

# VM3COP01.3

## Historic Documents & Records

ISO 9001, ISO 13485 and the MDD Council Directive 93/42/EEC including many of its derivatives require a document and/or a record.

### Historically

The documents and records were located in Red Binders (still available)

With the advent of Paperport documents were scanned filed in Paperport files and transferred regularly to CD's

ID Doc 3760

ID Doc 9565

9690

Paperport is an electronic filing and storage system.

Imagine a Filing cabinet with drawers and individual files.

Some files can be opened by anyone in the company others are restricted.

In Paperport the files open to all start with a letter (A)

Electronically there can be more levels of filing than in a paper system

e.g.

Take ISO.

All our ISO files are found (D) ISO Information Level 1

There can be many or few major groups of files in Level 1

In the ISO system we will usually have 6 or 7

(D) BSI information This contains basic information on BSI

(D) ISO Quality Manual This contains the latest and most current Viamed company Quality manual

(D) ISO EN Documentation This contains the actual BS : EN ; & ISO standards

(D) ISO 9000 Current ( year) This contains all the current company procedures

Manufacture

Repairs

Administration

QA procedures

Office procedures

Vandagraph procedures

(D) Management reviews This contains the Management review minutes

(D) ISO 9000 2000 ISO 13485 This file will change its name as standards change. It the update file when the procedures are amended but are are yet included in the current procedures

All the groups (A) >> follow a similar format + means there is another level of files

### New information & Upgrades

Files in an electronic system can easily be modified and erroneous information inserted without traceability. For this reason all the open Files are read only. Upgrades and new information can only be added by a director.

### **New information**

New Information should be scanned into pp update

### **Upgrades**

To upgrade a file first duplicate it in Paperport

Add a postnote with the modification or highlight the errors and add text.

Print the modified page to Paperport either black & white or colour.

*CHECK The graphic is set to 200 dpi or 300 dpi*

Once the information is in Paperport duplicate the documents as paperports documents, stack, rename, and delete the original image.

Most the product files available on CD are still available as backups.

New CD's or DVD's can be made from existing Paperport files.

### **Personal Filing**

Every member of the staff who has a need to store information has a Folder on T drive.

These are backed up regularly and stored in remote locations.

Documentation can be printed out to be used on a once only basis. Any modifications can be added by the user but must then be submitted for confirmation and updating by senior personnel into the system.

### **Intrastats**

Intrastats program was written to solve an EU Intrastat requirement of regularly documenting sales for EU & Non EU areas.

The success of this program led to the expansion, to include documentation and procedures etc.

It soon became obvious that "Intrastats" could Document, Record, and control the main elements required by the company. It not only includes QMS but also HSE. Marketing & Sales etc.

Co-incidentally with the introduction of "Intrastats " documentation and communication by email become the norm. All the communications are records stored in either system. They are recoverable even though Goldmine our Contact and communication system was outgrown and emails were replaced with Gmail.

Paper records for this era do not necessarily exist. Some of the important documents have been converted into Intrastats for speedy delivery to the MHRA as samples if an incident ever occurred.

### **Conclusion**

The original documents are still in existence. The Intrastat system is a live evolving system that is paper free.

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