NEON MANUFACTURING QUALITY PLAN

PREPARED BY	ORGANIZATION	DATE
Angelo Reyes	MFG	11/19/2012

APPROVALS	ORGANIZATION	APPROVAL DATE
Hanne Buur	PSE	12/10/2014
Michael Rodriguez	RAMS	12/10/2014

RELEASED BY	ORGANIZATION	RELEASE DATE
Judy Salazar	CM	12/10/2014

See configuration management system for approval history.

Change Record

REVISION	DATE	ECO #	DESCRIPTION OF CHANGE
A	12/10/2014	ECO-01638	Initial release

TABLE OF CONTENTS

1 DESCRIPTION

1.1 Purpose

The purpose of this document is to define the general practices used by NEON in the manufacturing process. These practices would be applied across all assemblies manufactured by the Production. It defines the following processes:

- Inspection Process
- Assembly Process
- Test Process
- Quality Control and Change process
- Training

1.2 Scope

This plan is limited in scope to the manufacturing quality, test process, and end of life management of NEON designed products. In the case of any discrepancies between this plan and the Product Manufacturing Quality Plan (PMQP) or Manufacturing Plan (MP), the PQPP takes precedence.

1.3 Responsibility

The position within the company who has ultimate responsibility that this MQP is followed by personnel trained in this procedure are:

Title	Responsibility
Manufacturing Manager	• NEON MQP • MES development • Training to MQP, VMS, Tech Inspection Process
RAMS	• Incoming inspection Process definition • Quality Audits • Production and Manufacturing Process review and approval • • PFMEA
Manufacturing Engineering	• Generation of PMQP/MP • Generation of VMS • Definition of in process inspection • Production and Manufacturing Process review and approval Tech Inspection process definition
Development Engineering	• Assembly definition • BOM development • Process Production and Manufacturing Process review and approval

Systems Engineering	• Design verification

2 RELATED DOCUMENTS AND ACRONYMS

2.1 Applicable Documents

Applicable documents contain information that shall be applied in the current document. Examples are higher level requirements documents, standards, rules and regulations.

AD [01]	NEON.DOC.000006	NEON Quality Management Plan
AD [02]		
AD [03]		
AD [04]		

2.2 Reference Documents

Reference documents contain information complementing, explaining, detailing, or otherwise supporting the information included in the current document.

RD [01]	NEON.DOC.000008	NEON Acronym List
RD [02]	NEON.DOC.000243	NEON Glossary of Terms
RD [03]	NEON.DOC.000612	Manufacturing Quality Plan Template
RD [04]	NEON.DOC.000605	Incoming Inspection Procedure
RD [05]	NEON.DOC.000164	HQ Warehouse Receiving Procedure
RD [06]	NEON.DOC.000769	Electrostatic Discharge Prevention Procedure
RD [07]	NEON.DOC.004254	Configuration Management Procedure
RD [08]	NEON.DOC.004202	NEON Review Definitions and
RD [09]	NEON.DOC.000994	Calibration
RD [10]	NEON.DOC.000705	NEON Bolt Torque Specification
RD [11]	NEON.DOC.000621	Supplier Quality Management Handbook
RD [12]		

2.3 External References

External references contain information pertinent to this document, but are not NEON configuration-controlled. Examples include manuals, brochures, technical notes, and external websites.

ER [01]	IPC-A-610 Class II standards
ER [02]	*ANSI/ESD S20.20-2007 standard*
ER [03]	

2.4 Acronyms and Definitions

- **Product**: components, manufacturing materials, in- process assemblies, finished assemblies, and returned assemblies.
- **Device Master Record** (DMR): a compilation of records containing the procedures and specifications for a finished product.
- **Device History Record** (DHR): a compilation of records containing the complete production history of a finished device.
- **Enterprise Change Order** (ECO): an Enterprise Change Order (ECO) is used to release configuration controlled documents and parts, change the revision or obsolete CM Items in the CMS. The ECO is the means used to document changes. Each ECO has a description and reason for change, affected CM items list, and approval signatures. No CM Item in the CMS can change revision without an ECO.
- **Product Manufacturing Quality Plan** (PMQP): a plan for starting up and maintaining manufacturing of an complex product in the manufacturing facility. This is used in place of the MP when the complexities of the product dictate more detail in the plan. The Grape PMQP is an example, but is in the draft status. (NEON.DOC.000147 Grape Controller Manufacturing Quality Plan)
- **Manufacturing Plan** (MP): A plan for starting up and maintaining manufacturing of an individual product in the manufacturing facility
- **Visual Methods Sheet** (VMS): a procedure based on visual (photographs or drawings) step-by-step assembly work instruction.
- **Production Release**: release of a product to production allows for the procurement and manufacturing of that product for deployment to the field.
- **Commercial off-the-shelf (COTS):** material readily available off-the-shelf and not custom made.
- **Bill of Material (BOM):** list of parts which make up an assembly
- **Reliability, Availability, Maintainability, Measurability, and Functional Safety (RAMS):** the team responsible for the overall quality of the assemblies deployed in the field
- **Deviation(DEV):** a process to depart from a particular requirement(s) of a CMS Item's current approved configuration documentation for a specific number of units or 90 days, whichever is shorter. (A deviation differs from an ECO in that an approved ECO requires a revision or part number change; whereas a deviation does not.)
- **Waiver:** a Waiver provides after-the-fact approval of a product or CMS Item not built according to the required configuration and specifications. Nominally Waivers are requested during system integration, verification and validation where requirements can't be passed due to performance or technical issues and provide justification as to why the system specification cannot be met. In some cases impacts may exist that impact the overall program and the governing board must grant approval to move forward with the delivery of the system. In the CMS Waivers can be found under Deviations.

- **Material Review Board (MRB):** the group and process responsible for the disposition of discrepant material. This includes the root cause analysis, risk analysis, and project effects of the discrepancy. Develops the plan to resolve the discrepancy.
- **Configuration Management System (CMS):** the electronic system used to control the configuration of assemblies and documents. The ECO process utilizes this tool release assemblies and documents through a defined review and approval process.

3 PLAN

3.1 General Requirements

The NEON Manufacturing Quality Plan is the general plan for NEON which addresses the process associated with the inspection, assembly, test, and quality control associated with the manufacturing and testing process. It will also define the work groups associated with the different requirements or actions. As this is an overriding document, individual MP's or PQMP's will be generated for all given assemblies as required by the IPT process.

3.2 Product Description

NEON products utilize both COTS materials as well as custom designs completed in house. Most final assemblies are a combination of COTS parts and custom parts and/or slight modifications to better fit the NEON application. The assemblies include mechanical, electrical, and electro-mechanical assembly types.

3.3 Process Description

The general process is depicted in the flow chart found in Appendix A. As it shows, there will be an incoming inspection of most custom parts and the COTS sensors. Development Engineering determines which parts are inspected, whether COTS or custom. Where appropriate there will be a custom fixture utilized in the incoming inspection test. This test ensures proper termination, One-Wire chip functionality, and general functionality for sensors, cables, and sensor assemblies (sensors terminated with connectors). Mechanical parts will be inspected using standard gauges, measuring tools, and Poka Yoke fixtures when required.

In process quality will be performed as part of the standard manufacturing process, including P/N and revision verification prior to work start. There are two types of inspections completed as part of the process: a "check" which consists of a peer review of the work completed at the previous step. This is completed by trained personnel within the process. This method allows for immediate feedback and resolution to non-conformances found at each step increasing the efficiency of the rework/repair process as well as improved workmanship based on the feedback. The second inspection type is a "verification" which is a check of the work completed in the steps specified by the verification step. This is performed by someone OUTSIDE of the particular assembly process being executed.

3.3.1 Workspace

The Production lab is depicted in Appendix B. The diagram is a general diagram. There may be specific bench location changes based on space availability and the appropriate process flow. This diagram will not be updated unless significant process change occurs due to floor space allotment.

3.3.2 Material Flow

See Appendix A.

3.3.3 Sub-Assembly Definition and Process Flow

Appendix A contains a sample of the sub-assembly structure which will be used for assembly break down. This allows for stocking of sub-assemblies as is appropriate. It also contains the high level process flow from material receipt to final assembly to transfer to the warehouse.

3.4 Product-Specific Documentation

All product specific documentation will be defined in the individual MP/PMQP for that product. It may include a Work Order, individual or batch traveler test records, drawings, BOM's…….

3.4.1 Workmanship Standards

Standard mechanical assembly practices are to be followed. All torque requirements will be derived from RD[11] or industry standards unless otherwise specified. All PCBA work is to be completed to ER[01]. ESD precautions meeting the *ER[02] standard* are to be taken at all times when handling PCBA's outside the protective ESD packaging. See RD [07].

3.4.2 Production Equipment and Environmental Requirements

3.4.2.1 Tools

Standard mechanical tools will be used in the assembly process. This includes but is not limited to:

- Pneumatic, hand, and battery powered screw drivers
- Wrenches
- Calibrated torque drivers
- Hex bits
- Ratchet

3.4.2.2 Manufacturing Equipment Calibration

All calibrated equipment will be tracked on an individual piece basis. All calibrated items shall be tagged with effective calibration date. This date will be verified prior to work start. Should a tool be found to

be out of calibration, it is to be pulled from use and sent out for calibration. Reference NEON.DOC.000994 Calibration

3.4.2.3 Fixtures

Various custom manufacturing and test fixtures will be utilized where appropriate. All manufacturing fixtures will be specified in the assembly documentation and MP/PMQP associated. Final assembly testing will occur after the top level assembly is completed.

3.4.3 Environmental Conditions

General heating and cooling controls, suitable for working conditions in lab.

3.5 Inspection and Test

3.5.1 Material Receiving Inspection

All receiving requirements will be driven by HQ Warehouse Receiving Procedure RD [05] and the Incoming Inspection Procedure RD [06]. Details are also included in the inspection form along with part document/drawing associated with the item or assembly. The Inspection Record also dictates the general requirements (AQL level, vendor information, etc…) which notes all inspection results.

3.5.2 Process Validation Requirements

Process validation will be completed as specified in the individual MP/PMQP. It will be based on completion of a minimum of 5 units utilizing the released documentation associated. A summary report will be completed noting the results and any action items generated during the validation. This will be released in Agile and tracked with the product development package. The same process validation may be applied to several assemblies should those assemblies be similar in assembly process and utilize the same tools.

Should a given assembly be taken out of production for more than 6 months AND a qty beyond 10 pieces is required, execution of the accepted validation plan shall be required. However, only a quantity of two will be required for the subsequent execution. This assures the line has been properly set-up and the instructions are still applicable and executed properly. If the qty is less than 10, the manufacturing engineer responsible for the product will oversee the production of this small run to ensure all steps are followed and the quality checks are executed.

3.5.3 In-Process Verification

The inspections are completed as part of the process: a “check” which consists of a peer review of the work completed at the previous step. The second inspection type is “verification” which is a check of the work completed in the steps specified by personnel trained to the procedure but not actively

working the particular assembly process being executed. This process is inclusive of WO/Kit verification and comparison of all document/assembly revisions to the current revision as noted in the CM system.

3.5.4 Error Proofing

Where the design allows, error proofing aka Poka Yoke, must be incorporated. Where it cannot be, checks and verifications will be put in place to ensure proper execution of the previous step. This is accomplished via check points in the assembly instruction, particularly those steps where the next assembly steps restricts access to work completed in previous steps. Where possible, fixtures can be used to ensure proper assembly.

3.5.5 Test Process

There shall be testing as part of the manufacturing process at the lowest level possible to increase yield at the upper level. The test process may be a combination of manual and automated mechanical and/or electrical test. Testing is to be completed on both mechanical and electrical assemblies as appropriate. All specifications associated with the testing shall be generated by manufacturing. They shall be agreed upon with development and systems engineering prior to implementation. The assembly process will include an End of Line test, in the case there is no separate test procedure for the assembly in question.

3.5.6 Final Product Verification

A final verification will be completed based on the final step in the assembly process. This is to be completed by trained personnel. It includes, at a minimum, the following:

- Visual check that all hardware has been installed
- If an assembly requires special handling, verification it has incurred no damage and is properly protected and identified for transport within NEON HQ
- Configuration of all assemblies (mechanical/electrical/sensor) are most current as required. This verification is to be completed using the CMS as the guide.
- All associated travelers, configurations (mechanical and electrical), and test data/reports have been completed and are correct
- Final paperwork verification: work order closure, material adjustment and transfer in Maximo

3.6 Material Handling and Control

At the end of the manufacturing process all assemblies shall be labeled with the P/N and revision as designated by the WO. This labelling can be in the form of permanent ink, stamp, permanent labels, or etching.

3.6.1 Material Handling Issues

The material handling requirements include the ability to transfer material with a length of up to 20'. The ability to maintain control of all sensors during the assembly process, protection for all sensitive sensors to ensure they are not damaged during the assembly process. For material flow reference Appendix A.

3.6.2 Equipment Safety – ESD protection per ANSI/ESD S20.20-2007

An ESD area is to be noted where work is to be performed. This area shall be no smaller than the 7' X 12' area surrounding the work benches. Grounding of the benches is required. In addition to the bench ground, a location for a personal ground will be present.

3.6.3 Moisture Sensitivity

If there are NEON designed parts or assemblies sensitive to moisture, they MUST be identified in both the CM system as well as labeling of the part or assembly. Proper storage during the assembly process must be maintained per the individual part documentation or as directed by the assembly MP.

3.7 Quality Considerations

3.7.1 Identification of Key Components

Specified in the individual MP/PMQP and provided by Development Engineering, these are the components to be tracked via lot code or S/N as designated in the individual MP/PMQP. This information is to be gathered at the time of inspection or assembly as appropriate. If at inspection, this information is to be gathered and tracked on the inspection record. If at the assembly level, this should be noted on the traveler for the associated assembly. Records are to be kept either electronically under the production folder on the network or paper copies

3.7.2 Critical Parts List and Mitigation

RAMS defines Critical Parts as configuration-managed parts that have been identified as Single Point Failures and meet two or more of the following:

- Sole sourced
- Over $5000
- Less than 5 year Mean Time Between Failure (MTBF)
- Lead time greater than 6 weeks.
- Technical Risk

Design engineering defines critical components as any component or assembly which may cause a single point of failure. If the component can either shut down the associated assembly or cause data loss it is a critical component.

3.7.3 Device History Records

The DHR will be used as specified in the individual MP/PMQP. It may include test information, assembly information, S/N information as well as lot code information when applicable. It is the responsibility of the production team to maintain the records in either physical form or electronic.

3.7.4 Release for Production

The documents and processes required for release of an assembly to production are:

- CM approved BOM
- CM approved drawings for parts and assemblies
- CM approved VMS
- CM approved test procedures
- Executed and approved process validation/verification
- CM approved PMQP/MP
- Systems Engineering completed design verification

3.7.5 Process Verification

As part of the input to the production release process, the summary report from the Validation executed under 3.5.2 shall be included. A PFMEA (Process Failure Mode Effects Analysis) will be performed as required by the associated validation. This is an analysis of the process and the potential for failures. What mitigations have been put in place and lists those failure modes not addressed. The RAMS team will be responsible for this review and is to be completed in parallel with the validation execution.

Standard verification will be completed via the inline process checks and verifications.

3.7.6 Training Requirements

Training to all NEON procedures required by the manufacturing process shall be completed within 1 week of employee start date. At a minimum it will include the following:

- NEON.DOC.000106 NEON Manufacturing Quality Plan
- NEON.DOC.000605 Incoming Inspection Procedure
- NEON.DOC.000769 Electrostatic Discharge Prevention Procedure
- Maximo training as it pertains to their position

Training to assembly and test instructions will be completed by manufacturing engineering prior to the process verification. General manufacturing practices training will be verified.

3.7.7 Post Delivery Requirements

3.7.7.1 Service

Per individual MP/PMQP. Most sensor assemblies will require yearly calibration. Field Operations will be trained to the assemblies in order to complete field service per operation requirements. Development engineering and Systems engineering will be required to produce the maintenance procedures for the associated assemblies.

3.7.7.2 Risk Management

The product hazards analysis (PHA) will be completed by RAMS, EH&S per OSHA standards. The results will be referenced by this procedure upon release of the analysis when applicable.

3.7.8 Software/Firmware update Requirements

The Grape Assembly is one of many assemblies which NEON controls the software/firmware. It can and will be remotely updated per the process identified in NEON.DOC.000295 when applicable. For individual sensors which are not Ethernet ready, a One-Wire programmable chip is used to identify the sensor via a NEON defined XML file, firmware. This firmware is controlled via SVN/Agile. However, NEON defines the sensor firmware version/revision which the manufacturer is to supply with their sensors where appropriate. In the instance the supplier and NEON cannot agree on a specific version, design engineering and the associated science group will determine if the new version is acceptable. ECO's will be completed as appropriate.

3.7.9 Process Change Notification

Reference section 5.6 of RD [12].

3.7.9.1 ECO

Enterprise Change Order (ECO) Approvals: Standard ECO process to be followed per NEON.DOC.004254. Upon implementation of an ECO, deviation, or waiver manufacturing shall review all affected processes/documents, retrain personnel to the newly released process/documentation.

3.8 Special Requirements

3.8.1 Unique Documentation Requirements

To be defined within the MP/PMQP associated with the individually assembly.

3.8.2 Serialization

Only those assemblies specified in their individual MQP/MP shall be serialized. The serial number shall be a unique number to that assembly and typically notes the week, year, and a sequential number. In the case of the Grape assemblies, a unique MAC Address will be issued and tracked as the serial number.

3.8.3 Shop Floor Tracking

Shop floor tracking is to be completed via paper and/or electronic travelers. A database shall be generated to maintain all pertinent information associated with the travelers and/or test data as specified in the individual MP/PMQP. A Manufacturing Execution System (MES) may be put in place to replace the paper system and will pull all relevant information out of Agile to ensure current documentation is used during the assembly process.

3.8.4 Disposal / Recycling

Disposal/recycling of manufacturing related materials and refuse shall be disposed of in accordance with local requirements. Specific instructions may be given in individual MP/PMQP as required.

3.8.5 Counterfeit Part Prevention

To be mitigated by NEON RAMS team and the suppliers.

3.8.6 End of Life Analysis

Upon notification of component obsolescence, Engineering and Manufacturing will form a working group to research potential alternative solutions including component swap, circuit redesign, and related sub-assembly obsolescence.

3.8.7 End of Life Notification

As hardware changes become necessary, a panel will be formed to assess backward compatibility and required obsolescence. Once all changes have been identified and the formal ECO process has been implemented, removal from service and full/partial recall of affected assemblies will be performed to bring all units up-to-date or retired from service. Again, any units that meet these criteria will be broken down and any useful parts will be inspected and salvaged.

3.8.8 Long Lead Time Management

Logistics, Production, Procurement, and Engineering will work together to formalize a component forecasting system. This system will be employed to track shortages and related lead times in advance of production demand. Long lead times will influence deployment and repair schedules as required.

3.9 Labeling

3.9.1 Product

All assemblies will be labeled according to the MP/PMQP, in general only TOP level assemblies (parent assemblies) will be labeled. This will allow for easy recognition during installation. All specifications for this labeling are noted in the drawings associated with each individual P/N.

3.9.2 Shipping

All shipping will be completed per NEON shipping requirements. Reference section 5.13 of RD [12].

3.9.3 Packaging

Custom packaging will be designed by NEON for shipping all assemblies. In addition, custom packaging will be designed for individual sensors associated with sensor calibration cycle and spares shipment for repair.

3.10 Measurement, Analysis and Improvement

3.10.1 Quality Reporting

The current plan is a Manufacturing Execution System (MES). This tracks workflow through the production floor. It will have the ability to track discrepancies as product moves through the production process. Reports will be generated tracking defects per unit, first pass yield, and if possible, defects per opportunity.

3.10.2 Continuous Quality Improvement

All significant issues will be corrected to attain 100% first pass yield.

3.11 Control of MQP

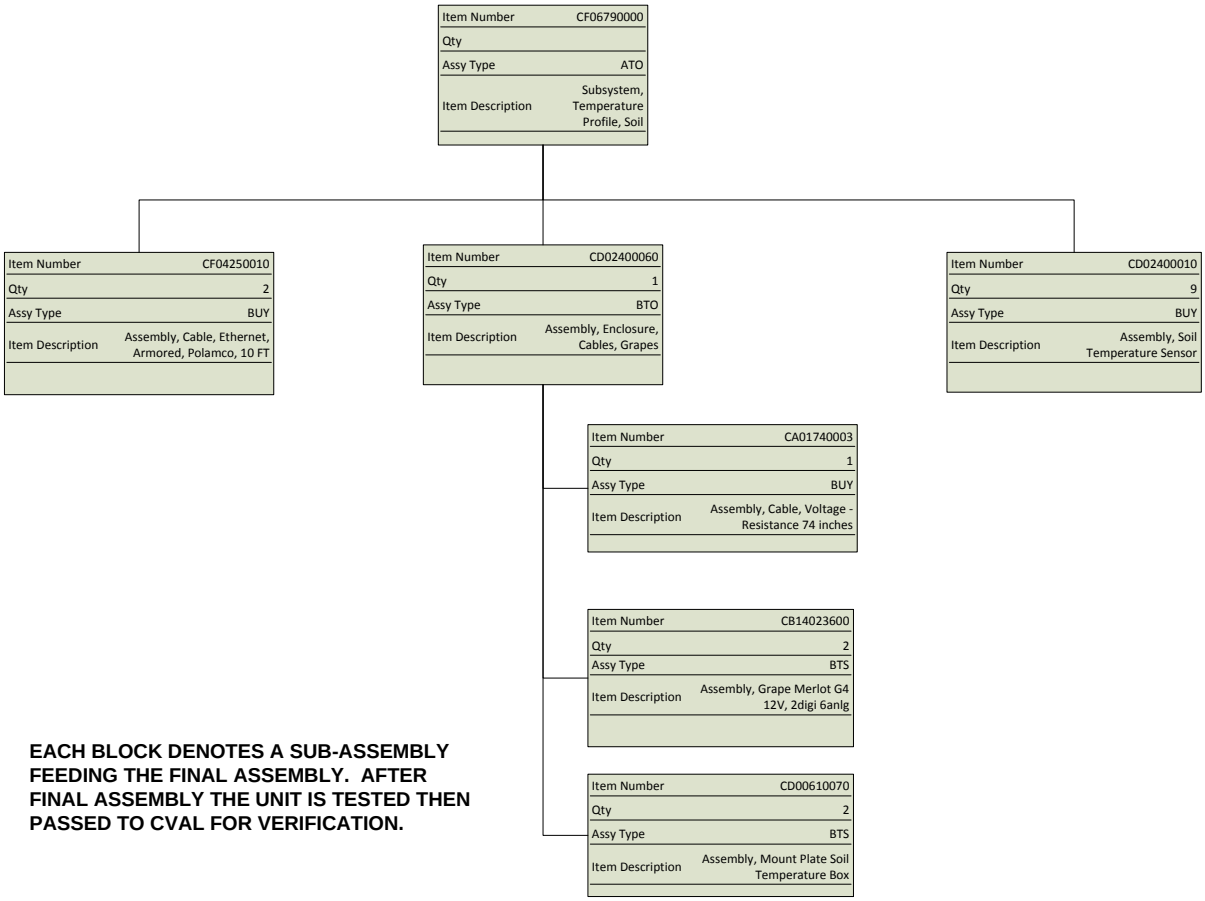
The NEON Manufacturing Quality Plan shall be maintained as a controlled document for the life of the project. The plan should be reviewed and updated as often as necessary.

The personnel whom shall be trained to the MQP include: assemblers, project engineers, and manufacturing technicians.

All changes to the plan must be made according to the ECO procedure.

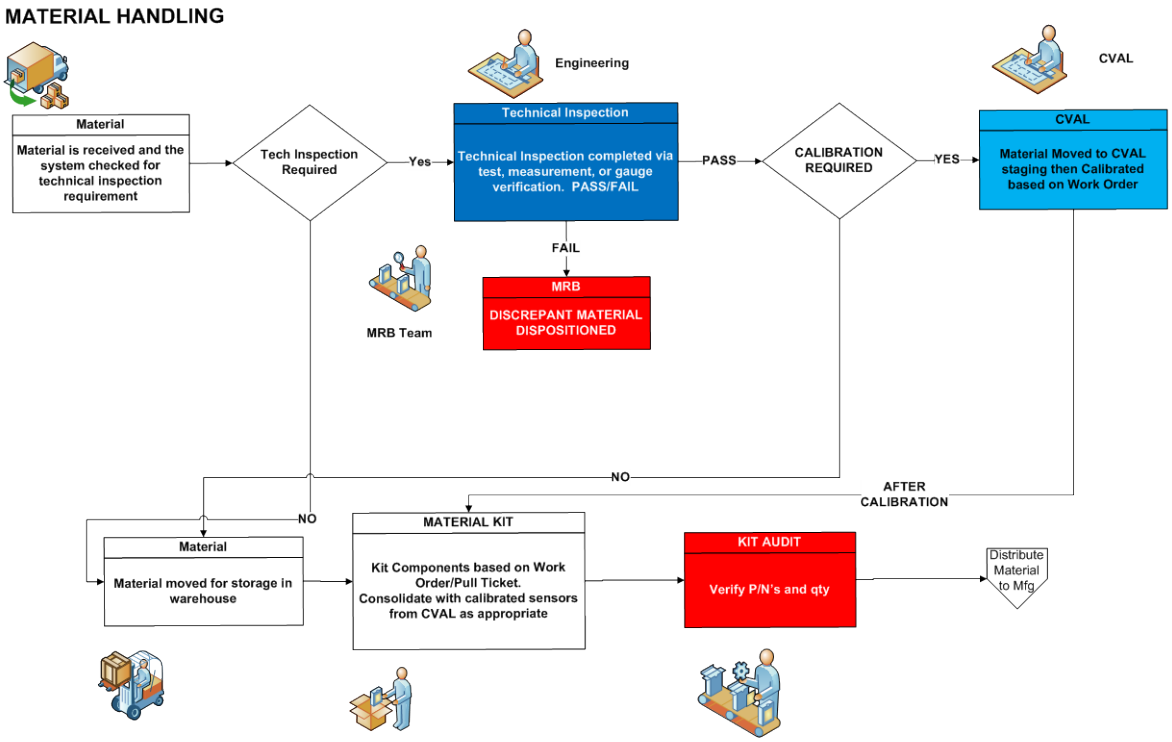
APPENDIX A

SAMPLE SUB-ASSEMBLY TREE

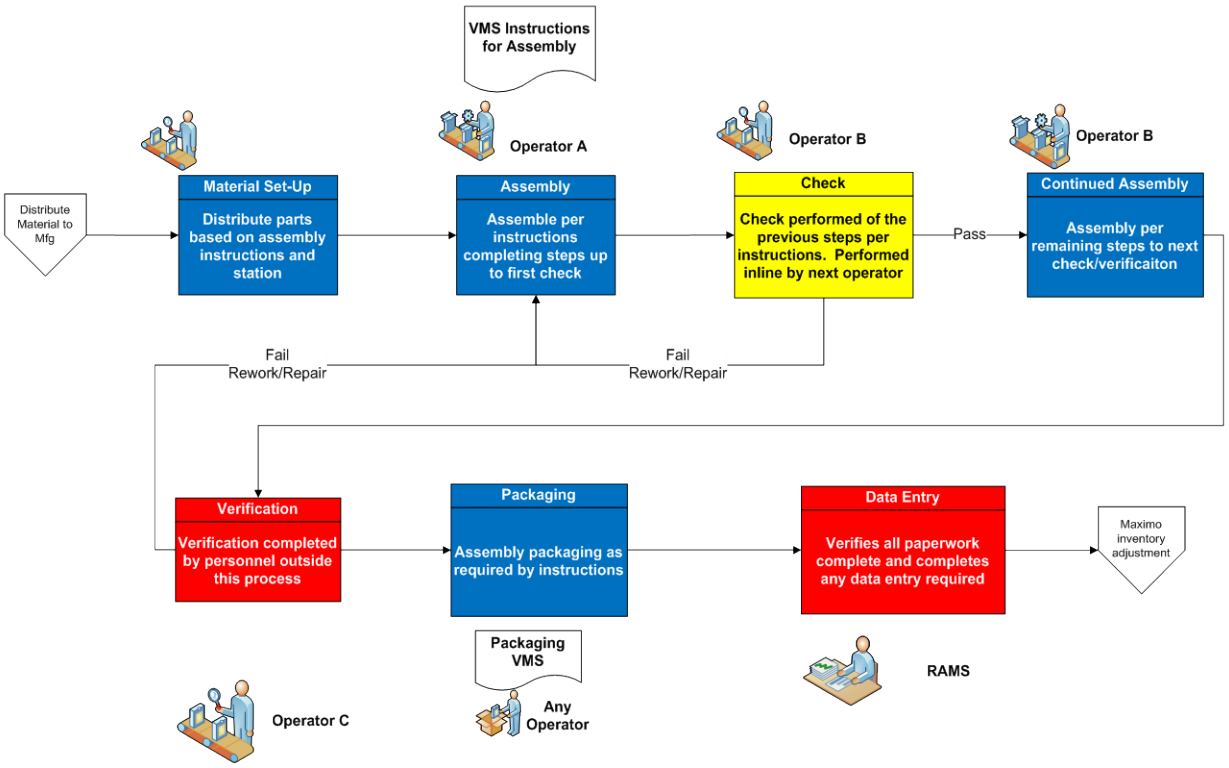


EACH BLOCK DENOTES A SUB-ASSEMBLY FEEDING THE FINAL ASSEMBLY. AFTER FINAL ASSEMBLY THE UNIT IS TESTED THEN PASSED TO CVAL FOR VERIFICATION.

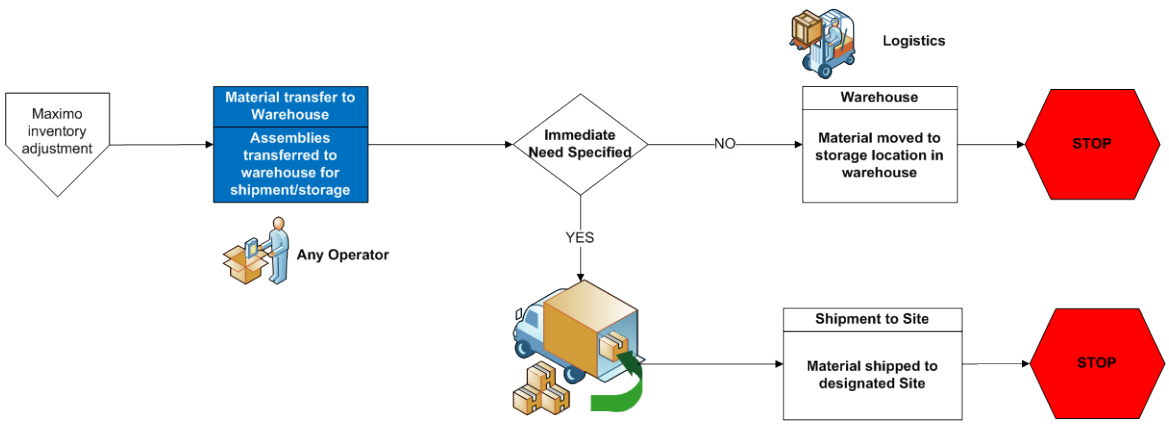
General Product Flow Diagram



ASSEMBLY & INSPECTION PROCESS



Shipping/Logistics



APPENDIX B

TECH FACILITY MANUFACTURING AND REPAIR AREA