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Example Flow Charts

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### **Flowchart**

# A diagram that uses graphic symbols to depict the nature and flow of the steps in a process

#### **Benefits of Using Flowcharts**

- Promotes understanding of a process
- Identifies problem areas and opportunities for process improvement
- · Provides a way of training employees
- Depicts customer-supplier relationships

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Example Flow Charts

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### **Symbols Used In Flowcharts**

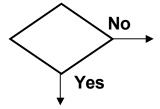
Start / End



**Process Step** 



**Decision** 



Connector



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Example Flow Charts

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# Notes & Commentary

### Required Level II Flow Charts (Procedures)

#### Procedures 'Required' By the 2000 Revision

- 4.2.3 Control of Documents
- 4.2.4 Control of Quality Records
- 8.2.2 Internal Audit
- 8.3 Control of Nonconformity
- 8.5.2 Corrective Action
- 8.5.3 Preventive Action

### **Partial Listing of Procedures** 'Required' By the 1994 Revision

- 4.3 Contract Review
- 4.4 Design Control
- 4.5 Document and Data Control
- 4.6 Purchasing
- 4.7 Control of Customer Supplier Product
- 4.8 Product Identification and Traceability
- 4.9 Process Control
- 4.10 Inspection and Testing
- 4.11 Control of IM&TE
- 4.12 Inspection and Test Status

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# Notes & Commentary

If you read through ISO 9001:2000, you will find 6 places where Documented Procedures are specifically stated to be a requirement. Some folks have been saying how nice it is that the documentation requirements have been reduced. While this is technically the case, it is really a non-issue. For the most part companies are not going to be reducing their documentation significantly if at all.

What about new implementations? Will this be a big help to you? No - not really. You will have to have the 'appropriate' documents in place regardless. Take for example 7.4 Purchasing. There is very likely that your company will need a purchasing procedure. Often there are a number of purchasing 'procedures' (systems) which will require some type of documentation. The absence of the requirement does not exempt your company from having documentation 'where appropriate'. Where appropriate will be determined by a common sense look at the process in context.

One must remember that to comply with the 1994 version, most companies adopted the Level II approach - make 20 top level procedures or flow charts to address each element of the standard.

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### Some Other Expected Process Maps

- ° Planning (5.4, 7.1, 8.1, 8.5.1)
- Management Review (5.6)
- Resource Management (6)
- Training (6.2.2)
- ° Customer Processes (7.2)
- Customer Communication (7.2.3)
- Design and Development (7.3)
- Purchasing (7.4)
- Operations Control (7.5.1)

- Product ID / Traceability (7.5.2)
- Customer Property (7.5.4)
- Preservation of Product (7.5.5)
- Validation of Processes (7.5.2)
- Process Measurement / Monitoring (8.2.3)
- Product Measurement / Monitoring (8.2.4)
- Analysis / Improvement (8.4, 8.5)

Note: Some of these may not be relevant to your company. An example is Product Identification and Traceability. If you are a *service* company, Product Preservation will probably not apply to your situation. Remember, however, that exclusions are limited to requirements within Element 7 - Product Realization.

THIS LIST IS NOT INCLUSIVE!

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Example Flow Charts

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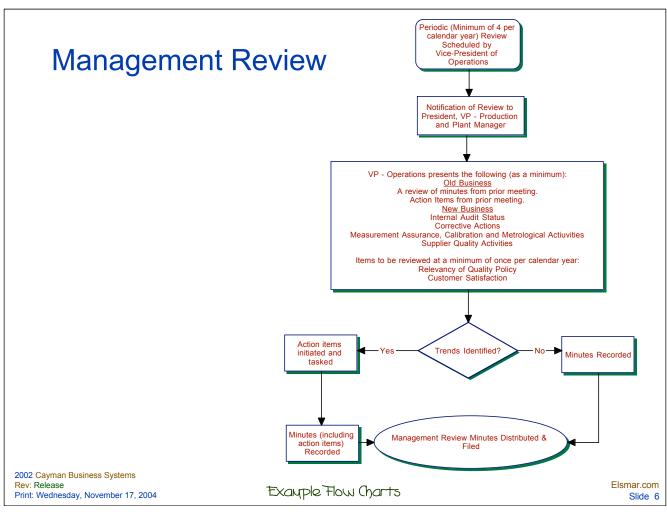
# Notes & Commentary

As you can see, most of the documents in the above listing are parallels to the 20 'old' ISO elements. It may be that the new standard does not specifically require a document to cover each of these, however it will most often be the case that your company will have to document these systems at least minimally.

As I have stated before, the level of documentation your company will need cannot be determined by a book or reference. Your company may have relatively simple systems and on-the-job training may be utilized more than at another company. You may be a facility which is part of a corporation where there are flow-downs you will have to comply with (some of which will probably be documentation requirements). Or, your company may only consist of 8 souls who provide a service - your documentation will probably be minimal.

You have to review, within your company, what you are doing now and making some common sense determinations of where documentation is relevant and 'necessary'.

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### **Planning For Quality**

Procure, examine and derive requirements from the accepted quotation or contract relating to the product being planned;

Review Standards of Acceptability for all features and requirements including those containing a subjective element that must be clarified;

Consideration of any quality standards,, legal requirements, regulations or codes that apply or may be affected; Ensure the compatability of the design, the production process, inspection and test procedures and other applicable documentation

Confirm or determine the necessary documented procedures, instructions,, drawings, or other documentation required

Confirm or determine the resources needed including raw material, machinery, number of employees, etc. Identify and acquire any controls,, processes, inspection equipment, total production resources ands skills required to achieve the required quality.

required to achieve the required quality.

Update, as necessary, quality control, inspection and testing techniques and development of new instrumentation, if required.

Examine the production operatrions, sequences and tests and inspection test points required;
Identify and define responsibility for the preparation of quality records

VP - Operations retains records file

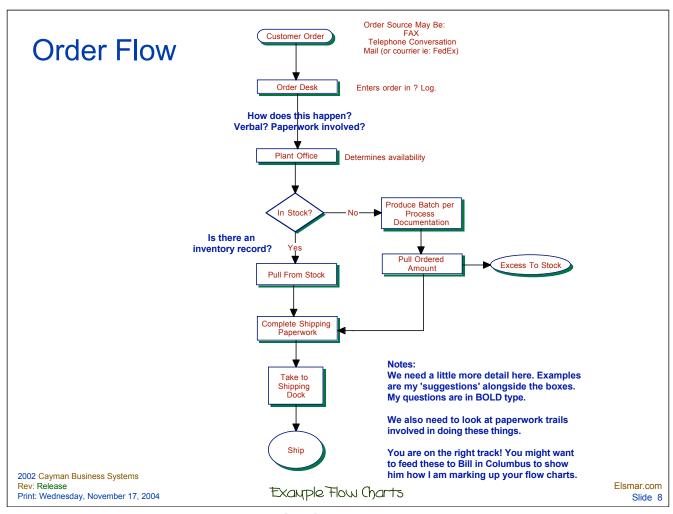
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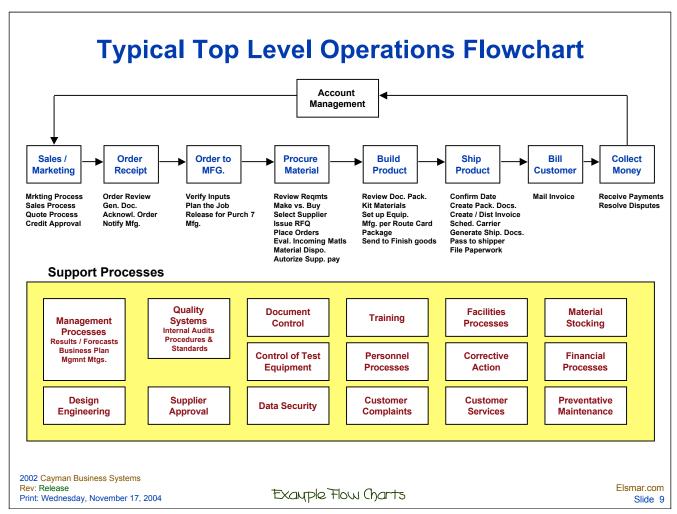
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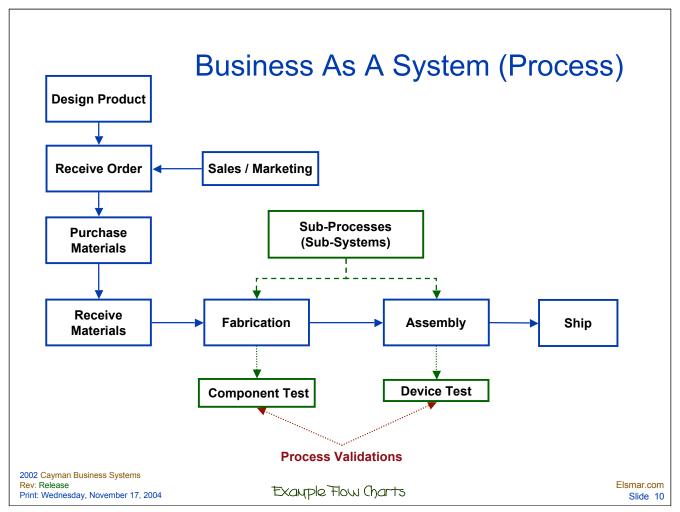


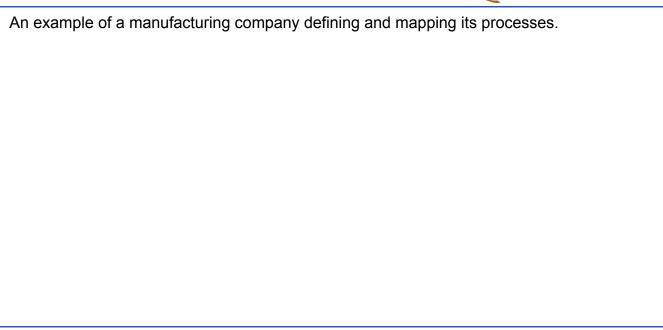
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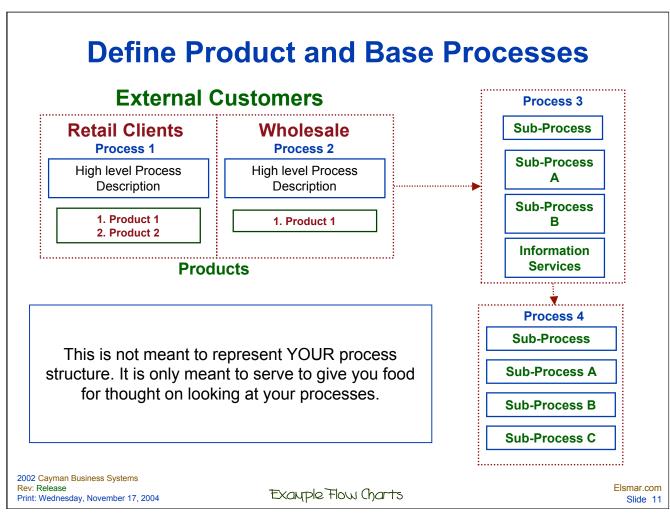






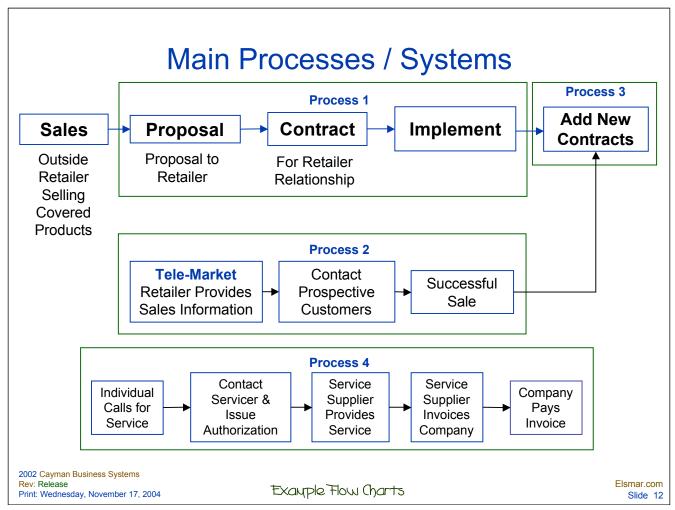








An example of a service company defining and mapping its processes.



An example of a service company defining and mapping its processes.

#### **Miscellaneous Sub-Processes**

### Contracting & Compliance

- Contract Negotiation
- Compliance to State Regulations
- Maintenance of Fulfillment Process

#### **Client Services**

- Load client data electronically
- Dealer Set Up
- Table maintenance
- New client installations (implementations)

#### **Data Entry**

- Load client data manually
- Process
   Cancellations

### Warranty Administration

#### Claims

- Review & Approve Payments
- OTL authorizations for retail contracts

#### Customer Service

- Entitle & issue all initial authorizations
- Inbound Sales Calls
- · Calculations for cash out

#### Service Recruitment

- Maintain Servicer Database
- Satellite Customer Service

#### Compliance & Training

- New Employee Training
- · Quality audits of staff
- · QA Card review & reporting

#### PC Help Desk

Entitle & issue all initial authorizations

### Direct Marketing

- Campaign Planning
- Execute Direct Mail
   Telemarketing
   campaigns
- Reporting for Client and management

#### Sales & Marketing Support

- Develop proposals
- Control collateral materials

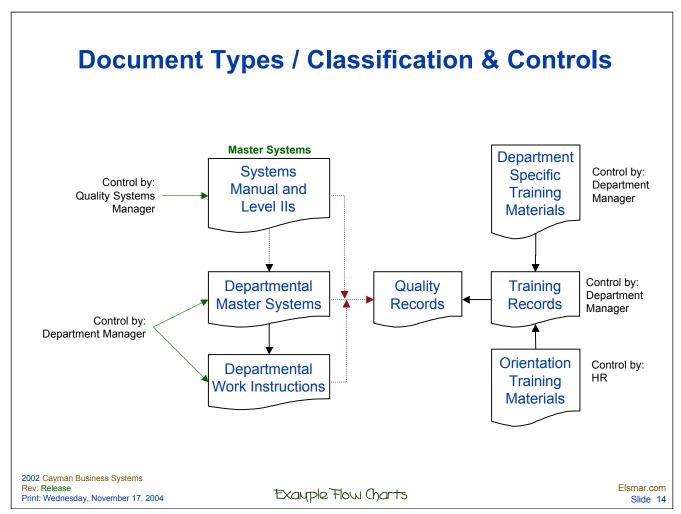
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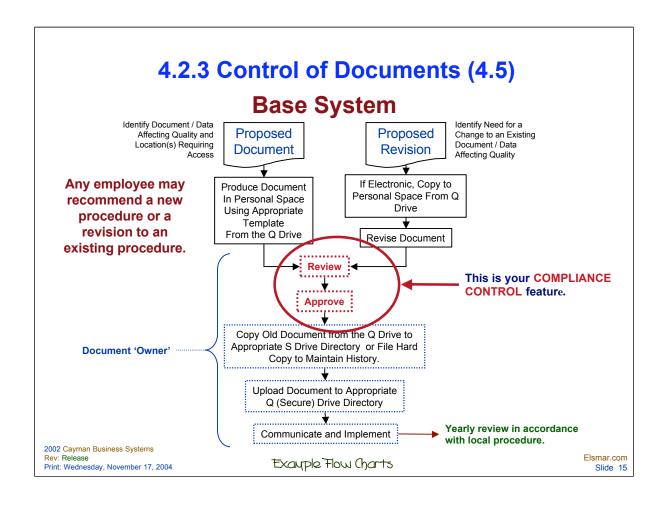
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An example of sub-processes in a service company.



Specific requirements are detailed in Clause\_Interp\_and\_Upgrading.doc



The above is an example of where a company had a simple centrol system. Masters are kept on a protected drive. Each person responsible for a document 'owns' a directory which only s/he can write to. Control is, obviously, very decentralized.

Companies control documents in many was. Some use canned software. Some smaller companies have everything on paper. The position of the computer today makes paper systems very rare, but there are some that still exist. This is only to say that your system has to meet some basics but the variability makes it impossible to predict.

Important elements of your system should include:

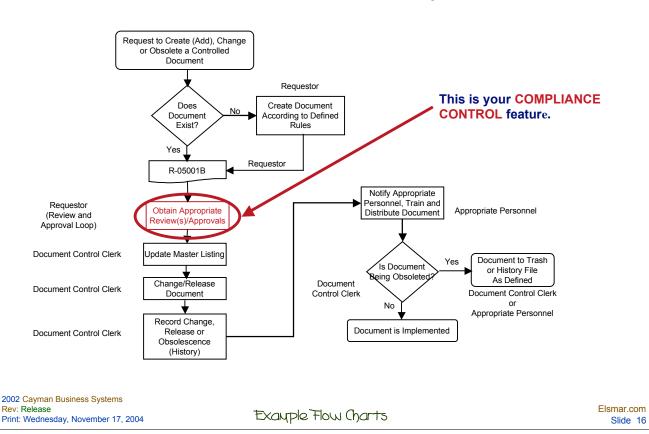
Approval

Review - during initial construction, when changed and "...on a regular basis..." (which may be yearly).

Change control

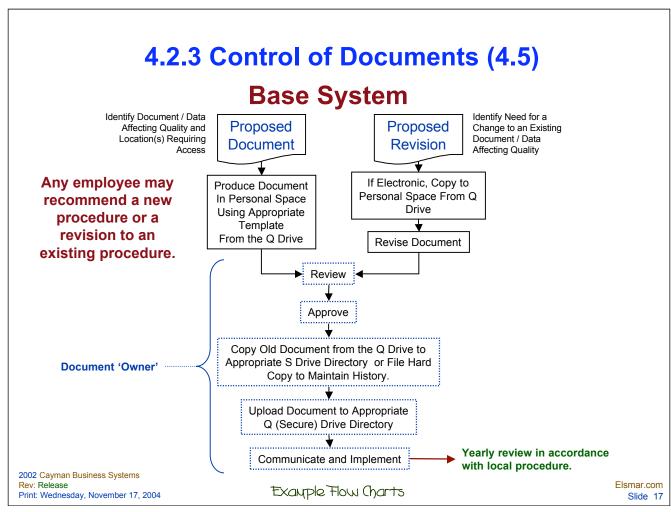
Availability

### A Document Control System



# Notes & Commentary

This is an example of a more complex document control system.



The above is an example of where a company had a simple control system. Masters are kept on a protected drive. Each person responsible for a document 'owns' a directory which only s/he can write to. Control is, obviously, very decentralized.

Companies control documents in many was. Some use canned software. Some smaller companies have everything on paper. The position of the computer today makes paper systems very rare, but there are some that still exist. This is only to say that your system has to meet some basics but the variability makes it impossible to predict.

Important elements of your system should include:

Approval

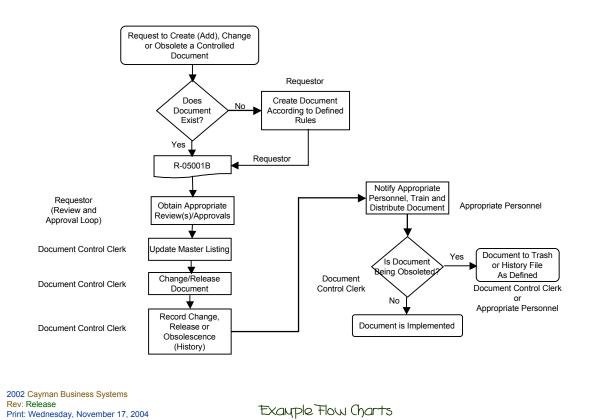
Review - during initial construction, when changed and "...on a regular basis..." (which may be yearly).

Change control

Availability

See Clause Interp and Upgrading.doc for details.

### A Document Control System

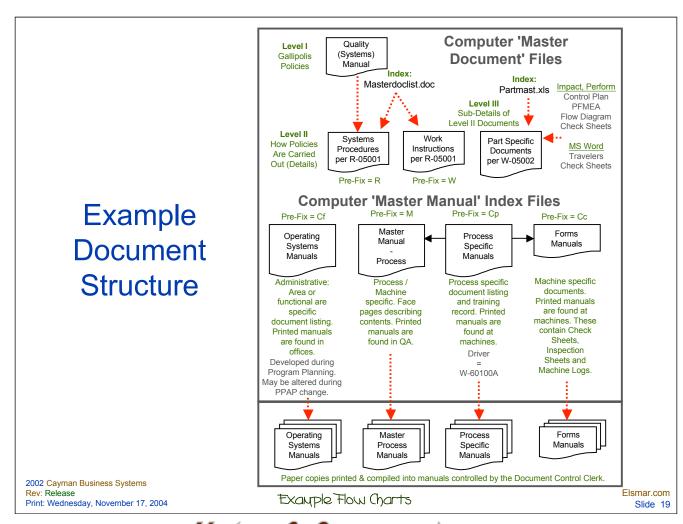




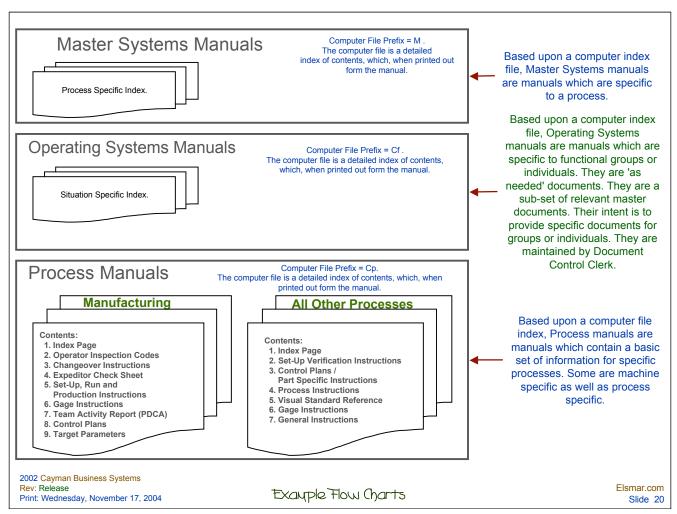
This is an example of a more complex document control system.

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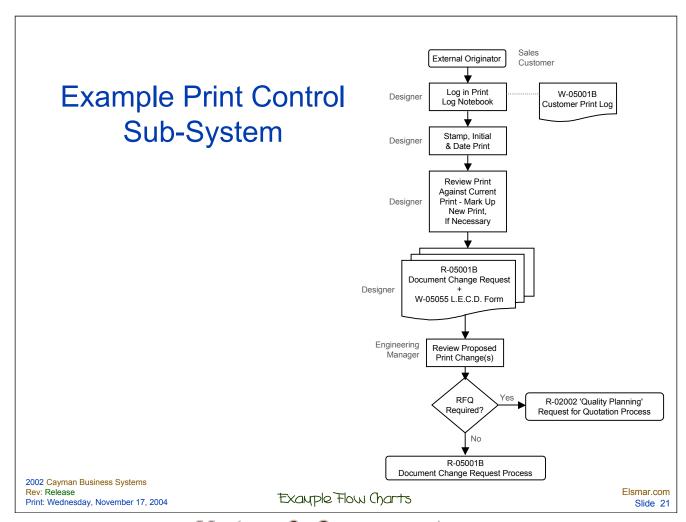








Example of a manufacturing document structure.





### Example External Documents Control Sub-System

Forward to Document

Control Clerk

Does

Document

Exist?

Update Document

Cross Listing

Identify

Is Document

Being Obsoleted

Document is

Available In Book Shelf

No

Departmental

. Manager

Document Control

Clerk

**Document Control** 

Clerk

Document Control

Clerk

Document Control

Document to Trash

or History File

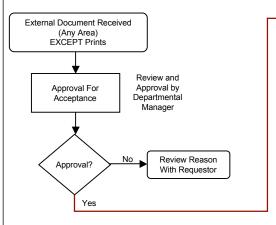
As Defined

Document Control Clerk

Create Document

ID in Cross Listing

In PartMast.xls file



#### Rules:

Controlled Documents of External Origin are maintained by the Document Control Clerk.

Controlled Documents of External Origin are identified by a "Controlled Document" stamp inside the front cover and an ID Number hand written beside it. The ID number is derived from the listing in the PartMast.xls file. ID numbers are not reused once a document is removed from control.

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No Action

Document Control Clerk

Check for Latest Revision

Documen

Revised?

Order/Receive

Document

Update Document Cross Listing

**Document Control Clerk** 

Yes

Document

Control

# Notes & Commentary

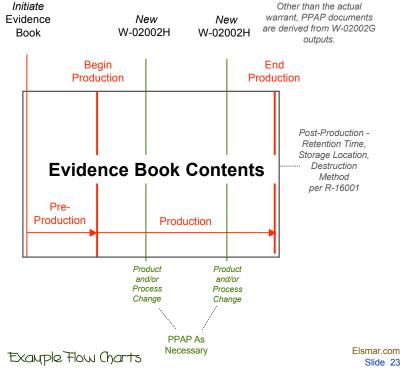
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# Example Design Process Records System (Configuration Management)

#### Base Rules:

- 1. Evidence Book Base Contents Defined By W-02002H 'Evidence Book Contents Page'.
- 2. New Evidence Book Initiated Only For New Part Number.
- Changes to Process and/or Product Initiates New W-02002H 'Evidence Book Contents Page'. Actual additional contents determined by change details and Customer Requirement(s).
- 4. Removal of any document from the evidence book requires an 'Inquiry Sign Out Sheet' R-02002C.

NOTE:

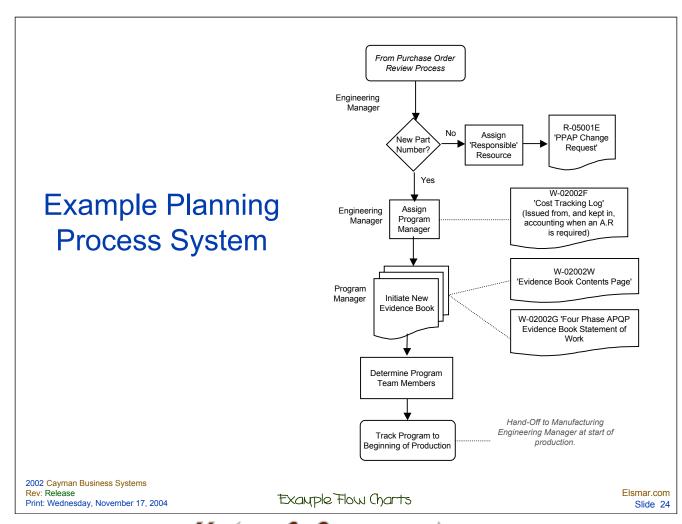


Notes & Commer

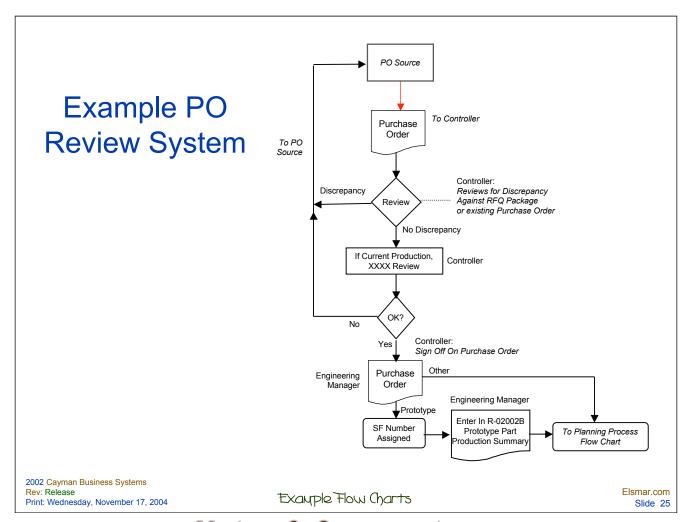
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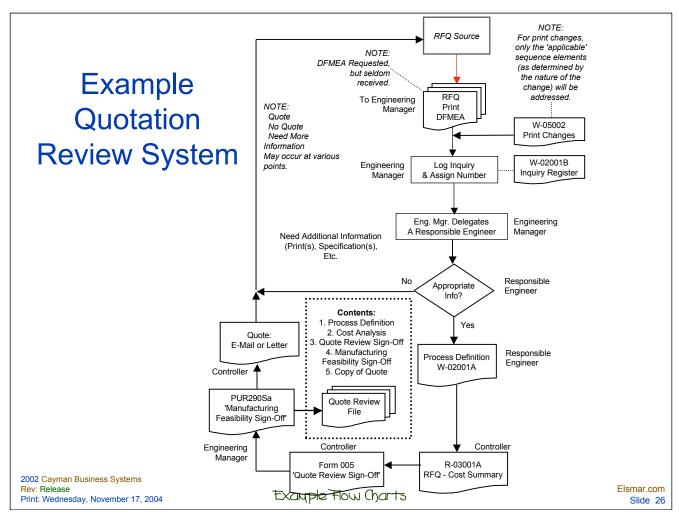
Rev: Release

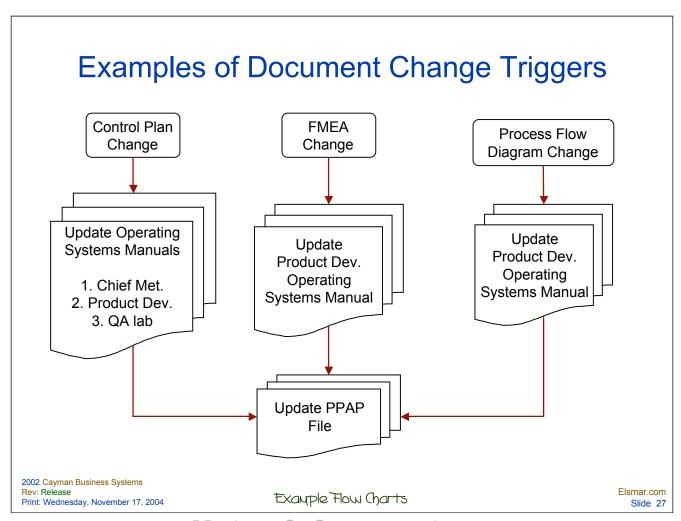






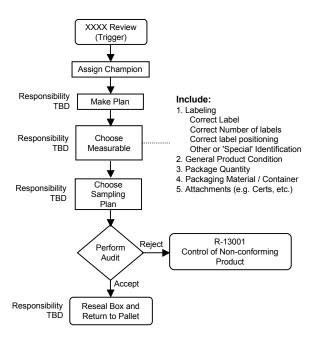








### **Example Dock Audit System**



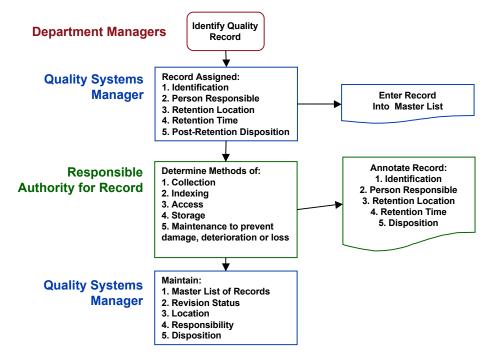
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#### 4.2.4 Control of (Quality) Records (4.16)



Quality Records are defined in: XXXXXX.xls

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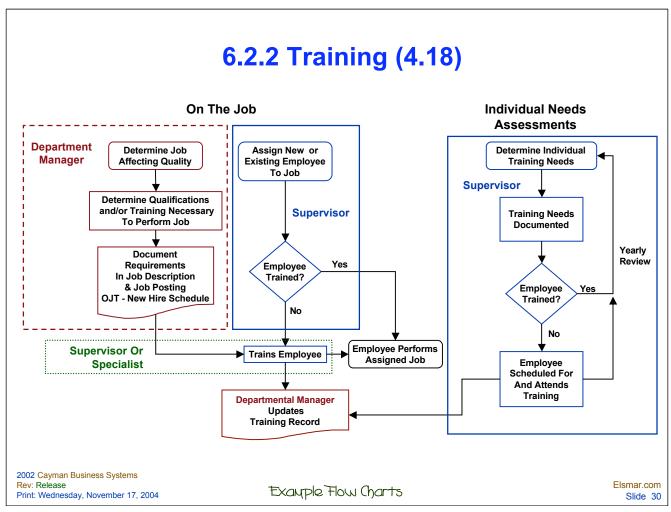
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# Notes & Commentary

It is important that you can show that you determine what is and is not during planning stages. If you are going through implementation, you probably already have quality records defined - you don't go back. The point is planning now is very important. Any planning you do - product, process or other system - should include an evaluation for quality records requirements. These may be (only a few examples) taking of data, traceability or status related. In addition, feedback from a process or system may drive the need for 'new' quality records.

Remember that records typically start out as forms. Those forms must be controlled just as procedures / flow charts are.

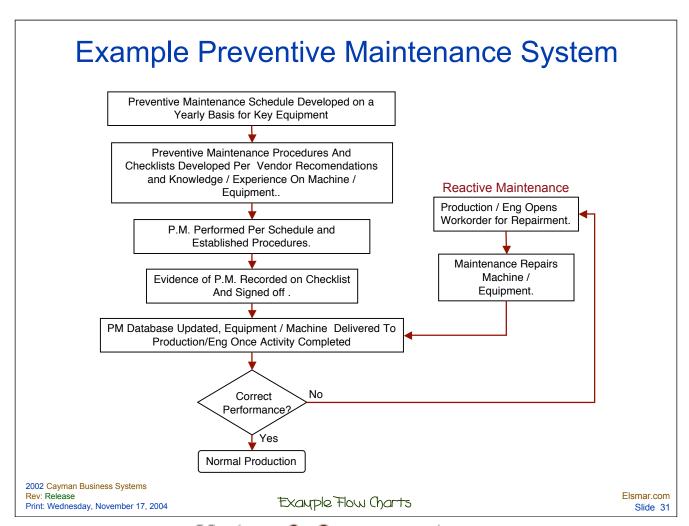
White-out on a quality record is a very questionable practice. I advise you to establish a company policy, and implement / communicate it, which states where and when white-out may be used (if anywhere).



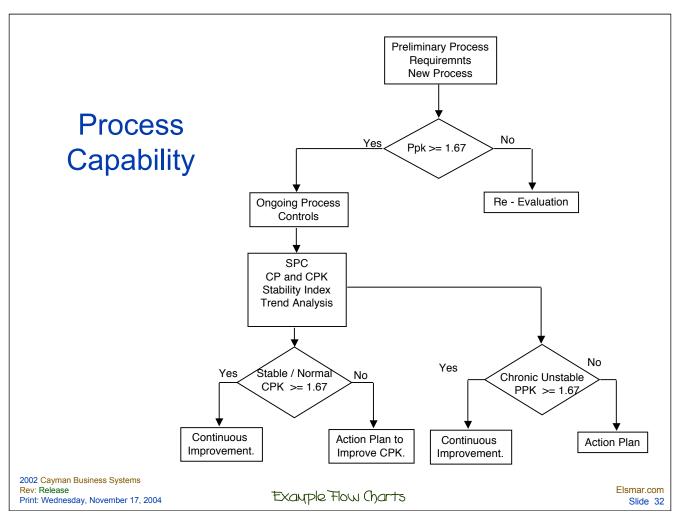
Note that there are different types of training. You must address all types. The 'typical' **Big Five** are:

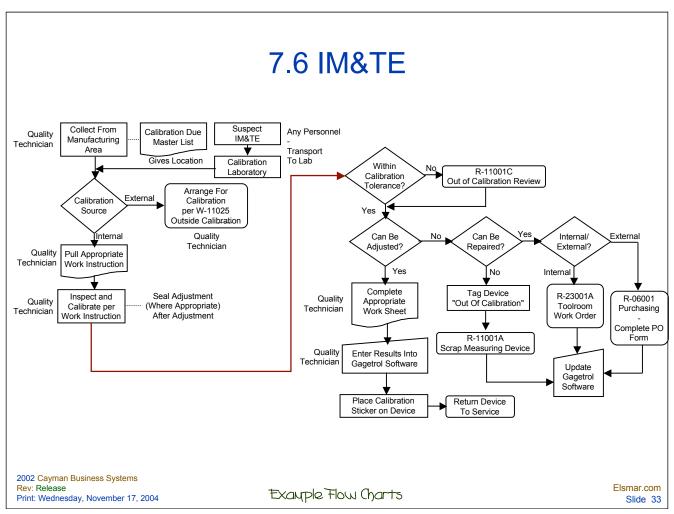
- Orientation Basics given when someone starts their employment.
- On-The-Job An example would be training on how to run a machine.
- Systems / Procedure Changes Whenever a procedure or system is trained, this
  has to be 'communicated'.
- Individual Needs Generally training which will help in the future. An example would be managers training for someone
- Elective

Records: No records, it never happened. Training records and their control is absolutely a top priority and will, not maybe, WIL be assessed during the registration and subsequent audits.



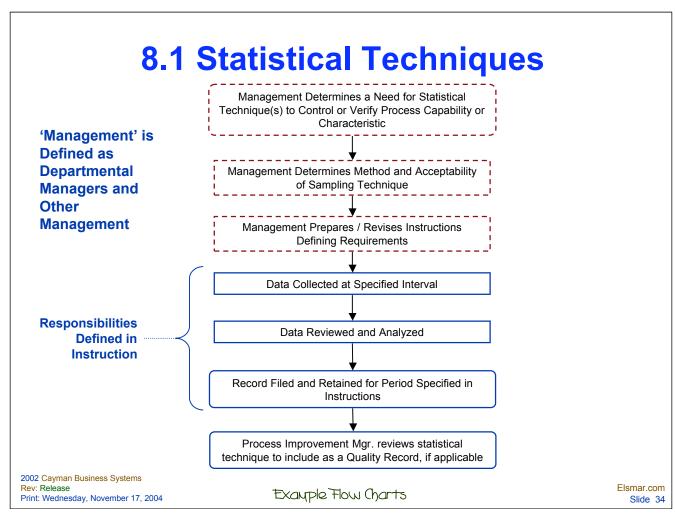








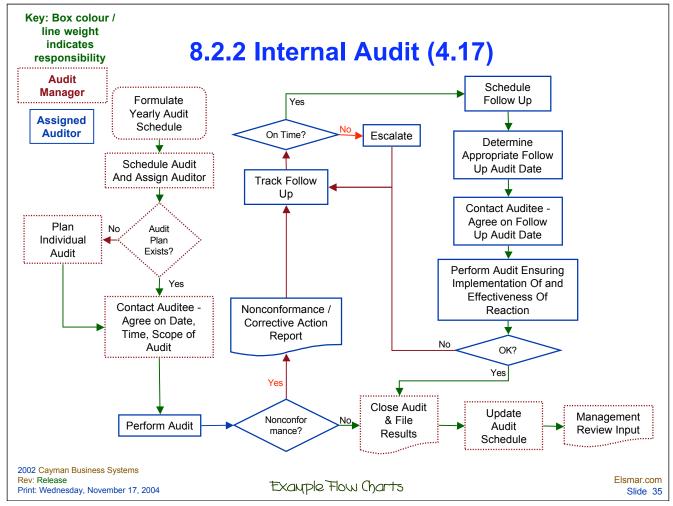
An example Inspection, Measurement and Test Equipment calibration control system.



The standard assumes a high reliance upon management by data analysis (acting on data). This was a problematic area for some companies - especially small companies. The key to their compliance was ISO 9001:1994 specifically required a company to "... identify the need for..." statistical techniques. As long as you could show you evaluated the need for statistical techniques and found none (typically during a management review meeting) you didn't have to do any. This has not really changed. But - try to convince some auditors.

The point of 8.1 is to make sure you evaluate where data analysis would benefit your company. An example might be an analysis of nonconformances over time. I have to agree that every company does have such a need, even small companies.

Most companies are already doing some type of data analysis. Remember, this reads statistical techniques, not statistical process control (for some reason this used to be misunderstood regularly by auditors but isn't much of a problem these days). One client was a small trucking company. They insisted they had no need. I pointed out that they tracked delivery time. And they reacted to 'bad' trends. Statistical techniques can be simple stuff. A bar graph. A trend line. Don't over complicate the issue.



Your internal audit system should include:

- Schedule at least 1 year, preferably 2 years.
- · Trained auditors
- Much of the response to a nonconformance should go through a system like your
  corrective action system. Many companies use one database to track nonconformances
  from all areas. That is nonconformances found in audits (internal and external),
  production, customer complaints, etc. all are tracked in 1 database. The key to this
  methodology is well thought out 'defect' categories. I recommend using Access or other
  database software and that you make your own database. Canned software seldom has
  the flexibility which you will find you need.
- A method of escalation when findings are not acted on. This is really part of your corrective action response system.

Take a read through http://Elsmar.com/Audit/ for more details on Internal Audits.

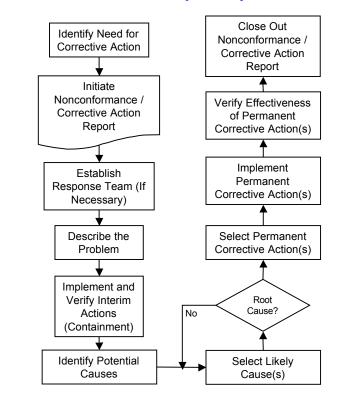
#### 8.5.2 Corrective Action (4.14)

This flow diagram illustrates the core elements of the corrective action investigative process from the point where the need for a corrective action is identified.

Responsibility will depend upon the specifics of the identified need, but the Process Improvement Manager is the responsible authority for overseeing and administrating the Corrective Action system.

See section 8.5.2 in the Company Systems Manual for overall system specifics.

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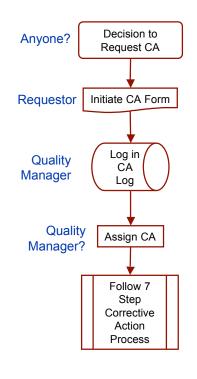
# Notes & Commentary

Important parts of a corrective action system include:

- You MUST have 'triggers' and 'escalation' paths.
- That you understand that you have multiple sources for nonconformances. Not just product, but also audits (internal and external), customer complaints, etc.
- That you have a method of ensuring evaluation of nonconformances for a determination
  of whether a partial or complete corrective action should / must be started. If you don't
  you will find you are requiring corrective actions for every nonconformance which will
  quickly overload your system and have everyone up in arms.
- You MUST ensure every corrective action is evaluated for effectiveness.
- You should follow the 8-D system. One reason is it touches on every requirement and fulfills it.

Take a read through http://Elsmar.com/8D/ for more details on corrective actions.

### 8.5.2 Corrective Action (4.14)



#### **System Requirements**

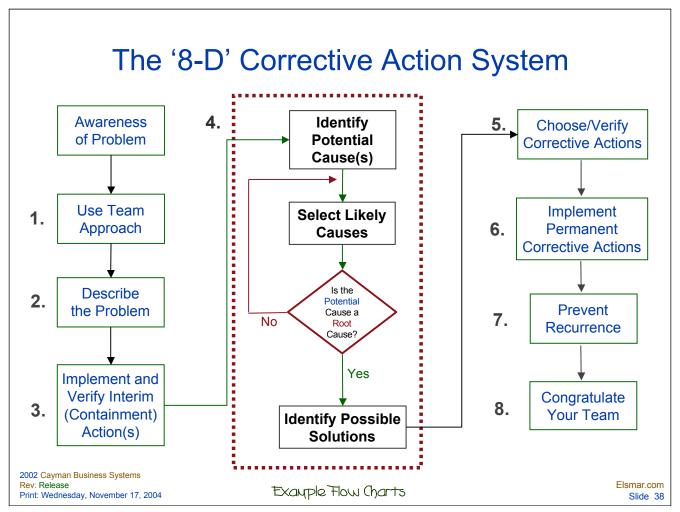
Quality Manager is responsible for tracking corrective actions. The person assigned the CA has 7 days to give an initial response to the CA. If (1) a response is not obtained, or if (2) the CA becomes 'bogged down' or (3) is insufficient in the opinion of the QM, the CA will be escalated to the responsible person's immediate superior.

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Example Flow Charts

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# Notes & Commentary



#### The 'D' in 8-D stands for Disciplines

Teams are important. Why do you think this is so?

Normally people in a company have skills, experience and abilities which complement each other. A company as a whole is complex - a set of systems with different functional experts in different areas. The areas complement each other and many have interactions. Quality affects manufacturing. Design affects quality. Quality affects design.

The 8-Disciplines methodology requires a team effort to ensure that there is communication between 'interested parties' and that interactions are identified and effects assessed.

You might want to take a read through http://Elsmar.com/8D/ for details on the 8-D Corrective Action / Prevent Recurrence process.

Thoughts About

# **Databases**

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#### **Items To Track**

NOTE: Parts of some of these may be included in the current MRP software system.

- Receiving Inspection
- Suppliers including Supplier Rating and Approved Supplier List (Excel Spreadsheet)
- Customer Concerns/Complaints (Excel Spreadsheet)
- Nonconformances (Database)

Internal

External

- Corrective / Preventive Action (Database)
- Internal Audits

Tracking (Calendar) (Excel Spreadsheet)

Audit Forms (Excel Spreadsheet)

Management Reviews

Tracking (Calendar) (Excel Spreadsheet)

Meeting Form (Excel Spreadsheet)

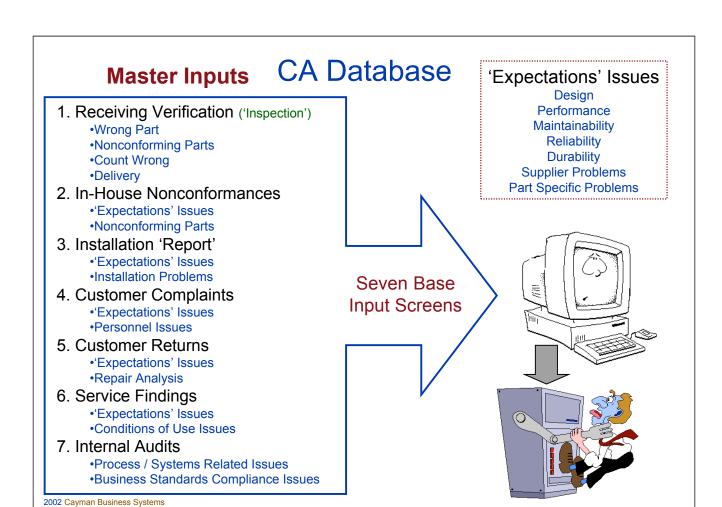
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#### **CA Database**

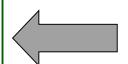
#### **Outputs** (General)

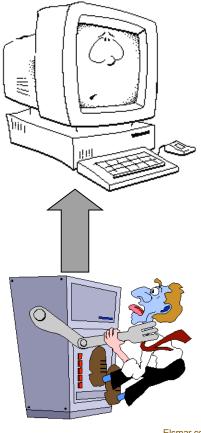
• 'Standard' Reports (Scheduled)

Must Define Measurables, then
Weekly Reports

Monthly Reports

•Ad Hoc Reports





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# Notes & Commentary

#### **CA Database Files**

#### **Considerations**

How you handle your corrective action system will, obviously, be dependent upon your current systems. You may or may not have a MRP or other 'control' software. If you do it may or may not be accessible by outside programs.

Supplier Data Nonconformance Action Data Internal Audit Data

#### Flat-file vs. Relational

There are canned stand-alone databases you can purchase. If you have someone who is OK programming Access, I recommend that over canned software. However, again, I want to say that your solution will be specific to your company. Some companies do not want to be beholden to canned software vendors. Some companies have no one proficient in Access (or other database software). In addition, there are hardware issues.

This said, if you would like to discuss your situation I'd be happy to talk with you. But the solution will not come from a phone call alone.

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### **Common Database Fields**

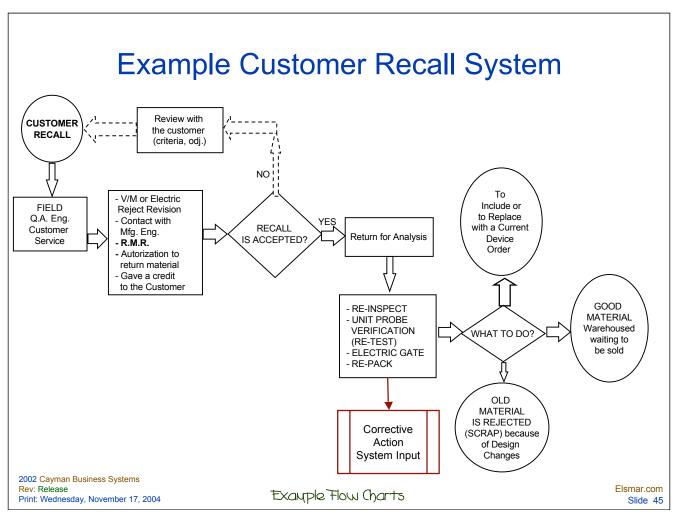
- Customer Name / Number
- Product ID
- · Serial Number

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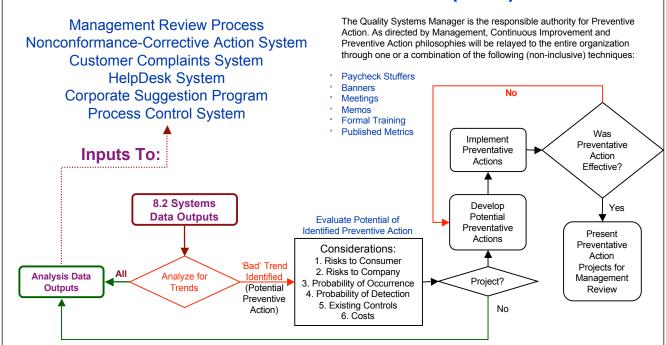
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#### 8.5.3 Preventive Action (4.14)



The person responsible for the project is assigned by the Quality Systems Manager and is responsible for the initiation of preventive action and application of controls to ensure it is effective. The Quality Systems Manager feeds back project outputs to Management Review.

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Example Flow Charts

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# Notes & Commentary

This is an example of a way to address the Preventive Action documentation (system) requirement. As with the other maps, this map shows the 'main' points of the system. Who does what in your company (responsibilities) is company dependant.

If you do FMEAs, these are Preventive Actions and should be identified as such.

I have addressed Preventive Action within Clause\_Interp\_and\_Upgrading.doc which is a part of this package. I suggest you take a read through it as you consider your system design.