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IDENTIFICATION AND TRACEABILITY

1.0 Policy

All parts used in the manufacturing process, either purchased or manufactured in-house, are identified by a part number which links the part to its drawing, specification, and/or description.

When required by contract or at Product Resources' discretion, and always for product controlled under either the ATEX Directive or the Medical Device Directive, the final product can/will have an individual serial number and record maintained for each unit shipped.

All final product has a lot number, serial number, or both. Product is marked with this identity by means of labeling, stamping, etc.

2.0 Responsibility

The Manufacturing Department has the responsibility to assign all serial and lot numbers. The Engineering Department has the responsibility to assign part numbers to Product Resources products for sale. The QA Department has the responsibility to assign part numbers for Quality system documentation and test equipment; Engineering may also assign part numbers for test equipment but must inform QA of new test equipment added so that QA may include this equipment in the calibration database. The Engineering Department has the responsibility to assign part numbers for all other purposes.

It is the QA Department's responsibility, and ultimately the QA Manager's responsibility, to ensure that critical components have been identified for product controlled under either the ATEX Directive or the Medical Device Directive. Critical components are determined in cooperation with the customer and are normally based on risk analysis or the Quality standard for the given Directive instructing that the given component shall be considered critical.

For such critical components, QA or Engineering shall devise a method for the collection of their identities – their lot numbers or serial numbers – such that their identities are listed along with the serial number of the product for sale in the product's test record, or Device Master Record. This normally is in the form of a unit configuration form designed by QA or Engineering and completed and filed by a technician.

3.0 Numbering Systems

Unique part numbers are assigned to each part used in the manufacturing process per the part numbering procedure found later in this document.

Serial numbers are assigned per the procedure found later in this document.

The lot number of product is the job order number that created that product, and so no further procedure for lot number is required.

4.0 Specific Additional Requirements for Medical Devices

For ISO 13485, to which Product Resources' Quality system applies when handling medical devices, there are specific requirements for traceability as it applies to implantable medical devices.

Implantable medical devices is excluded from Product Resources' scope for medical devices / for ISO 13485; see 90-2000-4.1. Should implantable medical devices be included in the future, the Quality Manual shall be amended with specific policies, procedures, and responsibilities to govern their traceability.

INSPECTION AND TEST STATUS

1.0 Policy

Material that has either been partially or wholly processed must be identified as to its inspection and test status. Information must be available that gives the status of the material in the manufacturing cycle.

2.0 Inspection and Test Status

Products moving through manufacturing operations and processes are accompanied by a traveling job order. The job order and accompanying manufacturing documentation list all processes and inspection points. The sign-off on the job order time sheet (80-2030) is simultaneously an inspection record and an identification of the operation status. Product received into the stockroom provides evidence that all identified operations have been completed, as all identified operations must be complete as a condition of stockroom receipt.

3.0 Responsibility

Production Control is responsible for releasing the documentation that defines sequences of production, inspection, and test operations. Manufacturing is

responsible for testing per the documentation and for maintaining inspection sign-offs on job orders and test records.

4.0 Nonconforming Products

4.1 Products that fail inspection or are determined to be nonconforming are labeled with a REJECTED tag (80-1018) stating the problem, along with the part number identity of the rejected item, the quantity, the serial and/or lot numbers as applicable, and the item description. Rejection tags are signed or initialed by the party documenting the rejection (normally the operator who detected the nonconforming condition, or otherwise the area supervisor or manager, or sometimes QA if QA has been called to witness the condition) and dated.

4.2 Products failed at receiving or incoming inspections are moved to a designated quarantine area.

4.3 Products failed by an in-process inspection are normally left in the production area while awaiting disposition, but are segregated and removed from the main stream of the production flow.

4.4 Finished products failed at the final inspection are segregated.

PART NUMBERING SYSTEM

1.0 Purpose and Policy

This procedure describes the Product Resources part numbering system and the requirements to take out a new part number.

All part numbers are unique and describe one and only one item. The ERP system will not permit the creation of more than one instance of the same part number.

There shall be no re-use of part numbers for purposes other than their original one once the part has been released to Manufacturing.

2.0 Procedure

Each part used in the manufacturing process must have a standard Product Resources part number. The number consists of at least six alpha-numeric digits and one dash (-). The first two digits identify a general category of part (see below). An effort should be made to place parts in the correct category.

Next follows a dash. The next four or five digits are numeric and identify the unique part in the category. These digits may be assigned in any appropriate pattern, but the number must be unique within the category. Some categories have their own schemes for these digits; if so, it will be detailed below.

The basic digits may optionally be followed by an additional dash (-) and then additional numbers, characters, and/or symbols. These additional digits represent variations on the same basic part, or members of a common family.

Here are some examples of valid Product Resources part numbers*:

15-3213
07-7327-B
52-1423-4-2
90-2000-7.5.3
21-5438-7.5kg
15-12654
DL-11276
DL-11462-2

*These are not necessarily actual company part numbers but are for example only.

2.1 The part categories are: (blanks are unassigned at this time)

01 - Sub-Assemblies
02 - Diodes & Terminal Semiconductors (Not LED's)
03 - SCR's & Other 3 & 4 Terminal Semiconductors (Except Transistors)
04 - Integrated Circuits & Semiconductors with 4+ Terminals, Hybrids
05 - Enclosed PCB Sub-Assemblies, Logics
06 - Terminals, Plugs, Sockets, Connectors
07 - Wire and Cable
08 - Fuses and Fuse Holders
09 - Inductors, Transformers, and Other Wound Components
10 - Switches, Joysticks
11 - Grease, Adhesives, Liquids & Compounds
12 - Magnets, Magnetic Material
13 - Thermostats, Thermistors & Temperature Actuated Devices
14 - PCB Fabrications
15 - Fabricated Metal Parts
16 - Fabricated Non-Metal Parts
17 - Threaded Hardware

18 - Washers, Spacers, Metal Tube
19 - Non-Threaded Fasteners
20 - Wiring Harnesses, Wire Assemblies, Terminated Leads
21 - Separable Sub-Assemblies
22 - Schematics
23 - Wire Run Lists, Wiring Diagrams
24 - Heatsinks – Catalog, Off-the-Shelf Type
25 - Capacitors
26 - PCB Assemblies
27 - 1/4 W Resistors
28 - 1/2 W Resistors
29 - Resistors 1 W and Over, Potentiometers
30 - Transistors
31 - Relays & Electromechanical Switches, Power Supplies
32 - LED's, Lamps, Lights, Bulbs, Optical Fibers
33 - Motors, Fans
34 - Shunts
35 - Artwork
36 - Tape
37 - Metal, Raw Material
38 - Non-Metal, Raw Material
39 - Labels, Packing Material, Package Inserts (Documents)
40 - Program Modules
41 - Final Assemblies for Sale
42 - Meters, Instruments, Test Rigs, Gauges, Fixtures
43 - Procedures (Test Procedures, Assembly Procedures, Installation Procedures, Work Instructions, SOP's)
44 - Springs
45 - Suppressors, Metal Oxide Varistors (MOV's)
46 - Standards
47 - Batteries
48 - Kits
49 - Tools
50 - Drawings, Misc. for Customer Use
51 - Charts, Graphs, Genealogies
52 - Valves, Pneumatics, Regulators
53 - Fittings
54 - Sensors, Transducers
55 - Computer Components
56 - Software
57 - Software Assemblies
58 - 1/8 W Resistors
59 - 1/16 W Resistors (Typically Chip-Style Surface Mount)
60 - Encoders
61 - Bearings, Pulleys
62 - Optical Components (Windows, Lenses, Mirrors)

63 - Photovoltaics
64 -
65 - Gloves
66 -
67 -
68 -
69 -
70 -
71 - Backup/Temporary Items (For System Admin. Purposes)
72 - Technical Specifications, Data Sheets, Technical Reports
73 - ECOs (prior to SyteLine ERP, which integrates ECNs)
74 - Price Lists
75 - Shipping Materials
76 -
77 -
78 -
79 -
80 - Company Forms, Quality System Forms
81 -
82 -
83 - Mechanical Parametric Models
84 -
85 - Gases
86 -
87 -
88 -
89 -
90 - Quality Documents (Quality Manual, Quality Instructional)
91 -
92 -
93 -
94 -
95 -
96 -
97 -
98 -
99 - Spare Parts for Sale
DL - Parts Used in Digilab Products - Additional Guidelines Follow:
DL-XYZZZ
X = 1 for Accent, 2 for Microgrid II, 9 for common Digilab parts
Y = 0 for assemblies, 1-9 for other parts
ZZZ = sequentially-assigned, unique numbers
TH - Threaded Hardware - Additional Guidelines Follow:
The format of the part numbers used for the TH category is an exception to the above stated rule; the format takes various

forms after the TH- portion, done so to facilitate the describing of different types of standard hardware.

TM - Training Material

2.2 Part Number Creation and Responsibilities for Creation

Refer to 43-2537, Entering a New Part Number, for detailed information about entering a new part number into the ERP system.

Engineering creates part numbers for those items that Product Resources sells, 41-XXXX and 99-XXXX part numbers. For these items, Inside Sales creates cross-references to the customer's part numbers and revision levels using the Customer Item Cross Reference feature of the ERP system.

Engineering creates part numbers for all items below those items that Product Resources sells. At the same time, Engineering creates cross-references to the customer's part numbers and revision levels (when the revision level differs between Product Resources and customer) when available using the Customer P/N field of the item record in the ERP system.

Quality creates part numbers for Quality system documentation and test equipment; Engineering may also create part numbers for test equipment provided that Quality is notified of new equipment thus facilitating the adding of the new equipment to the calibration database.

2.3 Part Number Revision Levels

A part's revision will depend on how many changes have occurred to that part's definition. The revisions are assigned as follows:

XX.YY where
XX = Document/Part Revision
YY = Routing Revision

Document/Part Revision

(1) If the part is released under document control and there is a drawing/document, then XX = - (dash), A, B, C… The letters I and O are to be avoided due to their similar appearance to the numbers 1 and 0. But if our customer uses the letters I and O, we may use them for the sake of having matching revisions.

(1a) The first-release document/part revision may be chosen to be other than - (dash) for the convenience of being able to match a customer's revision. For instance, if a customer has a part that is at Rev. C, and if Product Resources' first contact with that part is at that Rev. C, then Product Resources will typically for convenience use Rev. C for the first release of the corresponding Product Resources part number.

(1b) Redline Revisions: Redline revisions, indicated by "r" followed by a two-digit number following the current - (dash) or letter revision, are used when intermediary revisions are needed. The typical scenario is that we must document a change or clarification, but we do not want to (yet) go up to the next letter revision because we are waiting to do so in lockstep with the customer. In this scenario, we will make a redline revision, do an ECN that moves the document to the redline revision, provide our customer with the redline document as input, and then move to the next letter revision when our customer makes the change. Another scenario is that a quickly-done revision is needed, and a redline revision will be produced by hand, by writing on the current revision, adding notes, crossing out and correcting, etc.; this will be followed up by the next revision as soon as possible incorporating these changes via, for example, CAD software. Here is an example of how redline revisions are written, starting with B as the last full release: B, Br01, Br02, and so on.

(2) If the part is not released to Manufacturing and there is a drawing (such as Engineering projects that are pre-release), then XX = 01, 02, 03, 04… Note that whole numbers are to be used because, if a decimal point were used, the digits following the decimal point would not be distinguishable from a routing revision. If the use of a decimal number cannot be avoided, then surround the number with parentheses, for instance, (5.3).

(3) If there is a significant change to purchased catalog item (i.e., standard, off-the-shelf, not made to Product Resources' specifications, no drawing) that requires or would benefit from an ECN, then XX = *N where N = A, B, C… The * (asterisk) indicates that there is no drawing.

(3a) A purchased catalog item when initially created may be created with a XX = *N revision (as above) if ECNs should be required upon changes. If a part already has such a revision, then an ECN must be used upon any significant change to this part.

Routing Revision

(4) If the part has a routing, then YY = .01, .02, .03, .04… This represents the routing's revision. The initial release of a routing is .01. Parts that have routings for ERP administrative purposes only, for example a Document Control operation which is required to process an ECN on a part that would otherwise have no routing (normally a purchased custom part described by a specification drawing), do not receive routing revisions, however.

SERIAL NUMBER SYSTEM

1.0 Purpose and Policy

This procedure is designed to describe the Product Resources Serial Numbering System. Serial Numbers are assigned to final assemblies so that tracking of the product can be maintained.

The default system is described below. Other serial numbering systems may be used as the customer and/or the product may require. Such other systems are documented either by the inclusion of a product-specific (or product-family-specific) serial number procedure in the product's routing or by the inclusion of a specific label part in the product's routing, or both.

Products controlled under the ATEX or Medical Device Directives always receive serial numbers. The Manufacturing Manager shall ensure that, for such products, serialization is enabled on the item for sale in the ERP system.

Production Control shall ensure that such finished product is received into inventory by serial number. (The ERP system will enforce this once the feature is enabled.)

Whenever possible, serial numbers should be created with bar codes to enhance the ease and accuracy of tracking by serial number.

2.0 Procedure

A Product Resources Part Number and a Serial Number will uniquely identify a specific product. The serial number consists of at least nine (9) digits. The first digit is always a P (for Product Resources). The next four digits are a date code (month/year), and the final four are serially or otherwise assigned as the units are processed – they are unique to the part and to the month/year. If Product Resources manufactures more that 9999 units of a part in a single month, then the serial number will have more digits added to the end as required.

MM = Month Number
01 = January
02 = February
...
12 = December

YY = Year of Assembly
99 = 1999
...
05 = 2005...

XXXX = Number of Unit

The Serial Number is constructed: PMMYYXXXX
Example: P11120246 - the unit 246 built in November of 2012

3.0 Device Test and/or Configuration Record / Device History Record

A device test and/or configuration record shall always be created and present for product controlled under the ATEX Directive or the Medical Device Directive, medical devices. This type of record is referred to as a Device History Record, or DHR, for medical devices. All such regulated items will be assigned a serial number, and these device test/configuration records will indicate the product's serial number and will be kept and filed by serial number.

For medical devices, the Device History Record shall include the identity of the manufacturing job that created the device.

For product in general, as required by the product and/or by the customer, a final test record and/or final configuration record – one for each serial number unit – is maintained.

The test/configuration record describes the unit's testing and configuration by indicating that steps have been completed, by recording pass/fail results, by recording numerical values, and by indicating the serial or lot number identities of installed critical components. These records, in addition to the serial and lot number records in Product Resources' ERP system as well as incoming inspection records, allow for traceability from final product to the manufactured and purchased components that make up the final product. In addition, these records demonstrate conformance to test criteria.

In addition for ATEX and Medical Device product, in any case that a product is re-tested and/or components changed (either because of initial nonconformance or in the case of an RMA return or field service) in the future, then this record shall be appended to with the new record so that the overall record will reflect the entire history. New records added should note the scenario surrounding the new

record and the specifics surrounding any change. For example, the firmware or software has been updated from Version X to Version Y. Or some specific critical component of serial number A has been replaced with one with serial number B. Or the unit has been recalibrated, and so on.

Records are retained per the Control of Records procedure 90-2000-4.2.4.