/A	N/A
25	**4-24ANN-C**	22-04290	001	X	X	X	N/A	N/A

Table 7: OVP Assemblies

ITEM	Catalog	Final/Pilot ECN	DATA Rev.	PHASE 1			PHASE 2	
				Labels	Inst. Sheet	Bag Assy	Quantity Required for Functional Test	QTY Required for Environmt. (HTHH)
1	**4-NET-SM**	19-02250	003	X	X	X	N/A	1
2	**4-NET-MM**	19-02250	003	X	X	X	N/A	1
3	**4-NET-SMH**	19-02250	003	X	X	X	N/A	1
4	**4-NET-SMD**	19-02250	003	X	X	X	N/A	1
5	**4-NET-SMU**	19-02250	003	X	X	X	N/A	1
6	**4-CAT-SM**	19-02250	003	X	X	X	N/A	1
7	**4-CAT-MM**	19-02250	003	X	X	X	N/A	1
8	**4-CAT-SMH**	19-02250	003	X	X	X	N/A	1
9	**4-CAT-SMD**	19-02250	003	X	X	X	N/A	1
10	**4-CABLUSBLG**	19-02253	003	X	X	X	N/A	1
11	**4-NET-XT**	19-02243	004	X	X		2	1
12	**4-NET-CAT**	19-02250	003	X	X	X	N/A	1
13	**4-FWAL-CAT**	19-02250	003	X	X	X	N/A	1

Table 8: Customized Components and Low-Level Mechanical Assemblies

ITEM	Catalog	Final/Pilot ECN	DATA Rev.	PHASE 1			PHASE 2	
				Labels	Inst. Sheet	Bag Assy	Quantity Required for Functional Test	QTY Required for Environmt. (HTHH)
1	**4-CABL0502**	19-02267	003	X	X	X	N/A	1
2	**4-CABL0504**	19-02267	003	X	X	X	N/A	1
3	**4-CABL0509**	19-02267	003	X	X	X	N/A	1
4	**4-CABL0542**	19-02267	003	X	X	X	N/A	1
5	**FSB-PC4**	20-03296	002	X	X	X	N/A	1
6	**FSB-PC4LW**	20-03296	002	X	X	X	N/A	1
7	**4-FIL**	19-02247	003	X	X	X	N/A	N/A
8	**4-2ANNFA**	19-02247	003	X	X	X	1	1
9	**4-4ANNFA**	19-02247	003	X	X	X	1	1
10	**4-6ANNFA**	19-02247	003	X	X	X	1	1
11	**4-8ANNFA**	19-02247	003	X	X	X	1	1
12	**4-4X2ANNFA**	19-02247	003	X	X	X	1	1
13	**4-NET-TP**	19-02250	003	X	X	X	N/A	1
14	**4-NET-TP-HC**	19-02250	003	X	X	X	N/A	1

Appendix B
Manufacturing production and test flowcharts

CCC Audit Table

GB4717-2005 Clause	Test Description	Test Frequency
4.3.3.1	test on information display and query function	triennially
4.3.3.2	test on power function	triennially
4.3.3.3	electrical strength test	triennially
4.3.3.4	test on radiation immunity of the radio-frequency electromagnetic field	annually
4.3.3.5	test on immunity of conducted disturbances induced by radio-frequency fields	annually
4.3.3.6	electrostatic discharge immunity test	annually
4.3.3.7	electrical fast transient/burst immunity test	annually
4.3.3.8	surge (impact) immunity test	annually
4.3.3.9	constant damp heat (operation)	annually

General Manufacturing Process – PCBA and Subassemblies

Figure 3: General Manufacturing Process – PCBA and Subassemblies - flowchart