## Change History

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1 PURPOSE

The purpose of this procedure is to outline the steps necessary to verify electrical and mechanical hardware for new products or existing products. The Engineering and Management teams may determine that some of the phases do not apply to a given project or that some of the deliverables can be pulled up into an earlier phase. In such cases, the reasoning behind the decisions will be documented and stored in the SharePoint Project Repository. In addition, the Project Plan will be modified to eliminate the unnecessary phases and to update the deliverable milestones.

If scope changes are requested, they are negotiated, approved and documented using the Project Scope Change Form or some other appropriate means. Records of the project scope change are kept in the Design History File (DHF) in compliance with the Records Matrix.

2 INFORMATIVE REFERENCES

- ISO9001:2000 5.2 Customer focus
- ISO9001:2000 7.3 Design and development

3 FLOW CHART

4 HARDWARE ENGINEERING PROCESSES

4.1 Pre-Pilot Phase

The Pre-Pilot process involves testing and verifying samples, either hand-assembled or built on the contact manufacturer’s or the supplier’s manufacturing line. The assembly line and redlined processes and procedures will be developed and fine tuned during this phase.

The deliverables may include, but are not limited to:
- Verification Test Report
- Update to Independent Testing Authority (ITA)
Risk Matrix update
Manufacturing line at CM designed and built
Redlined Manufacturing Processes and Procedures
Hard tooling ordered
Beta Test results
Pilot Test Plan

4.1.1 Release Mechanical Design for Tooling

Once the development samples have been approved, the 3D models and the 2D drawings are sent to suppliers on the Approved Supplier List to get an estimate of the cost to buy the tooling to produce the mechanical parts for the product. Once an agreement has been reached, the part drawings are released in the ECO process and a Purchase Order (P.O.) is generated to authorize the supplier to buy the tooling.

The supplier, when appropriate, may send samples of the parts made with the actual tooling for Hart’s review and approval.

4.1.2 Release PCB Layout and BOM

Once the development samples have been approved, the PCB Layout and BOMs are sent to suppliers on the Approved Supplier List to get an estimate of the cost to buy the PCBs and the components to produce the PCBAs for the product. Once an agreement has been reached, a Purchase Order (P.O.) is generated to authorize the supplier to purchase the parts and manufacturing support hardware.

The supplier, when appropriate, may send samples of the PCBAs for Hart’s review and approval.

4.1.3 Inspect Pre-Pilot Components and Subassemblies

Custom components and subassemblies are sampled and ordered from the suppliers in quantities dictated in the Verification Test Plan. A First Article Inspection (FAI) report is created by the supplier on the components and subassemblies identified in the Verification Test Plan as needing an FAI. The supplier, the Contract Manufacturer or Hart Engineering assembles the components and subassemblies into products, which are evaluated and verified according to the Verification Test Plan.

4.1.4 Engineering and Manufacturing Evaluation and Verification

Upon receipt of the Pre-pilot samples, Engineering conducts various tests as described in the Verification Test Plan, which may require verification that all items are present, that there are no interference issues with electrical or mechanical components, that the parts supplied meet the required drawing dimensions and that the pre-pilot samples are functional.
If the Contract Manufacturer produces the pre-pilot units, they may evaluate and submit a report on their Design For Manufacturability (DFM) and Design for Test (DFT) issues.

Beta testing, which is the release of a product to a controlled group to verify design criteria, may be conducted during this phase. Beta testing results, if required, are reviewed and appropriate design changes are incorporated into the design.

Beta Test results are maintained in the SharePoint Project Repository in compliance with the Records Matrix.

4.1.5 Cross-Functional Design Review

Upon completion of the verification tests and inspection report by Engineering and Contract Manufacturing, a meeting is held between the Engineering groups, Program Management and the CM (when necessary), to review information and identify issues. Every item on the Functional Specifications document may be reviewed as necessary. Approved changes are incorporated into the electrical and mechanical designs accordingly.

Records of the Pre-Pilot Phase Cross-Functional design review and approval are kept in the SharePoint Project Repository in compliance with the Records Matrix.

4.1.6 Design Control

All pertinent documents reviewed at the Cross-Functional Review Meeting including, but not limited to, drawings, specifications, Gerber files, BOMs, Firmware, etc. shall be submitted to Document Control and controlled under the Engineering Change Order procedure.

4.2 Agency, Reliability and Environmental Pre-certification Testing

Once the Pre-Pilot process is completed, product samples are submitted to the appropriate regulatory agencies, such as UL or an FCC accredited lab and product samples may also be tested for shock, vibration and environmental conditions, as described in the Verification Test Plan, to begin the certification process.

Submitting samples earlier in the design process helps recognize design issues sooner and reduces schedule delays later in the development process. When the Pilot Phase is completed, a new product sample may be submitted if there are substantial changes from Pre-Pilot to Pilot phases to ensure that the modifications are also certified.

4.3 ITA Certification Procedure

Once the Pre-Pilot Process is completed, the predetermined quantities of product samples are submitted to the ITA to begin the ITA certification process.
The process is monitored and appropriate action is taken based on the ITA’s requests and their test results.

4.4 Pilot Phase

The Pilot Phase is a process that tests and verifies a pilot build representing production intent products manufactured by the CM on their manufacturing line, using their manufacturing documents and procedures. The Quality Plan and Final Assembly Test are in place during the pilot build. Production parts are used for the build. All part numbers are released. Products can be saleable and placed in inventory after full acceptance is achieved.

The deliverables may include, but are not limited to:
- Pilot Run Test Report
- Update to ITA
- Production Release

4.4.1 Engineering and Manufacturing Evaluation and Verification

Upon receipt of the pilot build samples from the CM, Engineering conducts various tests and inspection to ensure that the pilot units meet the requirements listed in the Pilot Test Plan.

The Pilot Run Test Report is maintained in the SharePoint Project Repository in compliance with the Records Matrix.

4.4.2 Cross-Functional Design Readiness Review

Upon completion of the verification tests and the Pilot Run Test Report, a meeting is held between the Engineering groups, Program Management and the CM (when necessary) to review information. Every item on the Functional Specifications document may be reviewed as necessary. Agreed changes are incorporated into manufacturing processes accordingly and the product is released to Production.

Records of the Pilot Phase Cross-Functional Design Readiness Review are kept in the SharePoint Project Repository in compliance with the Records Matrix.