**DOCUMENT CONTROL SYSTEM**

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# DOCUMENT CONTROL SYSTEM OVERVIEW

**1.0 PURPOSE AND SCOPE**

This "Document Control System" document contains the guidelines and instructions necessary to define the Document Control System, its interaction and function at Larson Davis. This document is divided into sections that address different areas and/or responsibilities of the system and may include reference to other documents in the Quality Management System.

**2.0 APPLICABILITY & DISTRIBUTION**

Applicability and Distribution of this document is to all departments and to the employees of Larson Davis as required by the responsibilities and authority detailed in each section.

**3.0 REFERENCE DOCUMENTS**

D0001.1008 Systems & Data Integrity

D0001.1009 Design Control Procedure

D0001.0014 Quality Addendum for Intrinsic Safe Products

D0001.1015 Obsolescence Procedure

D0001.1021 Document Change Order (DCO)

D0001.1022 Engineering Change Order (ECO)

D0001.1023 Waiver Procedure - Process / Materials

D0001.1024 Item Creation Procedure

D0001.1126 Quality Records

D0001.1126-1 Quality Records Matrix

Alphabetical Index of Item Categories (also referred to as the Item Creation Bible)

Finished Goods Product Categories

Index of Product Primary Numbers

**4.0 RESPONSIBILITIES & AUTHORITY**

The applicable responsibilities and authority required for implementation and documentation of the requirements of each section (see "Table of Contents") are contained in the individual sections.

**5.0 DEFINITIONS**

**Assembly:** An assembled electronic circuit including a printed circuit board and its components

**BOM:** Bill of Material

**BSD:** Business Systems Database

**OEM:** Original Equipment Manufacturer

**OEM Items:** Items that are purchased from another manufacturer and then sold directly to a customer without modification.

**CAR:** Corrective Action Request; also referred to as QC Quality Concern.

**Controlled Document:** Controlled documents are all Quality System policies, procedures, work instructions, records and other quality or process documents as may be defined by Management. Engineering controls the Document Control process and function. Controlled documents require a DCO or ECO to be changed.

**DCO:** Document Change Order. The method by which documents are changed, modified or released; including process, procedures, work instructions, policies, manuals and literature.

**ECO:** Engineering Change Order. The method by which a manufactured product, its components, manuals or specifications are changed and documented by an engineer prior to release to production.

**LD:** Larson Davis a Division of PCB Piezotronics, Inc.

**Management:** The term "Management" is used to reference those individuals that are part of the LD Management team. **MRP:** Material Resource Planning

**pcb:** Printed Circuit Board

**PDF** – Portable Document Format computer file

**Primary Number:** The first alphanumeric portion of a manufactured item

**Proprietary Documents:** Documents, as identified by Management, which may contain information that is proprietary and confidential to Larson Davis. These documents have restricted access and distribution.

**Prototype:** An item or product that has not been released for unrestricted manufacturing

**QA:** Quality Assurance

**Sub-Assembly:** The combination of assemblies, mechanical items or other items to form a portion of a product.

**6.0 SAFETY PRECAUTIONS**

No special safety considerations are required beyond basic office safety practices.

**7.0 EQUIPMENT & MATERIALS**

Access to:

* Current computer system
* Printer
* Photocopy machine
* Network connectivity
* E-mail program
* Microsoft Office Suite
* Access (as applicable to responsibility) to templates created for editing, writing and controlling documentation
* Applicable rights in the current Business System Database (BSD)
* Necessary files/cabinets capable of storing required documentation
* Office supplies and workspace as needed

**8.0 INSTRUCTIONS**

This procedure has been written in sections to accommodate document control activities that may include responsibilities, authorities and requirements for Document Control that are different from activity to activity. The "Table of Contents" lists each section and a brief list of topics.

**9.0 INSPECTION**

Inspection, where required, is detailed in each of the sections.

**10.0 RECORDS**

Records for each activity and in general are detailed in each section.

**11.0 DISTRIBUTION**

Distribution is included and detailed in item "2.0 Affectivity and Distribution".

**12.0 ATTACHMENTS**

None

**13.0 REVISION HISTORY**

The "Revision History" is found at the end of this procedure.

# DOCUMENT NUMBERING PROTOCOL

This section provides an overview of the document numbering protocol for quality related documents including records, forms, work instructions, procedures, policies and publications.

**RESPONSIBILITIES & AUTHORITY**

* QA Manager has the responsibility for maintaining the Document Numbering Protocol.
* Document Control issues document numbers and maintains the master list of approved documentation in the BSD (Business System Database) by following this protocol. A master list of approved documents is maintained by Document Control and titled “Procedure Index and Revision Level”. This list does not have a revision number; it is controlled by a date code and page numbering. The Procedure Index and Revision Level document is located with the controlled Policies and Procedures documents in the Quality Management Systems folder. A Work Instruction Index document of all work instructions is also maintained in similar fashion, with a date and page number and located in the Work Instruction folder of the Quality Management System.

**1.0 INSTRUCTIONS**

The part numbers that are given to the documents covered by this instruction all start with the letter “D”. This enables the grouping of the documents in the business system database. The numbers are assigned by the level of the documentation and who is the primary user. The range of numbers set aside for the quality system is D0000.0000 to D0009.9999 and the series set aside at this time for Sales / Marketing literature is D0500.0000 to D0500.9999

**1.1 Upper Level Policies and Procedures**

Upper level policies and procedures typically are applicable to multiple departments and may represent an official policy for the company. The documents receive a number of one of the following formats:

D0001.0XXX This designation is for corporate policies and the Quality Manual. This includes policies such as the Warranty Policy (D0001.0005) or the Travel Policy (D0001.0007). The criterion for these documents is that they have a broad-based applicability throughout the company.

D0001.1XXX This designation is for procedures or processes that are applicable to more than one department and/or are required by national or international standards, i.e. ISO 9001 or ISO 17025.

**1.2 Department or Process Specific Documents**

Department or process specific documents include work instructions, checklists, forms, posted reminders, etc. The number given to these documents is based on the department or function to which the document applies.

|  |  |
| --- | --- |
| **Number Format** | **Application** |
| D0001.2XXX | Administrative, Human Resource & Finance instructions, forms, etc. |
| D0001.3XXX | Marketing & Sales instructions, forms, templates, etc. |
| D0001.4XXX | Document Control instructions. Engineering processes, forms, instructions, checklists, etc. |
| D0001.5XXX | Purchasing instructions, forms, templates, reports, etc. |
| D0001.6XXX | Logistics, processes, instructions, forms, templates, etc. |
| D0001.7XXX | Production processes, instructions, forms, checklists, templates, schedules, etc. |
| D0001.8XXX | Technician specific documentation that includes product specific instructions, checklists, forms and templates. Also includes process specific and maintenance specific documents. |
| D0001.9XXX | Manufacturing Administrative instructions. These are not specific to a product or process but to how they are administered and how the results are communicated to other departments or customers. |
| D0002.0XXX | Calibration system administrative procedures for compliance with standards like ISO 17025, ANSI Z540, etc. |
| D0002.2XXX | Quality department instructions for the various levels of inspection, audit plans, report templates, forms, etc. |
| D0002.3XXX | Quality training documents and modules |
| D0002.5XXX | IT department instructions |
| D0005.1XXX | Safety related instructions, forms, templates, reports, training modules, etc. |
|  |  |

**2.0 RECORDS**

The Document Control Clerk issues numbers by looking in the BSD and assigning the next available number from the area specified above. The Document Control Clerk will enter created document numbers into the BSD where they will be kept until the date specified on a Product Obsolete Form in the “destroy controlled documents after” field.

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# ITEM NUMBERING

This section defines how document and item numbers are allocated. Item numbers (referred herein as “item designations” since they may contain alphanumeric characters) are assigned using the Item Creation procedure (D0001.1024).

**RESPONSIBILITIES & AUTHORITY**

* Document Control is responsible for the proper allocation of all item designations.
* Engineers determine item designations for all manufactured and component items for products. Items that require a BOM are created by Engineering and released by ECO.
* Marketing selects the item designation for final products (Finished Goods & OEM) and a project engineer will see that it is created appropriately. Sales may determine the item designation for marketing documents such as brochures, training manuals, etc.
* Any employee may request an item designation from Document Control for tools, supplies, materials, or other items that are used on a recurring basis in the performance of their job. Usually these items are purchased toward a General Ledger account and do not need an item designation, never the less, a standard item designation is allowed if necessary.

**1.0 INSTRUCTIONS**

## 1.1 Item Designation Requests

An item designation can be created by one of these methods (see Item Creation Procedure):

* Request an item designation from Document Control and then submit a completed Item Creation Form to Document Control.
* Submit a partially completed Item Creation Form to Document Control, with no item designation, to have the designation assigned by Document Control.
* Submit a completed Item Creation Form to Document Control with a suggested item designation and have the item designation verified by Document Control.
* Request a designation for a Quality System or Process document from the QA Manager or Document Control.

1.2 Item Designation Format

**1.2.1 Component Items**

Component Items are those items that are generally purchased to go on assemblies and subassemblies, i.e. resistors, integrated circuits, connectors, switches, screws, etc.

Component Items use an item designation template of “**xxxx.nnnn**”.

"**xxxx**" is a 4-digit prefix that references the categories defined in the Alphabetical Index of Item Categories. Items are grouped in categories to facilitate easier searches.

"**nnnn**" is a sequence number or item identifier. Most items are numbered sequentially. Some items, such as resistors and wire, encode the value or specification of the item in the item identifier instead of a sequence number. The Alphabetical Index of Item Categories contains a template for all items where ‘nnnn’ is encoded and not sequential.

**1.2.2 Finished Good Items**

The item designation for products (finished goods), that appear on company price lists and sales literature, is specified by Sales. This designation shall not conflict with either the **Component Items** or **Manufactured Items** designation system.

Generally, major products are given an alphanumeric designation such as **3000** or **820B**. This designation may be used as the primary number as determined by the engineer

Accessory products or systems are generally given a designation following the template of “**cccnnn**”.

“**ccc**” is a three letter category

“**nnn**” is a three digit sequential number

Some examples are “CAL250” for a calibrator, “MDM010” for modem, “MEM003-64” for a memory device (the –64 is the size in megabytes), “SEN012” for a sensor, or “VPS001” for a Vehicle Passby System. The list of defined categories is found in *Finished Goods Product Categories.*

**1.2.3 Manufactured Items**

Larson Davis manufactured items item designations use the template “**axxxx.nn[-s]**” where:

“**a**” is the manufactured item category and is one of the following alpha characters:

‘A’ – for electronic circuit assemblies

‘D’ – for documents

‘F’ – for firmware

‘I’ − for product instruction manuals

‘L’ – for manufactured labels

‘M’ – for manufactured mechanical items

‘P’ – for printed circuit boards

'S' − for subassemblies

'T' − for tools

"**xxxx**" is defined as the primary number (see section 1.2.3.1 below)

"**nn**" is a sequence number or item identifier and is generally two or four digits (more detail is given below).

“s” are optional suffixes that are primarily used to designate documents that relate to intrinsic safe products (see D0001.0014).

**1.2.3.1 Primary Number**

The primary number is key to the grouping of associated manufactured items in this system. The primary number may be related to a product or product family, or it may be a 4-digit sequence number. The Design Engineer has the responsibility to select the primary number with consideration of these things:

* The primary number may be based on a Finished Goods item designation, such as “3000” or “824” (see Finished Goods Items, section 1.2.3).
* The primary number should be kept reasonably short. All Human Vibration Meters, for example, could use the designation “HVM”, rather than the longer complete name of HVM100 and HVM105, as the primary number.
* The primary number may be based on a 4-digit sequence number that began at “0001”. If at the time the product is being developed there is not a Finished Goods item designation then the next number in a sequence may be used. Primary numbers using the sequence form will have zero (‘0’) as the first digit, which will likely prevent potential conflict with product model numbers. For example, if the previous sequence used was “0051”, a new product or product group would use “0052” as the primary number.
* An item that is being created for use with a number of related or unrelated products may use a sequence primary number. For example, a new case that is to become a standard package for many products may use a primary number of “0053” (i.e. M0053.01) if it were the next one available. This type of item may also be created using a Component Item category (such as 0986.0010; see section 1.2.1).
* Sequence type primary numbers are to be recorded in the *Index of Product Primary Numbers* as they are defined. The *Index of Product Primary Numbers* is also to be used when determining a new primary number (otherwise an engineer would have to scan all manufacture item categories in order to determine the next available number).
* The primary number should be used consistently on all items created for this product or product group, including Axxxx…, Dxxxx…, Ixxxx…, Lxxxx…, Mxxxx…, Pxxxx…, Sxxxx… and Txxxx categories (“xxxx” will generally be the same for all categories, see Example, section 1.3.10).

**Note:** ***Since any single item has the potential to be used on more than one product, it should not be assumed that all items in a product will utilize a common primary*** ***number (see Example in section 1.3.10)***

## 1.3 Item Designation Assignment

The Alphabetic Index of Item Categories contains a list of currently used item categories and is maintained by Document Control. Additional categories can be created by Document Control.

Component Item Category numbers are assigned such that when the categories are listed from lowest number to highest number the category titles are alphabetically ordered. Example, if category 1000 and 1010 are titled “Autos” and “Cars” respectively and a new category for “Boats” is to be created. The category number would be chosen such that it is greater than 1000 and less than 1010, i.e. 1005.

**1.3.1 Electronic Assembly Item Designation**

Electronic Circuit Assembly item designation follows the template “**Axxxx.nn**” where:

“**xxxx**” is defined as the primary number and is generally the same primary number used on the associated pcb, and “**nn**” is a two or four digit field that uniquely identifies the assembly. It is generally assigned sequentially beginning with 01 and increments for each additional assembly created for the primary number. A four-digit number may be used if the engineer anticipates that there will be more than 99 assemblies. A four-digit number may be used to show additional steps performed on the base item. These additional step numbers may correspond with the operation steps assigned in the manufacturing system software. The drawing numbers for these operation steps may thus correspond with the item designation given.

The assembly documentation may include but is not limited to the following:

* Associated schematic
* Bill of Materials (BOM)
* Related assembly drawings & procedures
* Other documentation as determined by the Design Engineer

**1.3.2 Document Designation**

Documents are given item designations that follow the template **“Dcccc.nnnn”** where:

“**cccc**” is a document category, and

“**nnnn**” is a sequence number, or sub-category and sequence number.

Categories are identified in the *Alphabetical Index of Item Categories.*

Categories D0000 through D0009 are reserved for the Quality Management System and Process related documents. The QA Manager, or designated representative, assigns these item numbers.

**1.3.3 Firmware Item Designation**

Firmware item designation follows the template “**Fxxxx**[**.nn**]” where:

“**xxxx**” is the [[primary number](#Primary_Number)](#Primary_Number), and“[**nn**]” is an optional two digit field that identifies the firmware uniquely. It is generally assigned sequentially starting with 01 and increments for each additional firmware set created for the primary number. The field may also be a short alphanumeric code that corresponds to some other meaningful designation.

The documentation for firmware is generally one or more electronic files on the computer network identified with the item or by a work instruction. Some example firmware designations are F820, F870.01, F824-RTA and F824-FFT.

**1.3.4 Instruction Manual Item Designation**

Product Instruction Manual item designation follows the template **“Ixxxx.01”** where:

**“xxxx”** is defined as the primary number, and

**“nn”** is a two digit field that identifies the manually uniquely. It is generally assigned sequentially starting with 01 and increments for each additional manual created for the primary number.

The documentation for manuals may include but is not limited to the following:

* Master Hardcopy
* Electronic Master (such as a PDF file or other graphical/textual computer files)
* Bill of Materials (BOM)
* Related drawings & procedures

**1.3.5 Label Item Designation**

A Label is generally a printed sheet material used to mark or identify a product, sub-assembly, etc. A printed item that combines major mechanical or electrical features, such as a membrane keyboard, is NOT a label and should use an ‘M’ designation.

Label item designation follows the template “**Lxxxx.nn**” where:

“**xxxx**” is the primary number, and “**nn**” is a two digit field that identifies the label uniquely. It is generally assigned sequentially starting with 01 and increments for each additional label created for the primary number.

The documentation for labels may include but is not limited to the following:

* Fabrication drawing
* Master Artwork/Copy
* Electronic Art Master (such as a [PDF](#Portable_Document_Format) file or other graphical/textual computer files)
* Related drawings & procedures

**1.3.6 Manufactured Mechanical Item Designation**

Manufactured mechanical items include items fabricated for Larson Davis to drawings and/or specifications provided by LD as well as purchased items that require modification prior to being used in a product.

Manufactured mechanical item designation follows the template “**Mxxxx.nn**” where:

“**xxxx**” is the primary number, and “**nn**” is a two or four digit number assigned by the engineer to provide uniqueness to the item designation. It is generally assigned sequentially starting with 01 and increments for each additional mechanical item created for the primary number.

A four-digit number may be used if the engineer anticipates that there will be more than 99 mechanical items for the primary number. A four digit number may also be used to show additional steps performed on the base item, i.e. a custom mechanical item purchased from a vendor may be designated M5555.03 and, after it is modified in some way, be designated M5555.0310, then M5555.0320, etc.

These additional step numbers may correspond with the operation steps assigned in the manufacturing system software. The drawing numbers for these operation steps may thus correspond with the item designation given.

Mechanical item documentation may include but is not limited to the following:

* Fabrication drawings & procedures
* Specification documents
* Other documentation as determined by the Design Engineer

**1.3.7 Printed Circuit Board Item Designation**

The pcb item designation follows the template “**Pxxxx.nn**” where:

"**xxxx**" is the primary number, and

“**nn**” is a two or four digit field that uniquely identifies the pcb. It is generally assigned sequentially starting with 01 and increments for each additional item created for the primary number. A four-digit number may be used to identify variations of the same design (such as after threaded inserts are added to the board) or to identify the various drawings used to create the item as deemed necessary by the engineer.

The associated documentation for each printed circuit board includes but is not limited to the following:

* pcb fabrication drawing
* pcb fabrication files
* Stencil files and 1:1 stencil drawings
* Other documentation as determined by the Design Engineer

**1.3.8 Sub-Assembly Designation**

Sub-assemblies are used to combine assemblies and other items, or to indicate processes to be performed on an assembly or other sub-assemblies. Sub-assembly item designation follows the template “**Sxxxx.nn**” where:

“**xxxx**” is the [[primary number](#Primary_Number)](#Primary_Number), and

“**nn**” is a two or four digit field that uniquely identifies the sub-assembly. It is generally assigned sequentially starting with 01 and increments for each additional sub-assembly created for the primary number. A four-digit number may be used if the engineer anticipates that there will be more than 99 sub-assemblies. A four-digit number may also be used to show additional steps performed on the base item. These additional step numbers may correspond with the operation steps assigned in the manufacturing system software. The drawing numbers for these operation steps may thus correspond with the item designation given.

The sub-assembly documentation may include but is not limited to the following:

* Bill of Materials
* Related assembly drawings & procedures
* Other documentation as determined by the Design Engineer

**1.3.9 Tool Designation**

Tools are used to modify items or assist in constructing items or assemblies. Fixtures, jigs, templates and specialized tools are examples of items included in the tool designation. In most cases general purpose tools (pliers, screw drivers, wrenches, etc.) should not be given a tool designation, unless it is beneficial to have a fixed designation for that itemicular tool. Tool item designation follows the template “**Txxxx.nn**” where:

“**xxxx**” is the [[primary number](#Primary_Number)](#Primary_Number), and “**nn**” is a two or four digit field that uniquely identifies the tool. It is generally assigned sequentially starting with 01 and increments for each additional tool created for the primary number. A four-digit number may be used if the engineer anticipates that there will be more than 99 tools.

A four-digit number may also be used to show additional steps performed on the base item. These additional step numbers may correspond with the operation steps assigned in the manufacturing system software. The drawing numbers for these operation steps may thus correspond with the item designation given.

The tool documentation may include but is not limited to the following:

* Bill of Materials
* Related drawings & procedures
* Other documentation as determined by the Design Engineer

**1.3.10 Projects Numbered Using a Prior Numbering System**

Projects that were started using a previous item designation system may continue to use that system until the project is completed. This will ensure consistency for the item designations within a project.

**1.3.11 Example**

Consider a finished good product that contains 2 subassemblies. The first subassembly contains 1 printed circuit assembly and 3 mechanical items and the second subassembly contains 2 printed circuit assemblies and 2 mechanical items. The structure may resemble the following example:

| **#** | **Level** | **Item designation** | **Comments** |
| --- | --- | --- | --- |
| 1 | 1 | 5555 | finished product (primary number and finished goods item designation are equivalent) |
| 2 | 2 | — S5555.01 | first subassembly |
| 3 | 3 | — — A5555.01 | circuit board assembly & associated processes, bill of material and/or schematic |
| 4 | 4 | — — — P5555.01 | first raw printed circuit board |
| 5 | 4 | — — — xxxx.xxxx | associated components |
| 6 | 2 | — M5555.01 | first mechanical item in this subassembly |
| 7 | 2 | — M5555.02 | the second mechanical item in this subassembly |
| 8 | 2 | — M5555.0320 | third mechanical item, with modifications |
| 9 | 3 | — — M5555.0310 | mechanical item, with modifications |
| 10 | 4 | — — — M5555.03 | third mechanical item, raw item |
| 11 | 2 | — S5555.02 | second subassembly |
| 12 | 3 | — — A5555.02 | circuit board assembly & associated processes, bill of material and/or schematic |
| 13 | 4 | — — — P5555.02 | second raw printed circuit board |
| 14 | 4 | — — — xxxx.xxxx | associated components |
| 15 | 3 | — — A5555.03 | circuit board assembly & associated processes, bill of material and/or schematic |
| 16 | 4 | — — — P5555.03 | third raw printed circuit board |
| 17 | 4 | — — — xxxx.xxxx | associated components |
| 18 | 3 | — — M5555.04 | fourth mechanical item associated with this primary number |
| 19 | 3 | — — M0976.02 | manufactured item used in multiple products including this one |

**2.0 RECORDS**

Document Control will enter created item numbers into the BSD where they will be kept until the date specified on a Product Obsolete Form in the “destroy controlled documents after” field. Document / Item numbers will not be destroyed until after all documents / items using the number have become obsolete. (See Obsolescence Procedure (D0001.1015 and SM026))

# CONTROLLED DOCUMENTS

This section details how product and process documentation is defined and controlled. Controlled documentation is not limited to product or process documents but may also include other types of documents as specified in this procedure, by Department Manager request or by consensus of Management.

This section addresses four classes of documentation.

1. Content Controlled
2. Controlled by regulation or specification
3. Non-content controlled
4. Records

**RESPONSIBILITIES & AUTHORITY**

* Management has the ultimate responsibility and authority for ensuring that a system for document control is implemented and maintained.
* The Larson Davis Engineering Department has the responsibility and authority for the supervision and management of the day-to-day operation of the Document Control System.
* Engineering is responsible to provide a Document Control Clerk and adequate space and resources for the distribution, maintenance and storage of the controlled documents and other documents or references that may need management.
* The Document Control Clerk has responsibility for the actual distribution, maintenance, management and storage of the controlled or specified documentation and references. This responsibility includes but is not limited to:
* Responding to requests for copies of documentation
* Making and distributing copies
* Managing the ECO / DCO process
* Filing of new and/or revised documentation
* Entering Document and Item numbers, information and revisions into the current manufacturing software (BSD)
* Entering new or editing of existing BOM's into the current manufacturing software
* Employees request from Document Control copies of documents. Employees are permitted to print or make copies of the online document; however, employees are responsible to ensure that they are using the most current revision for the process or procedure being performed.
* Documents may be temporarily modified with a waiver or with redline markings for clarifying manufacturing needs to an outside supplier or between edits to Production documents.  Engineering dates, initials, and marks the modification, then augments the current revision number with a “– {number}”. The Document Control Clerk scans the modified document and adds the electronic copy to the controlled document folder where the current document is located.  Production is responsible to add an entry into the bug tracking software so the interim fix is not forgotten and engineering is assigned a priority to completing the change request. Engineering updates the document with any changes via the DCO/ECO process at which time the next revision replaces both the previous revision and the modified document.

**1.0 INSTRUCTIONS**

The instruction details the types of documents that should be controlled and/or maintained. An overview of basic Document Control procedures to be followed is also included.

There are four types of documents that are controlled by the Document Control group or by other departments as designated by the applicable procedures. Those document types are:

## 1.1 Content Controlled Documentation

The content and use of these documents is controlled by Larson Davis. If changes are required they are made through the ECO / DCO process. Content controlled documents may include but are not limited to:

* Product Specifications
* Product Requirements
* Project Plans
* Engineering Documents
* Schematics
* Assembly Drawings
* Artwork
* Design notes & specifications
* Bill of Material
* Test results that verify that product meets product design specifications
* Forms
* Policy, Process & Procedure Documents
* Price Lists
* Product Manuals
* Quality Management System Manual
* Software
* Work Instructions

## 1.2 Regulation Required Control

Documents in this classification may be used in the design of the products and/or demonstrate product compliance to the regulated contents of the documents. The content of the documents is not controlled by Larson Davis. The documents are often referred to as "Standards". Standards are written and approved by National, International, or Industry specific organizations. Standards are sold and published through organizations such as ANSI, IEC, UL, etc.

Document Control maintains a list of the standards, their revisions and locations (if not in the Document Control area).

## 1.3 Non-Content Controlled Documents

These documents are generally written by other organizations and may be for a specific piece of equipment, process, software, design or workmanship reference documents. They may be referenced for use by controlled documents and therefore are controlled such that they are available to the employee for use. They are not written by Larson Davis nor are their contents controlled by Larson Davis.

Documents that are included in this classification may include but are not limited to:

* Equipment Operator Manuals
* Software User Manuals
* Industry Process Standards and / or Guidelines (example - IPC)
* Relevant Reference books

## 1.4 Records

Records that require retention are generated by numerous procedures and processes. However not all of the generated records are stored by Document Control.

The storage location and the type of records to be saved are detailed in the procedure that generates the record or in a departmental records matrix. Records may be stored on several different types of media - electronic, paper, microfiche, etc.

The records stored in Document Control may include but are not limited to:

* Project Meeting Minutes
* Completed Engineering Change Orders
* Completed Document Change Orders
* Completed Item Creation Forms
* Completed Document Approval Sign-off Forms

## 1.5 Document Access

* All documents required for correctly manufacturing, testing, inspecting or processing product are made available to the appropriate department.
* All documentation that affects the quality of a product is made available to the appropriate department.
* A new document is provided whenever a revision is made to a document or with the initial release to manufacturing.
* Documents are made available on paper, electronically, or both.
* Some documents are classified as trade secrets or proprietary. Access to those documents is restricted to authorized individuals. Restricted access prevents individuals that are not involved in the related procedure or are not department managers from obtaining copies of the documents. Additional details are in Section IV - Proprietary Documents.
* Copies of documents will be requested from Document Control using a document request form, telephone request or email request.

## 1.6 Identification of Controlled Documents

* Any paper copy of a controlled document is an unofficial copy.
* Unofficial copies of controlled documents may be used for inspection, production or by suppliers, if the revision and the revision date match the information on the Job Order Router or the information in the current BSD.
* The Master controlled documents will be maintained by Document Control; electronically, paper, or other media as appropriate.
* QA Documents such as the Quality Management System Manual or Calibration System Controls & Policies document are routinely sent to customers. These controlled documents should be put in “PDF” format prior to being sent to the requesting individual. QA or Management may request that non-proprietary document copies be sent to requesting individuals.

## 1.7 Obsolete Documents

The Product Obsolescence procedure addresses how obsolete documents will be handled through Document Control.

Each employee is responsible for properly disposing of obsolete or down-level revision documentation that they may have in their files or work areas. This does not apply to individuals that have the responsibility to repair, calibrate or support existing product.

**2.0 INSPECTION**

Inspection is an important part of the Document Control System. The Document Control Clerk is responsible to verify the information being supplied to Document Control. The verification process may include but is not limited to the following:

* Verifying that the approval process has been completed
* Verifying and updating revision levels
* Verify that the document package includes paper and electronic copies as applicable
* Verifying that the document package is complete
* Verifying that item and/or document numbers are not being duplicated
* Verifying that forms, descriptions, etc. are understandable and complete

# REVIEW, APPROVAL & RELEASE

This section provides information on the methods used by Larson Davis (LD) to review, approve and release documentation for use by employees.

**RESPONSIBILITIES & AUTHORITY**

**Employee -** Employees may be required to review documentation prior to approval for processes, procedures or work instructions that they may have responsibility. The purpose of the review is to verify that the process, procedure and/or work instruction has been accurately documented and is current with the method in place.

**Managers -** Managers may be required to review documentation that may have a broader impact than a single process or instruction. Documentation is reviewed for completeness, accuracy and implementation that may be required after approval. Managers are responsible for seeing that training occurs and communicating the release of and/or changes to documentation that may affect the responsibilities of their employees.

**Document Control -** The Document Control Clerk has the responsibility of processing documentation and verifying that proper approvals have been obtained prior to releasing documents for employee use.

**Quality Assurance (QA) -** QA, or a designated representative, has the responsibility to review documentation prior to release. The review may, at the discretion of QA, cover form, grammar, adequacy of detail, referenced documents, and compatibility with existing documentation and quality standards (i.e. ISO 9001-2008).

**1.0 INSTRUCTIONS**

This section defines the levels of documentation used at Larson Davis and the process to be followed for review, approval and release of new and/or existing documents.

## 1.1 Levels of Documentation

1. **Documentation Levels**

**Level 1 - Quality Management System**: The Quality Management System may also be referred to as the Quality Manual, QMS Manual, etc.

**Level 2 - Procedures / Policies / Processes:** This documentation is typically broader in scope and application. Instead of containing the details of every step of a process it may reference work instructions and provide an overview of the process, policy or procedure.

**Level 3 - Work Instructions:** These are very specific, detailed instructions that allow the employee to correctly perform the function or process described in the instruction. Work instructions are the "How it is done!" instructions. The instructions may be simple flow charts or detailed information.

**Records:** Records are the documentation that is used to demonstrate compliance, completion or other required information from the processes, procedures or work instructions.

## 1.2 New Documentation

1. **Responsibility**

Responsibility to write documentation may be delegated by any member of the management team as requested by the QA Manager or as a need for additional documentation is identified. In the case of records, the procedure or work instruction generating the requirement to maintain a record may also specify the responsibility, location and/or retention time for the record.

1. **Management involvement**

Members of Management have the responsibility to:

* Delegate responsibility to write documentation as needed
* Be knowledgeable of the Quality Standards that govern the Quality Management System and how the standards impact their area of responsibility
* Review documentation that affects their area of responsibility
* Training and implementation of affected employees on the new documentation after approval.

## 1.3 Existing Documentation

1. **Review and Re-write**

The quality management system is a living documentation system and requires regular review and update. Existing Level 1, Level 2 and Level 3 documentation should be:

* Reviewed at least once each year to verify that the documentation is still adequate and current. The review may be completed by any employee who has responsibility to use the documentation, QA, or by an auditor during an internal audit.
* Changed and/or updated when affected by a change to the process or related documentation by either ECO or DCO.
* Verified that it is still compliant to the Quality Standards chosen by Larson Davis.

1. **DCO / ECO Process**

Documentation is changed using the DCO process (D0001.1021), however an ECO may direct the requirement for the change. In that case the DCO would provide the evidence of completion required by the ECO.

## 1.4 Review & Approval Responsibilities

1. **Who should review?**

The following is a general guideline for determining individuals to review and/or approve documentation. Additional individuals may be added to the review and/or approval process as determined by QA, General Manager, or Department Manager.

**Level 1 Documentation** - This type of documentation affects the entire company and must be reviewed and approved by the members of Management and the QA Manager. Other employees may also be invited to review the documentation as appropriate.

**Level 2 Documentation** - This documentation may affect the entire company or be function / process / department specific. At the discretion of Management, all members of the team or those team members whose area of responsibility are affected will review and/or approve the documentation. In addition to Management, the QA Manager is also required to review and approve the documentation.

**Level 3 Documentation, Work Instructions** - This documentation is very detailed and specific and may apply to a very limited group of employees. Department specific documents will be reviewed and/or approved by the author of the document, QA, the department manager and other individuals as specified by the department manager. If the author does not have direct responsibility for the process / function then the individual with direct responsibility will also review and/or approve the document. Work instructions that are product specific will be reviewed and/or approved by the responsible engineer, QA, the author and/or the responsible employee(s).

## 1.5 Approval Process

1. **Complete the DCO form**

If releasing a new or editing an existing document, follow the Document Change Order (DCO) procedure and complete the DCO Form.

1. **Submit Documentation to Document Control**

Follow the DCO procedure.

1. **What if document is rejected?**

Refer to the DCO procedure.

1. **Document is approved and filed**

Refer to the DCO procedure for process details.

1. **Implementation**

Managers have the responsibility to ensure that their employees are trained on the new or revised procedures after they have been approved. Training should take place within 30 days of document approval.

All employees have the responsibility to implement released and approved procedures. A Supervisor, Manager, QA and/or Internal Audit review may be used to verify implementation at any time after training has occurred.

**2.0 RECORDS**

Copies of the approvals and the completed DCO's are maintained by Document Control per the DCO procedure.

# PROPRIETARY DOCUMENTS

This section specifies the process controlling proprietary documents.

**RESPONSIBILITIES & AUTHORITY**

Document Control is responsible for maintaining, securing, copying, and distributing proprietary documents.

Engineering Manager is responsible for identifying proprietary documents.

The Engineering Manager or the Manufacturing Manager is responsible to approve each distribution of a proprietary document.

Engineers, scientists, researchers, etc. are responsible to recommend documents that should be marked as proprietary to Management.

All employees that receive access to proprietary documents are responsible to keep them secure and not to disclose the information contained therein.

**1.0 INSTRUCTIONS**

This section describes the steps involved in:

* Determining what documents will be considered proprietary,
* How these documents will be marked and stored, and
* How authorized individuals will get copies.

## 1.1 Identifying Proprietary Documents

Any employee, especially engineers, scientists and researchers, may recommend to Management that a document be marked as proprietary.

Department or Division Managers will identify documents that they believe should be marked as proprietary and submit them to Management for approval. Management will evaluate the documents and make a determination on each.

The Engineering Manager will notify Document Control of any documents that have been determined to be Proprietary Documents and therefore require the control detailed in this section.

## 1.2 Marking and Storage of Proprietary Documents

Proprietary Documents will be stamped “**Proprietary**” and “**Confidential**” by Document Control and will be stored in the secured proprietary document area.

Individuals who receive copies of proprietary documents must store them in a secure location that has been approved by the Management member to whom they are responsible.

## 1.3 Obtaining Copies of Proprietary Documents

* Personnel who need to obtain copies of proprietary documents may request them from Document Control.
* Document Control will notify the Engineering Manager, or the Manufacturing Manager of all requests for copies of proprietary documents.
* The Engineering Manager or the Manufacturing Manager must approve the request before copies are given to the individual and sign the "Proprietary Documents Checkout Log" entry authorizing the distribution of the document copy.
* A copy of the proprietary document is made and the copy is stamped “Copy”. The “Proprietary” and “Confidential” markings must be clearly visible on the copy.
* Document Control records this distribution action on the "Proprietary Documents Checkout Log" and has the recipient sign the log entry.
* The person receiving the document must keep it secure in the approved location.

## 1.4 Disposal of Proprietary Document Copies

When a copy of a proprietary document is no longer needed it will be returned to Document Control. Document Control will file or destroy the returned proprietary document copy. If filed, it must be with the original in the secure area.

**2.0 INSPECTION**

An audit of the proprietary documents will be performed at least annually by a member of LD Management or by a designated individual i.e. an internal auditor.

The audit will:

* Verify the proper control, storage and handling of proprietary documents,
* Verify that proprietary documents listed on the master inventory list are in the secured proprietary document area, and
* Inspect the checkout log and verify that copies are being handled in a secure manner.

**3.0 LOGGING PROPRIETORY DOCUMENTS**

All Proprietary Documents will be indicated as such by Document Control under their item number in Item Maintenance in the BSD.

# DOCUMENT PROCUREMENT

This section provides instructions for viewing controlled Documents that are made available in electronic form and obtaining copies of documents from Document Control.

**RESPONSIBILITIES & AUTHORITY**

Document Control is responsible for the control of the electronic documents described in this section.

Employees have the responsibility to verify that any hard copy versions of any controlled document are of the correct revision prior to using the document. This is done by accessing the operating software and checking the current revision level.

Employees who have responsibilities that include using down-level documentation (older revision) are responsible to mark the documentation in such a way as to prevent accidental use.

**1.0 INSTRUCTIONS**

**1.1** Documents are stored electronically by Document Control in the Network Drives. The documents in the folder may include but are not limited to Procedures, Work Instructions, Product Specifications, Manuals and other miscellaneous controlled documents.

**1.2** Documents in the folder are read only. They may be viewed, printed or saved in other directories.

**1.3** If a document is not accessed from the controlled area on the network or from Document Control then it is not a controlled document.

**1.4** The document files are identified and designated by document number and title.

|  |  |  |
| --- | --- | --- |
| **LOCATION** | **DIRECTORY** | **DESCRIPTION** |
| Quality Procedures | Network: Quality Procedures | Procedures |
| Work Instructions | Network: Work Instructions | Work Instructions in applicable folders |
| Miscellaneous Documents | Network: ENG\Misc. | Miscellaneous Documents |
| Product Specifications | Network Engineering Specifications | Product Specifications |

**1.5** If a controlled paper (hard) copy is required or if assistance is needed in locating a document, contact the Document Control Clerk for assistance.

# GENERAL CONTROL OF RECORDS

Records are those documents used to provide evidence of conformity to the documented processes, procedures, policies and/or work instructions that comprise the quality management system utilized by Larson Davis. This section documents the method that may be used to define the need for records, what records are needed, when a record is documented, the individual(s) responsible for creating the records, as well as preservation and disposition of the records.

**RESPONSIBILITIES & AUTHORITY**

The IT group maintains the electronic storage of records per the requirements of the "Systems & Data Integrity" procedure.

All employees have the responsibility to follow the requirements pertaining to the generation, storage and retention of records as outlined in this procedure.

Document Control maintains those records as specified by the individual procedures and/or work instructions

QA maintains the "Quality Records Matrix", D0001.1126-1, as a reference.

**1.0 INSTRUCTIONS**

This section contains the generic procedures relating to defining, generating, managing and disposing of records. Specific and detailed information pertaining to the individual record(s) being maintained may be found in the procedure and/or work instruction that pertains to the record(s).

## 1.1 Defining the Need for a Record

Records are used to provide evidence and effectivity of the quality management system (QMS). Records are also used to provide guidance in improving the QMS in areas such as processes, policies, procedures, etc. Only those records that meet these needs should be specified. To determine if a particular document or data needs to be retained or tracked the following questions need to be answered:

1. Is the record required as evidence or proof of compliance to any standard to which Larson Davis is or seeking compliance to?
2. Is the record required by the customer?
3. How will the information (data) or record be used to improve the QMS?
4. Will the lack of the information or record negatively impact the ability to produce conformant product and/or customer satisfaction?

## 1.2 Types of Records Needed

* Quality Policy
* Quality Objectives
* Minutes from meetings such as Design Reviews, Management Reviews of Quality Management System, Customer Feedback, etc.
* Organization Charts and Job Descriptions
* Training Records
* Employee Records showing education, training, skills and experience
* Process Reports
* Customer Feedback including RMA's
* Customer Communication and Customer perception of satisfaction
* Corrective / Preventive actions taken, results and reviews of implementation
* Records required for product realization
* Contract Reviews
* Waivers
* Document and/or Engineering Change Orders
* Supplier Selection, Evaluation and Re-Evaluation
* Records of process validation
* Product identification and traceability
* Records of communication with customer in case of damage to customer property.
* Record of calibration & verification results for M&TE
* Records of internal audits and results
* Evidence of conformity with the acceptance criteria for products including signature of releasing authority
* Records of the nature of non-conformities and action taken
* Records of Recalls
* Data Collection & Analysis

## 1.3 Responsibility for Documenting

The responsibility for documenting the various records, data, meetings, etc. is specified in the individual procedures / work instructions governing the activity.

## 1.4 Preservation, Filing, Storage, Handling, etc.

The responsibility for maintaining the records is defined in the individual procedures / work instructions governing the activity. Maintaining the records includes storing the record such as to preserve the integrity, legibility and usability of the record. Those records that are stored electronically on the company network are maintained and their integrity preserved by the procedures used by the IT group. The procedure governing protection of electronic records and/or data is D0001.1008 Systems & Data Integrity.

## 1.5 Disposition of Records

Records may be disposed of after the specified retention time has lapsed but may be retained longer at the discretion of the employee responsible for maintaining those records.

Records that may include sensitive company information will be identified by Management and disposition will be through a method that destroys the usability of the record i.e. shredding, burning, etc.

**2.0 INSPECTION**

Records should be verified as containing the required information prior to filing. Information required will be dependent on the record being generated and its associated procedure and/or work instruction.

# REVISION HISTORY

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **DCO #** | **REV** | **DATE** | **INITIALS** | **CHANGES MADE** |
| 377 | B | 1/17/02 | JEB | Total re-write and combination of other document management procedures into one procedure. Procedures that were combined into this procedure and obsoleted as individual procedures were: D0001.1016 Review, Approval & Release of Documentation; D0001.1018 Document Procurement; D0001.1019 Document/Item Numbering; D0001.1025 General Control of Records; D0001.1026 Proprietary Documents. |
| 400A | C | 3/26/02 | CBS | The revision B D0001.1017 document was inadvertently created using an obsolete version of D0001.1019 (Item Designation). The revision C D0001.1017 was corrected using the previously approved D0001.1019 document. |
| 429 | D | 4/30/02 | KN | Add T prefix for tools to the item numbering system. |
| 462 | E | 9/17/02 | MB | Add D0001.1009 to reference docs; added that items requiring a BOM must be created by Eng; added definitions for OEM and OEM Items to section 1 - Document / Item Numbering |
| 647A | F | 10/13/03 | JB | Modified a couple of things in document. Anyone can ask for documents and they can make copies and stamp them. |
| 798A | G | 8/30/04 | SLB | Modified paths in the document |
| 1024 | H | 7/23/07 | HB | Updated document to reflects change to PCB Piezotronics, Inc / Larson Davis Division. |
| 1108 | I | 5/23/08 | DAR | Minor updates |
| 1247 | J | 7/31/09 | KC | Rewrote page 18 to make instructions read clearer and more accurate. |
| 1385B | K | 4/23/12 | HSA | Removal of extra page, replaced I: with Network |
| 1417 | L | 9/26/13 | JLD | Added extra naming conventions for intrinsic safe products. |
| 1500 | M | 5/15/14 | DAR | Added the Document Numbering Protocol to this document which was formerly a QA work instruction. This clarifies for all in one location document numbering protocols. |
| 1561 | N | 5/8/15 | DAR | Clarified document index protocol. |
| 1811 | O | 4/4/2108 | DWA | Changed redline drawing instructions under section Controlled Documents – Responsibility and Authority |