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| DOCUMENT NUMBER 91-4001 | REVISION F | TITLE Manufacture, Inspection, and Test of Material and Product | REV DATE 10/2021 | Page 1 of 7 |
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1. Purpose of Procedure

This document is intended to describe the manufacturing cycle, including the establishment, use, and responsibility for the documentation accompanying the manufacturing process, and including associated inspections and tests. It provides for a procedure and assigns responsibilities.

2. Scope of Process

The scope of this procedure is the manufacturing cycle, beginning with requirements for manufacturing through completion of finished material or product.

3. Process Owner(s)

- 3.1. Manufacturing Manager
- 3.2. Production Supervisor
- 3.3. Test Manager

4. Procedure

4.1. Demand for Production Job Orders within the ERP System

Job orders for materials or product may be demanded and initiated by any of the following sources:

4.1.1. Planner Workbench Requests

The MRP function of Product Resources' ERP system requests the job order from Manufacturing based on net requirements in light of customer orders and manufacturing orders inclusive of safety stock.

4.1.2. Project Module Requests

Occasionally, Engineering will be working on a project that requires Manufacturing assistance in manufacturing material. In this instance, Engineering will request the manufactured item via the projects module in the ERP system. The needed item will be entered in a project task as a resource. This requirement will be seen as MRP output as described above. See procedure 43-4757 for instructions on how to requisition items via the Projects module.

4.2. Job Order and Manufacturing Cycle

Every order to manufacture a product is transmitted to Production using either a digital job order for batch builds, or a production schedule or just-in-time for cell builds. Batch builds and cell builds are the two build types. Note that batch builds and cell builds can be combined in creating a product for sale. For example, a product can begin as multiple batch builds for lower-level subassemblies. A cell build can then produce higher-level subassemblies and a full product assembly. A batch build can then complete the product with final release testing, ancillary materials, and packaging.

4.2.1. Build Types

4.2.1.1. Batch Build

With batch manufacturing, Production will receive a physical job packet containing the printed 'Job Header Report' in a clear plastic folder to identify the electronic job order number as well as a time sheet (80-2030) for traceability purposes. This packet

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accompanies the product through all production phases. Production Control establishes a job order based on a net requirement as described above.

The electronic job order package is based on the item's current routing at the time of job creation and consists of the job header, the job order traveler, and the job operations listing (these three forms are ERP system reports). The 'Job Header Report', 'Job Traveler', and 'Job Operation Listing Report' will be written to \\Newton\Production Document Distribution\Released Job Orders\ by the ERP system for a given job number wherein each job gets its own folder at that location. Only active job orders are located here; when a job is completed, the associated folder is deleted. All required manufacturing documentation (assembly drawings, test procedures, etc) will be directly accessed by Production personnel by opening the Job Operation Listing Report and clicking on the hyperlink for the required document. This will bring up the current document in QT9 QMS.

The job order packet is released by Production Control to the Stockroom for kitting with the electronic job package available at \\Newton\Production Document Distribution\Released Job Orders\ . The job order packet and all materials for the job are then issued by the Stockroom, per procedure 43-2141, to the assembly area as the kit.

About the job package: Listed on the job order header are product and scheduling information. The Product Resources item number and a description of the product to be built provide a reference to the item. The date ordered and date issued provide job traceability. The quantity released, quantity completed, start date, and end date provide records of production scheduling. The job operation listing report provides identifies the routing and associated documents at given revisions as captured for the given job, which in turn provide product definition / DMR traceability.

Work assignment: The Production Supervisor or Manufacturing Manager is responsible for assigning jobs to assemblers. In assigning jobs, consideration is to be given to specialized skills needed to carry out the given job, for example soldering or crimping. Jobs are only to be assigned to assemblers with the skill set to carry them out. A skills-based training program complements this requirement.

Assemblers carry out in numerical operation order the instructions communicated via the job operation listing and via the referenced documents.

Assemblers sign/initial and date completion of job operations on the job time sheet. Document Control is not required to sign the job time sheet for Document Control operations.

Note: There are occasions where Engineering or Quality need to be involved in the build of a specific product and its assembly or test processes. In these cases when something needs to be corrected in real time, Engineering or Quality may mark up / "redline" a document along with initials/signature and a date. Production may act on these authorized redlines and build or test product according to the redline. In parallel with this, Engineering or Quality shall get a copy of the redline as input to change control processes.

4.2.1.2. Cell Build

With cell manufacturing there are two options available, a Production Schedule or Just-In-Time. There is no job order or job order package for either option.

Documents needed in the cell associated with the items made in the cell are kept within the cell as documents in distribution, maintained by Document Control. In addition, Document Control will utilize the documents in distribution mechanism to maintain current routings within the cell; the routings provided are those of the items made in the cell.

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Note: There are occasions where Engineering or Quality need to be involved in the build of a specific product and its assembly or test processes. In these cases when something needs to be corrected in real time, Engineering or Quality may mark up / “redline” a document along with initials/signature and a date. Production may act on these authorized redlines and build or test product according to the redline. In parallel with this, Engineering or Quality shall get a copy of the redline as input to change control processes.

All materials required for cell manufacturing are also kept within the cell. All raw material transactions within a manufacturing cell are backflushed and recorded when the item is finished.

Work assignment: The Production Supervisor or Manufacturing Manager is responsible for assigning assemblers to work cells. In assigning assemblers, consideration is to be given to specialized skills needed to carry out the work that takes place in the cell, for example soldering or crimping. Assemblers are only to be assigned to cells if they have the skill set to carry out the cell's work. As a work cell may involve multiple skill sets, an assembler may be assigned to certain assembly operations that take place in the cell but not to others. A skills-based training program complements this requirement.

Assemblers carry out in numerical operation order the instructions communicated via the current routing and via referenced documents.

Cell builds are designed specific to the item(s) build within them. Depending on the final product, the cell can utilize a combination of subassembly, final assembly, and test. Typically, cell builds are set up for higher-level assembly of a product. Lower-level assemblies are usually built as batch build (see above) and then fed into the cell build for final assembly. The Manufacturing Manager is responsible for which assemblies are built outside the cell as batch and which are built inside the cell, based on the process flow and assembly efficiencies.

A Production Schedule is set up by Production Control in the ERP system.

The use of Just-In-Time Production is the preferred method for cell builds. It is not tied to any job or production schedule, and therefore requires no delivery re-scheduling maintenance. The build schedule is transmitted by the area supervisor and is based on a customer order, the dispatch, or a forecast, wherein each gives a record of the quantity to be built for completion on what dates.

Cell builds do not require a job order time sheet, as they are set up with standard costing, and all assembly/test times are automatically figured in the operations.

4.2.2.In-Process Testing and Inspection

In-process tests and inspections can apply both to batch builds and cell builds. By an in-process test or inspection, we mean either one that is taking place on a product subassembly or one that is taking place in or in between assembly operations on any assembly. The purpose is either to ensure that an operation was completed satisfactorily and therefore the assembly can move to the next operation, or to ensure that a subassembly is conforming and therefore can move to the higher or top level assembly.

The party that is to perform the test/inspection is indicated by the work center (location) of the operation. If the specified test/inspection is found in an Assembly work center such as PROD (Main Assembly) or others belonging to Assembly, Assembly performs it. If the specified test/inspection is found in a Quality work center, always indicated by Inspct (QC Inspection), QC performs it. If the specified test/inspection is a Test work center, always indicated by Test (Test Department), Test performs it.

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The test/inspection to be performed is specified on the job operation listing (batch build) or current routing (cell build), which accompany the product during its manufacturing phases. Specification of the in-process test/inspection is via a procedure or form reference that appears in the operation or instructions written directly into the operation. In either case, the acceptance criteria are stated. If a specific measuring device must be used, it too is stated.

Not all routings will include an in-process test/inspection. The inclusion of and scope of an in-process test/inspection is determined by Engineering in cooperation with Quality.

4.2.2.1. Carrying Out the In-Process Test/Inspection

The responsible party follows the instructions given in the procedure, on the form, or directly in the operation.

If an in-process inspection/test requires the use of measuring devices, the inspectors are provided with, and are instructed in the use of, controlled and calibrated equipment suitable for carrying out the inspection/test.

Note that a measuring device's calibration status will be evident by its dated calibration sticker.

4.2.2.2. Recording the In-Process Test/Inspection

Record of completion is made by signing/initialing the associated operation on the job time sheet and, when applicable, by following the instructions given in the operation or in the referenced documents, including the use of any referenced forms. In some cases, the assembly is physically marked following completion.

When forms are completed or when there is any document output, these form part of the Device History Record (DHR) and are to be stored in the Device History Records file server space under the item number of the assembly. More information about DHRs can be found in 91-6005, Device History Records.

For handwritten data, all corrections shall be made by crossing out the incorrect data with a single line, writing in the correct data, and signing/dating the entry. All handwritten data shall be recorded using pen/ink and not with any erasable device, like a pencil. Handwritten data is scanned on completion for inclusion in the DHR space.

For electronically completed data, no history is to be deleted. Add additional lines for repeat inspections/tests.

4.2.2.3. First Article Inspections

Each job (batch build) receives a first article inspection, which is a form of in-process inspection. The first article inspection is a peer inspection wherein the peer has experience in building the item.

The first article inspection is a visual check of all of the item's operations, that the item is assembled as intended, with the expected level of workmanship.

This type of first article inspection has a dedicated sign-off location on the job time sheet. Job time sheets are, in turn, collected on job closure, periodically scanned, and stored in the Manufacturing file server space.

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4.2.2.4. Quality Use of In-Process Inspections for Outgoing Inspections

Quality and Engineering when designing a product's process will frequently decide that what is effectively the Quality Outgoing Inspection should take place prior to a product's packaging operation, or even prior to final product enclosure closure assembly operation. When the decision is made to handle Outgoing Inspection in this manner, an Inspct (QC Inspection) operation will be inserted into the routing at the process step that affords Quality the ability to perform the best inspection, to be able to see what Quality needs to see without the opening of product packages or product enclosures.

When this occurs in a job operation listing, product completed to that point is to be brought to the QC area for Outgoing Inspection or otherwise QC to the product's location (heavier or less mobile product) to perform Outgoing Inspection.

When such an operation occurs, QC is to sign/initial and date the job time sheet like all other operations.

Description of the Outgoing Inspection itself can be found in 91-1004, Customer Order Shipping.

4.2.3. Final Testing and Inspection

Final tests and inspections can apply both to batch builds and cell builds. By a final test or inspection, we mean either one that is taking place on a final, top-level product assembly – our shipping product. The purpose of a final test is to ensure the functionality of the shipping product and to configure it as per the customer and product needs. The scope of final testing and inspection can include hardware configuration, software and firmware configuration, burn-in, functional testing, and safety testing. At the conclusion of a final test or inspection, in concert with a Quality Outgoing Inspection where applicable, it is established that the product is ready to be shipped to the customer.

The party that is to perform the test/inspection is indicated by the work center (location) of the operation. Final tests and inspections are always performed by the Test Department, and the associated work center is Test (Test Department).

The test/inspection to be performed is specified on the job operation listing (batch build) or current routing (cell build), which accompany the product during its manufacturing phases. Specification of the final test/inspection is via one or more procedure or form references that appears in the operation or otherwise instructions written directly into the operation. In either case, the acceptance criteria are stated. If a specific measuring device must be used, it too is stated.

Not all routings will include a final test/inspection. However inclusion is the norm for routings for product assemblies. For spare part routings, inclusion is on a case by case basis. The inclusion of and scope of a final test/inspection is determined by Engineering in cooperation with Quality.

4.2.3.1. Carrying Out the Final Test/Inspection

The responsible party – the Test Department – follows the instructions given in the procedure, on the form, or directly in the operation. In addition the Test Department is to fulfill requirements below that are not stated on a per-routing, per-product basis, as they always apply. Combined, the final test/inspection tasks entail:

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-) Review of the job time sheet (batch build only) to check that the first article inspection and all preceding operations are signed off.
-) Visual inspection of the product for visual evidence that all specified preceding operations are complete.
-) Visual inspection to detect any visible quality problems.
-) Performing configurations, taking measurements, and testing as required per the routing-referenced test procedures or routing notes.
-) Recording the configurations, the actual measurements, pass/fail outcomes, and all other test results, following the routing and procedure instructions and using any specified forms.

If the final inspection/test requires the use of measuring devices, the technicians are provided with, and are instructed in the use of, controlled and calibrated equipment suitable for carrying out the inspection/test.

Note that a measuring device's calibration status will be evident by its dated calibration sticker.

4.2.3.2. Recording the Final Test/Inspection and Test Completion

Record of completion is made by signing/initialing the associated operation on the job time sheet and, when applicable, by following the instructions given in the operation or in the referenced documents, including the use of any referenced forms. In some cases, the assembly/product is physically marked following completion.

When forms are completed or when there is any document output, these form part of the Device History Record (DHR) and are to be stored in the Device History Records file server space under the item number of the assembly. More information about DHRs can be found in 91-6005, Device History Records.

For handwritten data, all corrections shall be made by crossing out the incorrect data with a single line, writing in the correct data, and signing/dating the entry. All handwritten data shall be recorded using pen/ink and not with any erasable device, like a pencil. Handwritten data is scanned on completion for inclusion in the DHR space.

For electronically completed data, no history is to be deleted. Add additional lines for repeat inspections/tests.

Once recorded, the product passes to its next operation, or if Test is the final operation to the product's stock location. This may be the STOCK (Main Stockroom) location or the OUT_INSP (Outgoing Insp) location, the latter if Quality Outgoing Inspection is set up to be performed on the completed product. Description of the Outgoing Inspection itself can be found in 91-1004, Customer Order Shipping.

4.2.4. Production Completion

4.2.4.1. For Batch Builds

Items received into stock provides evidence that all identified operations have been completed, as all identified operations must be complete as a condition of stockroom receipt. When accepted by the stockroom, the job is closed per procedure 43-2140.

Job time sheets are preserved as records of completion, with traceability to assemblers and technicians performing the operations.

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4.2.4.2. For Cell Builds

When items from a cell are completed, the quantity completed is entered into the Production Schedule or Just-In-Time by Production Control, and all raw material is then backflushed from the system upon completion of the cell-built item.

The completed items are simultaneously received into stock. Production Schedule and Just-In-Time records are kept within the ERP system as records of completion.

5. Control of Records

The storage location and retention period for records referenced above is given in 91-6002, Control of Records.