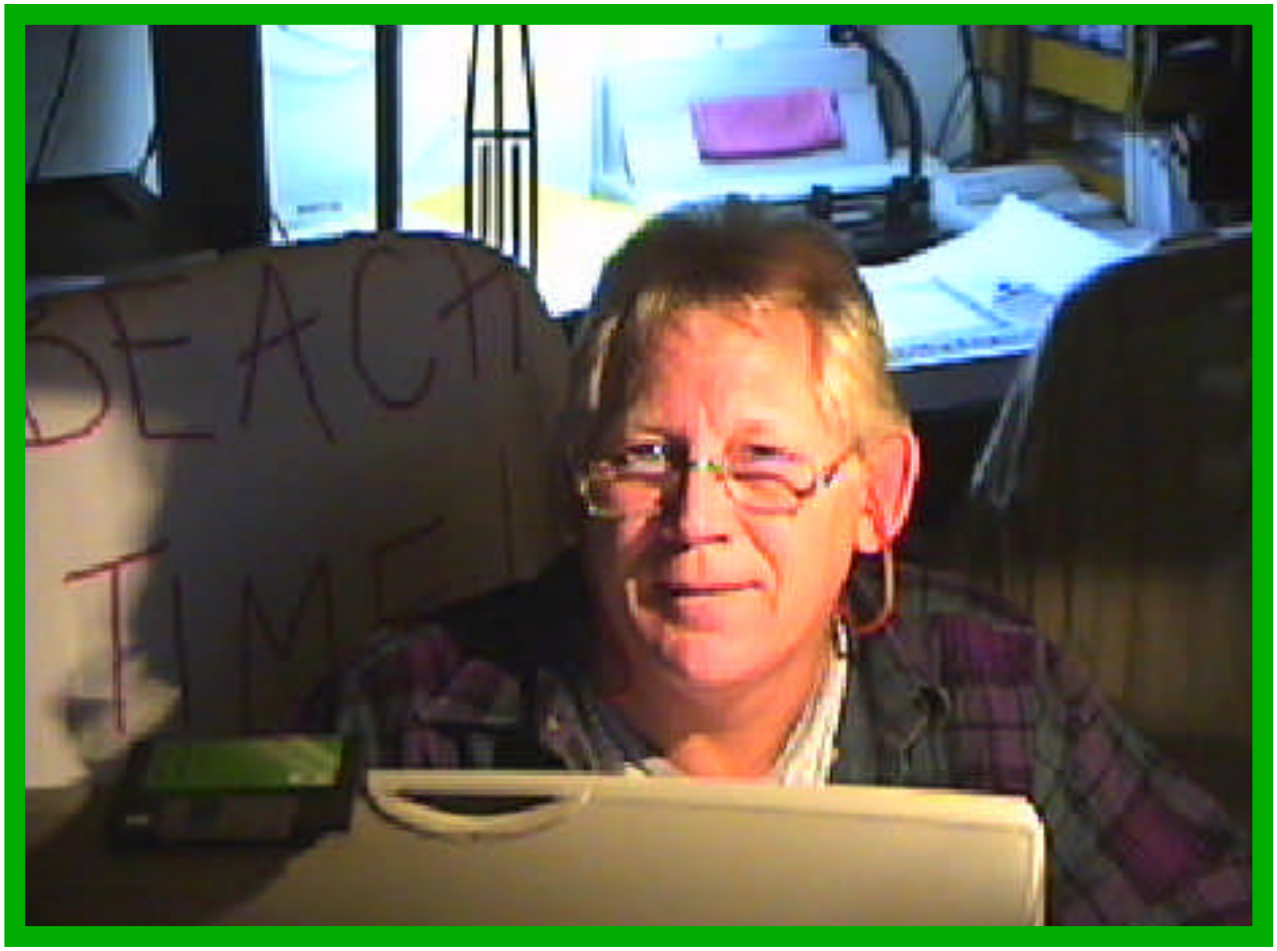
QS 9000

What It Is?
What It Means To You!



Hello! I’m Marc!
Thanks for inviting me!

Topics

- Relationship to ISO 9000
- QS 9000 Generalities
- Who's doing QS and Why
- About Auditors
- A brief 'How to get started' guide
- QS 9000 - Some Specifics
- QS 9000 - Element by Element
- Cautions and Wrap-Up

Where Did It Come From?

Liability

By defining practices, Liability is addressed. In fact, the whole ISO 900X series is the reaction to a need to assign

Responsibility

For international trade issues involved in bringing the continent together into the ‘European Union’. The foundation drifted to be a ‘quality standard’.

The Basics

QS Boiled Down To Its Base

Say What You Do

This means document your systems so you will consistently do the job the same way every time. We must make sure we have appropriate documentation.

Do What You Say

This is what the auditors want to see. Objective evidence that what you say you are doing in your documentation is what you are doing in practice.

ISO 900x Series
The QS 9000 Base

- QS 9000 is based upon ISO 9001. To understand QS 9000, you should consider the ISO 900x documents, including ISO 9004.

Global Competition Causes Surging ISO 9001 and 9002 Registrations

- Approximately 50% of all US firms will be registered by the end of 1998 (WSJ)
- Europe wide - EU (EEC)
- Pacific Rim embracing

ISO 8402

Management and Quality Assurance - Vocabulary

This document is an attempt to provide consistent definitions for major terms.

This document is important to the interpretation of the ISO 9000 Series of documents.

ISO 9001

Quality Systems - Model for Quality Assurance in Design, Development Production, Installation and Servicing

This is the main ISO 9000 Series document. It's contents guide the entire series. It is typically the document businesses register to. It contains provision for design development and control.

ISO 9002

Quality Systems - Model for Quality Assurance in Production, Installation and Servicing

ISO 9002 is the exact same document as ISO 9001 EXCEPT that design is not included. This is the model transportation companies register to.

ISO 9003

Quality Systems - Model for Quality Assurance in Final Inspection and Test

ISO 9003 is essentially a dead document. It's intended sector focus has embraced ISO 9002 or ISO 9001.

ISO 9004

Quality Management and Quality System Elements - Guidelines

ISO 9004 is essentially a series of ‘suggestions’. VDA-6 is based upon ISO 9004 and QS (as well as the next ISO 9001 revision) are expected to incorporate some ISO 9004 elements.

Foundation of ISO 9000 Series

- The linking thread through out the ISO 9000 standards is the emphasis on recording information that pertains to all aspects of quality and management.
- While there are several explanations of the reason for the origin of the series, the most basic reason for their coming into existence relate to ensuring responsibilities are defined for **Liability Issues**.

ISO In Detail

- **I**nternational **O**rganisation for **S**tandardization
- isos - from the Greek word meaning equal
- Founded 1946
- Based in Geneva, Switzerland
- ISO 9000 series begun about 1978
- Developed initially to support two-party contractual agreements (has expanded)
- ISO 9000 series released in 1987
- Over 80 countries have embraced as a National standard

ISO In Detail II

- International Standards on Quality Management and Quality Assurance
- Established by ISO Technical Committee 176 (TC176)
- Used by both manufacturing and service industries
- Recognised World-Wide:

  International Seal of Approval
- Defines an effective quality system

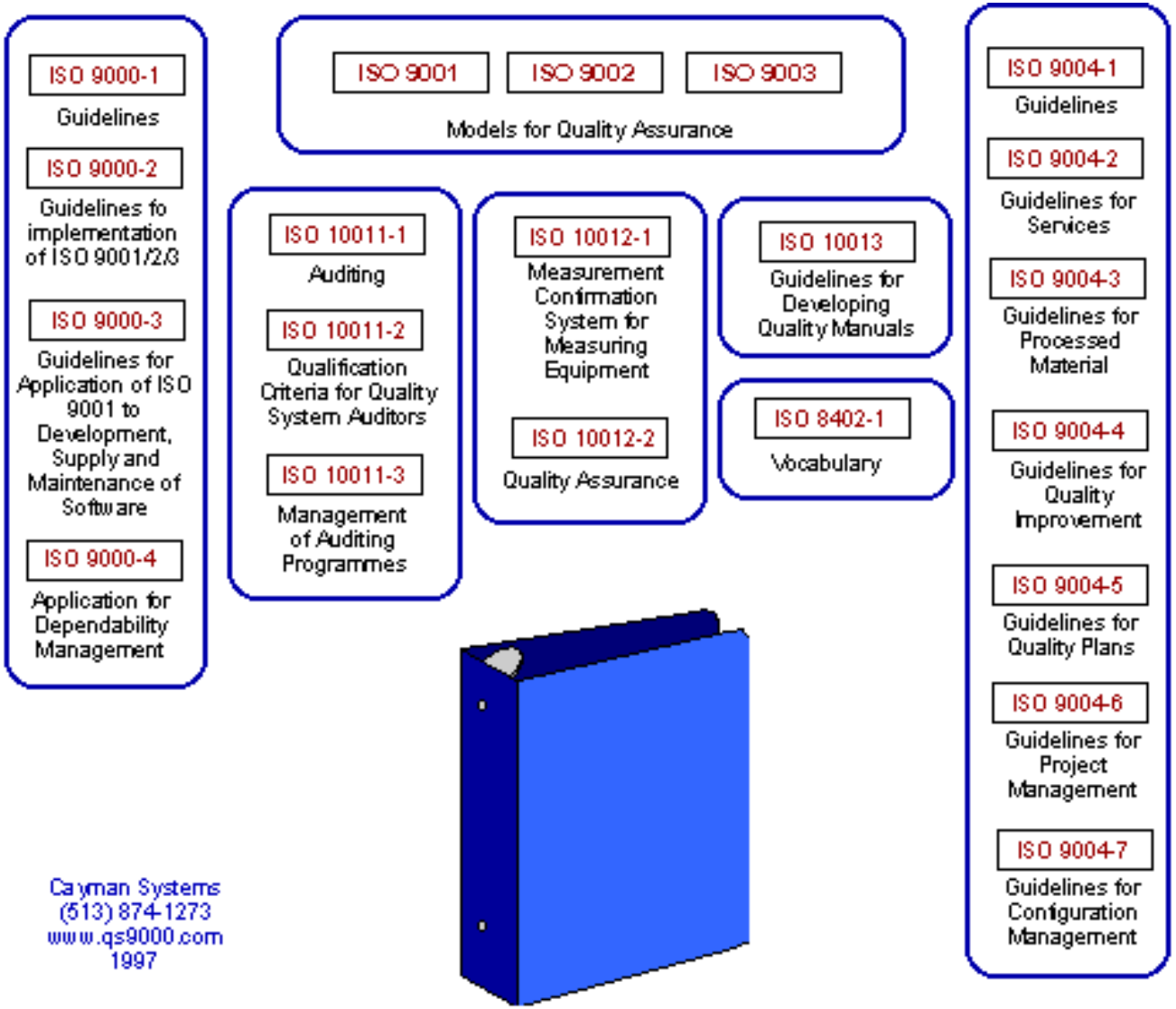
ISO In Detail III

- Requires documentation for quality system elements
- Requires 3rd party audits and registration
- Applies to all kinds of manufacturing and all kinds of service organizations
- Establishes consistent quality system practices that cross international borders
- Reduces or eliminates customer audits
- Provides a common language and set of terms

Scope of the Standards

- Clarify quality-related principles and concepts
- Provide guidelines
- Specific requirements to achieve customer satisfaction by preventing nonconformances
- Inspection and test conducted on finished products and services can be satisfactorily demonstrated

ISO 9000 Documents



Who's Doing ISO?

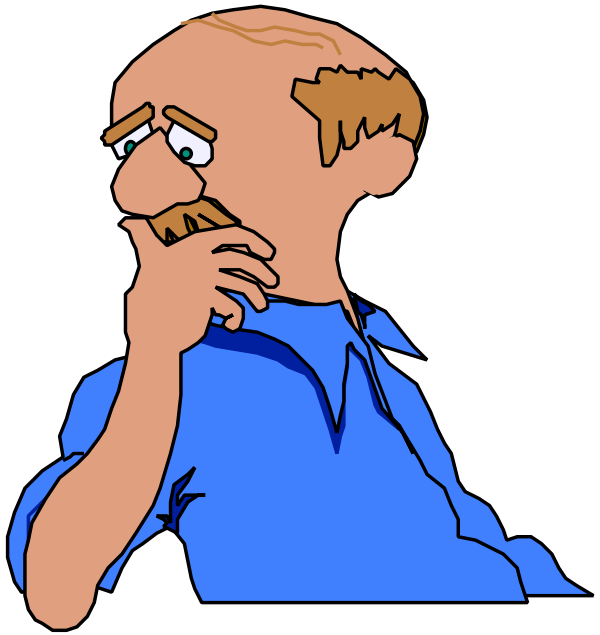
- European Economic Community
- The 'Big Three'
- DoD
- NASA
- Over 80 countries have embraced the ISO Series of standards as National Standard

Why ISO 9000 Registration?

- Improves Internal Operations
- Enhances Competitive Position
- Required for International Business
- Customer Satisfaction
- Foundation for a Quality Program
- Complement Existing Programs
- Market Share
- Competitive Pressures

Why Do Companies Register?

- Customer Requirement (>80%)
- Sales and Marketing ‘Tool’
- NOT for Quality Improvement



Enter QS 9000

ISO

A tool for any type of business

Non-Specific:

Any Industry

Any Product

Specific to:

3 Companies

Automotive Focus

QS

A tool for doing business with:

Ford

GM

Chrysler

Why QS 9000

QS 9000 came about from Cost Issues:

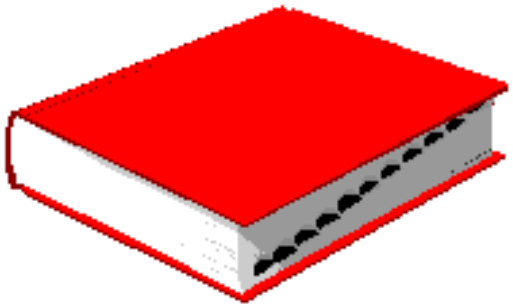
- A way for automotive makers to address suppliers with less input.
- Reduces ‘cronyism’.
- Reduction in liability issues.
- Increase synchronization.
- Increase consistency.
- Increase dependability.

QS 9000 Documentation Origins

ISO 9000

Ford Q1
GM Targerts for Excellence
Chrysler Pentastar

Ford, GM
& Chrysler
Mutual 'Needs'

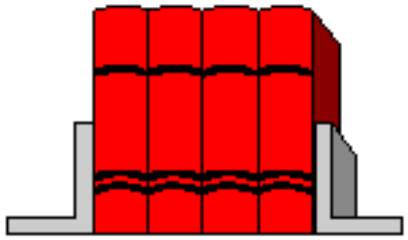


FAX In Questions to the 'Interpretations Committee

QS 9000
+
Current
Interpretations

Calls Out

AIAG
FMEA, APQP,
PPAP, MSA, SPC



Technically, What Is QS 9000 About?

- Quality Management
- Quality Assurance
- Quality System Deployment and Documentation
- Records and Information Management Play an Integral Role
- Has Little to do with Quality
- Does NOT Demonstrate Quality of Product
- Should Result in a Better Product and/or Service

More About QS 9000

- QS 9000 is a requirement of Ford, GM and Chrysler.
- The 'Big Three' are requiring all suppliers to obtain QS 9000 registration.
- Each has it's own specific supplier requirements.
- Even 'non-product' companies affected in some way.

Internal Effects

Effective, comprehensive quality management system

Blueprint for building quality into products and services

Increase potential growth, competitiveness and profit

Consistency of product and services leads to happier, more effective employees and pleased customers

Registration

- Your company will choose a registrar.
- Registration lasts for 3 years.
- Registration is NOT a ‘one-shot’ deal.
- Your company will be re-audited at least once a year.

Forever.

And ever.

And ever..... (Not a fairy tale!)

Registration Audit

Registration requires regular audits by your Registrar. These are called Third Party audits. Just as has been done in banks for years, auditing has reached every industry. Whether twice a year or once a year, your company quality system has to audited by the company which registers your company. That company is your Registrar.

Audits!

What & Why

Types of Audits

- Internal Audit
  - An audit of internal systems and/or procedures. An internal audit is most often performed by people how directly work for the company. Many companies hire outside firms (see third party below) to perform the audits.
- External Audit
  - Customer Audits
    - Customer audits are those where a customer (or a customer representative) performs the audit. A customer audit is not ‘objective’ because the customer is intimately involved with your company (the supplier to the customer). This involvement can BIAS the audit.
  - ‘Third Party’ Audits
    - Third party audits are like those you think of when you think of bank audits. Banks (and other financial institutions) must hire a company or person to audit their books and procedures. The company or person hired to do the audit cannot have an ‘interest’ in the business it is auditing. This is known as an ‘Independent Audit’.

Registrar Audits

- Document Review

  Adequacy of Documentation

- Pre-Assessment

  By Document Interview

  - Adequacy of Documentation, and
  - Understanding of Documentation

  By Objective Evidence

  - Performance to Documentation

- Assessment

  Performance to Documentation

Reasons For Audits

- QS 9000 Requires Them (4.17)
- A Control Mechanism Used By Management
- Tool For Continuous Improvement
- Correct Nonconformities In Systems
- Helps Ensure Ongoing Systems Operate As Intended And As Required

More Reasons For Audits

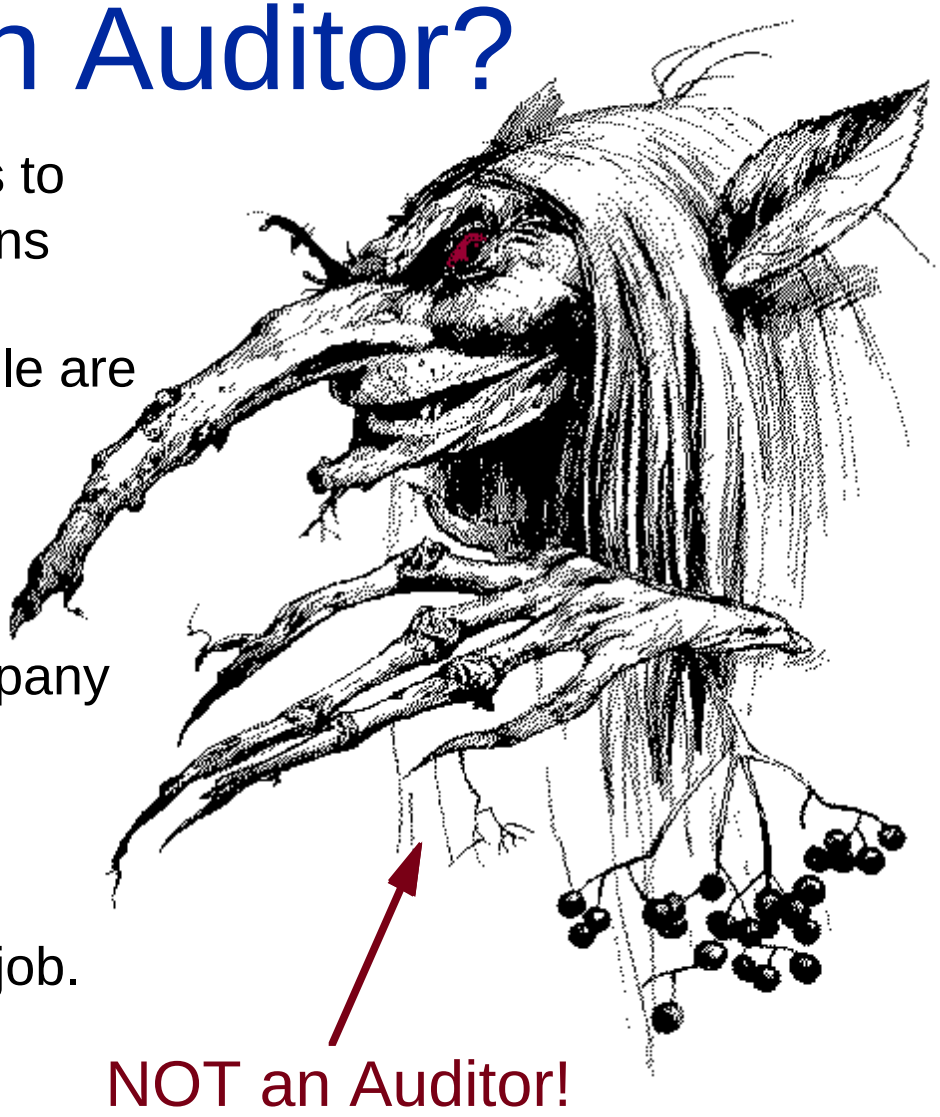
- Everyone is familiar with the idea of audits. One place we are all aware of audits is in the banking industry. For years, the government has required banks to submit to periodic audits by government agencies and/or external companies who specialise in auditing. Few people want to put their money in a bank where there are no controls such as periodic audits. If there are no audits, you have no way of knowing if your bank is using your money well. If the bank is not 'using your money well' the bank could easily fail - then you could lose all of your money.
- Audits in manufacturing industries are not new. Customer audits have been going on for years. But only recently has the idea of third party audits become reality. This is in large part due to the adoption in Europe of ISO 9000 and other international standards.
- The intent of third party audits is to provide assurance that a company complies with a standard or specification.
- Many people say that third party audits will eliminate customer audits. This has not been the case up to now in part because customers still see the need to ensure compliance to their specific requirements. Even QS 9000, specific to Ford, GM and Chrysler suppliers, does not eliminate customer audits.

What is an Auditor?

- An auditor is a person. Their job is to validate documentation. This means they look at documentation (instructions) and make sure people are following the documentation.

- Auditors go from company to company validating documentation.

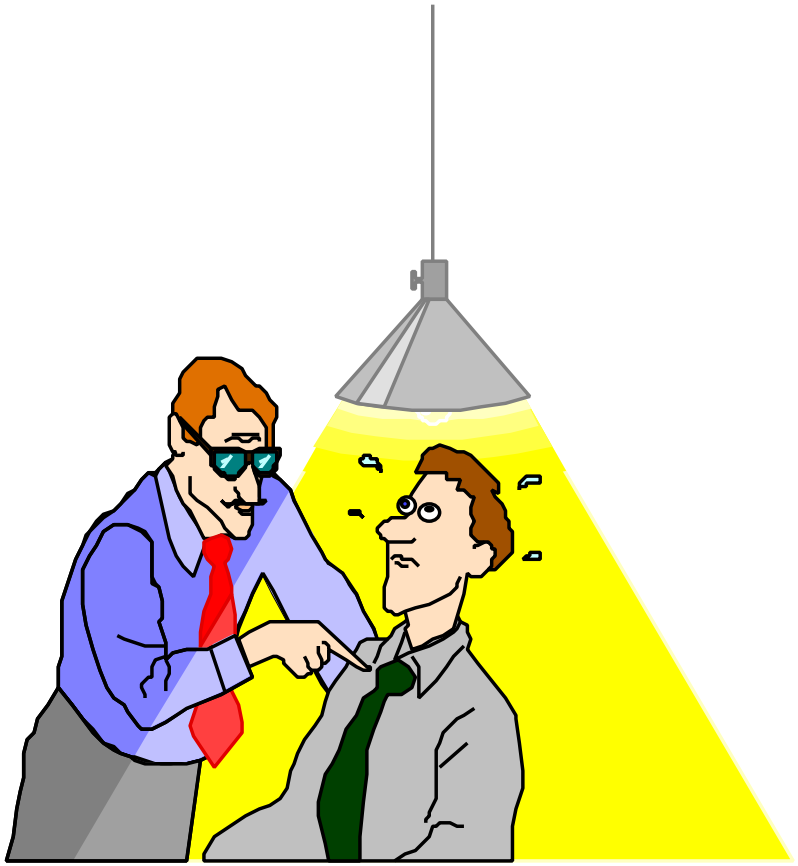
- Auditors are just people who ask questions about how you do your job.



NOT an Auditor!

Auditors Are Not!!!

- Inquisitors
- Fault Finders
- Rock Throwers
- Avenging Angels (Biased For or Against)
- Dishonest
- Overactive



What Will The Auditors Do?

- The auditors will look at written procedures and policies (verification).
- The auditors will then look at how people in the company do things. They will look to make sure each person is following written procedures and policies (validation).
- They will look at records to ensure everyone is properly completing paperwork (an example would be SPC charts).
- They will look to make sure everyone is properly trained to do their job.

Who Will Be Audited?

- Absolutely **Everyone** whose job affects quality is subject to the audit.
- And the farther up the corporate tree you go, the more difficult the audit is. This is because as you go up the tree (eventually to the CEO), job duties and responsibilities increase.
  - Corporate Personnel
  - Plant Manager
  - Departmental managers
  - Supervisors
  - Engineers
  - Technical personnel
  - Hourly employees

The Audit Team

- When you are visited by an auditor, he/she will NOT be alone. At the very minimum, there will be:
  - The Auditor
  - A Company Escort - This will be someone from within your company who knows the area and the specification well. The escort will try to provide structure to the audit and will try to help out when he/she can.
  - The Area Supervisor - The area supervisor or other person directly responsible for the area will be present.
- Remember - YOU ARE NOT ALONE!

QS 9000

General Awareness

What Will Happen If...

- If an auditor finds a problem, s/he will let the person being audited know immediately that a possible problem may exist. In NO case will the auditor 'find a problem' and not discuss it with the auditee 'on the spot'. They always tell the auditee the suspected problem and they will ask the auditee (or other company official present) to sign a statement of fact of what was found (statement of objective evidence). The auditee should know that signing the statement is NOT an admission of a problem. It is an agreement of facts found. Whether or not it is a problem is discussed during end-of-day and final review meetings.
- If an auditor leaves your area and says nothing about a possible problem, you can be sure no problem(s) were found. Auditors do NOT report findings to management without discussing it with the personnel involved FIRST. There are no tricks. Nothing is 'hidden' until later.

Things to Know

- Know what documentation affects YOU!
  - You must know what documentation applies to your job. This should have been told to you when you were trained to do the job. If you are not sure what documentation applies to you, ASK YOUR SUPERVISOR or TRAINER before the audit.
- You must follow all documentation that applies to you. If it says you do something a certain way, you must do it that way.
- You must complete all forms. If you are supposed to initial and date when you do something, the auditors will check to ensure you complete the form the way you are supposed to.
- Know what training you have had. If you do not know, ASK YOUR SUPERVISOR NOW! Don't wait until the audit!

Things to Do

- Listen closely before answering any question(s). If you are not sure you understand the question, ask the auditor to repeat it. If you still do not understand the question, tell the auditor you do not understand it. The auditor will try to better explain him/ herself. Never answer a question you do not understand!
- Never say "Sometimes I....". When you do something differently because of different circumstances, explain that "When ------ happens, I...., and when +++++ happens, I ....". Be specific.
- Always tell the Truth. Don't ever try to hide something. You may think you are helping someone - you are not. One lie can destroy confidence. Just like in a marriage, if one spouse lies to the other and the other finds out, the relationship may be in real danger. One lie could ruin the entire audit.
- Be patient. Wait for the audit to ask a question.

Things NOT to Do

- If you do not know the answer to a question, tell the auditor that you do not know the answer. Don't attempt to 'fake it'. If the auditor tries to explain again and you still do not understand the question, tell him/her again that you do not understand the question. The Escort will attempt to help if this happens.
- Do NOT try to hide from the auditor. All the auditor wants is to ask you about your job and how to do it. You know your job. You can tell the auditor about as easily as you can tell anyone else.
- Do NOT try to answer a question for another person. If the question is not about the job you are doing and you know who does that job, tell the auditor who they should ask if you know.
- Do NOT try to answer a question about another job. The only question an auditor is supposed to ask is about YOUR job. If the auditor asks you a question about someone else's job, you should answer "That is not my job." The GDL escort or the other GDL person with the auditor must take the lead from this point.

General Things To Know and Do

- Auditors are NOT trying to test your memory. If you have to look something up in your documentation, tell the auditor. The auditor will then tell you whether to look up the information or not.
- Only answer the auditor's question. Do NOT volunteer information. Do NOT try to 'help' the auditor with additional information.
- Answer with the shortest, simplest answer you can think of. If you can answer with a Yes or No, that's all you should do.
- Don't try to explain things. The auditor will ask questions to help him/her understand. Your job is to only answer questions asked.
- Do not tell stories or speculate what 'may' happen.
- If there is any documentation which you are using that you think or know is not correct, contact your supervisor immediately!

Questions to Expect

- What is QS 9000?
- What is the quality policy?
- What does the quality policy mean to you?
- What documentation do you follow? Where is it?
- How do you know you are using the most recent documentation?
- Who is the QS Management Representative?
- How do you know what to do? Tell me about your job and your duties.
- Do you ever have problems come up? How do you handle them?
- When you find nonconforming product, what do you do?
- What are your quality responsibilities?
- What are controlled documents?
- If your documentation says you should do something a specific way and someone else tells you to do it differently, what do you do?

If you do not know the answer to any of these questions, talk to your supervisor SOON! DO NOT WAIT!

Managers Should Think About...

- Work Instructions
  - Does Every Job Have Relevant Work Instructions?
  - Are Work Instructions Controlled?
  - Is Each Signed & Dated?
  - Who is the Keeper of a Master List & Where is it Kept?
- Hand Revisions
  - Have Any Work Instructions, Visual Aids, or Other Process Documentation Been Updated By Hand?
  - If So, Are They Signed and Dated?
- Equipment PMs
  - Are All Equipment PMs Up To Date and to a Schedule?
- Measurement & Test Equipment
  - Is All Measurement and Test Equipment Calibrated and properly Labelled?
- Defective Material
  - Is Defective Material Identified and Segregated?
  - Is A Defective Material HOLD Area Identified?
  - Is DMR Material Dispositioned in a Timely Manner?

Last Things to Think About

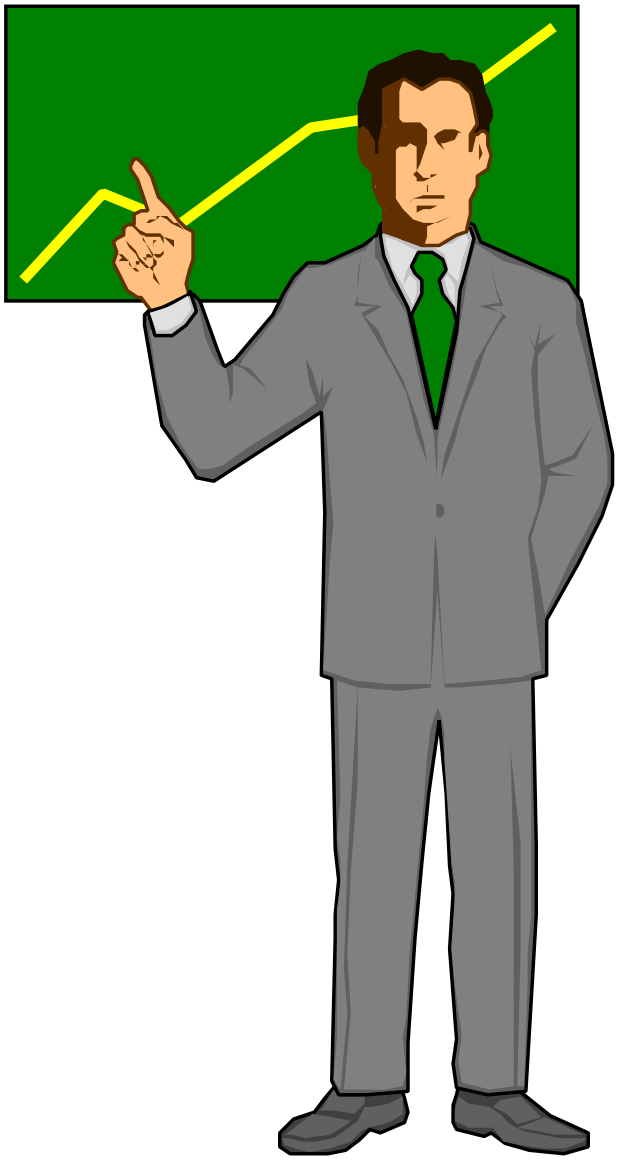
- Employee Training
  - Do You Know the Training Requirements Of Each Job Position?
  - Is Each Employee Trained?
  - Where Are Training Records Kept?
  - Are Training Records Up To Date?
- SPC
  - Are People Keeping SPC Charts Trained in SPC?
  - Are SPC Charts Current and Being Utilized?
  - Are Trends Identified and is Corrective Action Taken?
- Work Areas
  - Are Work Areas Clean and Orderly?
- Baskets, Boxes, Racks, Shelves & Other Containers
  - Is Each Properly Labelled (Identified)?
  - Are They Where They Are Supposed To Be?

Do **You** Have Questions?

- If any of this presentation confuses you, talk to your supervisor and ask him/her your question(s).
- The QS 9000 Team is another resource for you to ask if you have any questions.
- Don't hesitate to ask if you have a question. Better ask it now than to forget it only to remember it when the auditors come!

Payback

- Companies minimize deficiencies in supply and support of products and services.
- Companies identify problem areas and address them quicker.
- Companies identify customer needs more accurately.
- Companies become more consistent in their product and services.



We've Done This Before...

Why will this be different?

Audits Are The Key

- But what's the down side?
- Umm, well, ...

Implementation

OK, Already. Which Way Do We Go From Here?

Also - What do we mean by *Implementation*???

Implementation 101

Implementation is like going for an MBA. There is learning to be done and training to be accomplished. There are long nights and longer days. BUT - it is a learning process and it does not happen over night.

Some describe it as a cultural change and it often requires one. 'Typically' it takes from a year to 3 years for the change to occur.

The effort has to be driven DOWN from the top.

Implementation Skills

- Decision making skills
- Understanding responsibilities
- Knowledge of rules to be observed
- Understanding available options
- Must set
  - Goals
  - Ground Rules
  - Expectations
- Training related issues

Training Considerations

- Visual
  - The ‘Big’ picture
  - Notes as pictures
  - Overheads & other visual materials & presentations
- Auditory
  - Need to hear all the facts
  - Need to understand the logic
  - Details, statistics
- Kinesthetic
  - Learn by doing
  - Hands on practice
  - Small group discussions
  - Answering questions

First, Some Considerations....

- Your Product is ???
- Your Product is (technically) a ???
- Scope of intended registration???
- Your **SIC Code** is ???
- Length of program (timeframe)???

A ‘Typical’ Progression

Executive Management Education

- QS 9000 = New Business Process
- Things they must KNOW
- Things they must DO
- Resource Allocation Issues
- Impact on day to day operations
- Statement of Organizational Commitment
- Quality Policy and Related Basics

'Knowledge Bases' and 'Champions'

- Defining Responsibilities
- Steering Committee
  - Establishment
  - Defining Goals
  - Defining Authority and Responsibility
  - "Who's Steering the Ship?"
- Ensuring Cross-Functional Team Environment
- Learning QS 9000
- Determining a 'Preferred' Target Registration Date

Self Assessment

- Internal vs External
- Existing Systems
- Existing Documentation

Establishing a Tailored Company Plan

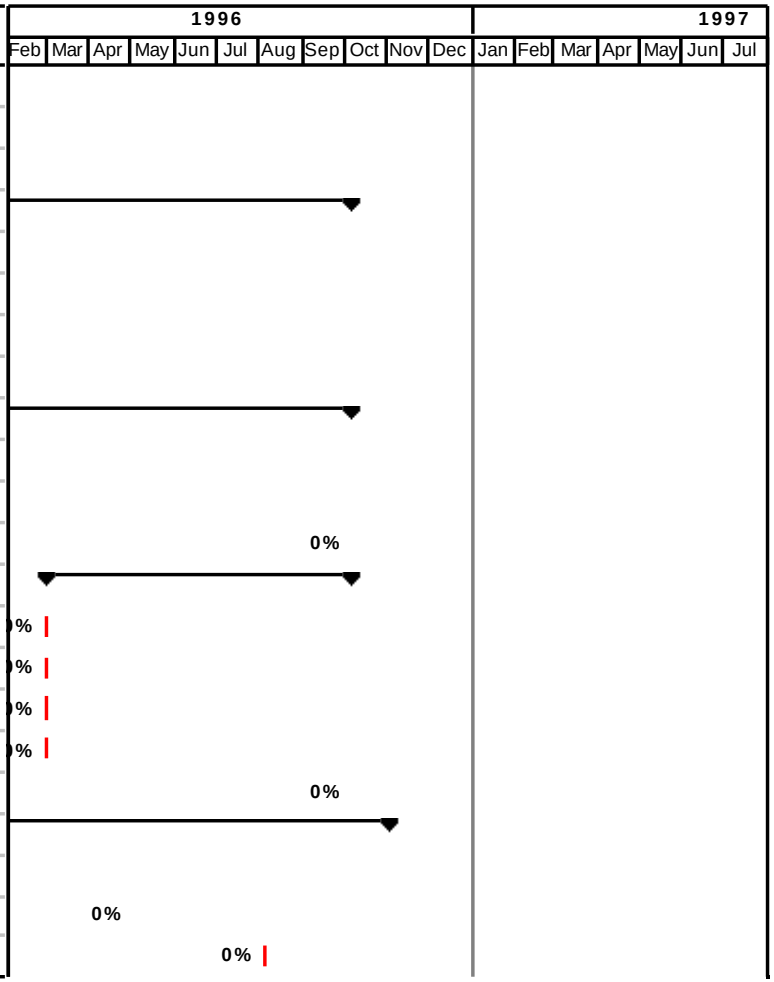
The Need for a PLAN

- Consideration of FUTURE Needs
- Technology Considerations
- Determination of Customer Requirements
- Defining the Scope of the Registration
- What are you doing RIGHT now?
- What are you doing WRONG now?
- Determination of TRAINING NEEDS
- Determination of Resource Needs
  - Personnel
  - Financial
  - Time

Establishing a TimeLine

Make a Project Plan!!!!

Task ID	Project Elements	Days	Start	Finish
1	**Determine Specific Requirement(s)**	1d	2/1/96	2/1/96
2	**Define Time to Complete Requirement**	1d	2/1/96	2/1/96
3	**Define Scope of Assessment**	1d	2/1/96	2/1/96
4	**Project Set-Ups**	**178d**	**2/1/96**	**10/7/96**
5	Write Company Quality Systems Manual	1d	2/1/96	2/1/96
6	Document Company Quality Policy	1d	2/1/96	2/1/96
7	**Define Documentation Systems**	**1d**	**2/1/96**	**2/1/96**
8	Document Master Numbering System	1d	2/1/96	2/1/96
9	**Establish Master Binders**	**178d**	**2/1/96**	**10/7/96**
10	Procedures History Binder	1d	2/1/96	2/1/96
11	Project Master Binder	1d	2/1/96	2/1/96
12		1d	10/7/96	10/7/96
13	**Contact Registrar**	**157d**	**3/1/96**	**10/7/96**
14	Agree on Scope	1d	3/1/96	3/1/96
15	Agree On Fees (Try to Bargain)	1d	3/1/96	3/1/96
16	Agree On Audit Date(s)	1d	3/1/96	3/1/96
17	Submit Required Documentation	1d	3/1/96	3/1/96
18		1d	10/7/96	10/7/96
19	**Awareness & Information Meetings - Hourly**	**198d**	**2/1/96**	**11/4/96**
20	ISO 9000 Awareness	1d	2/1/96	2/1/96
21	Work Instructions & Documentation	1d	5/3/96	5/3/96
22	Auditee Training	1d	8/5/96	8/5/96



Consultant Considerations

- Define Level of Involvement Expectations
  - Communication of Expectations
    - Expectations of the Company
    - Expectations of the Consultant
- Availability During the Implementation Process
- Costs
- Conflict of Interest
- Confidentiality

Registrar Selection

- Considerations
  - Availability During Implementation Process
  - Available Registration Dates
  - General Accessibility of Involvement
- The Contract
  - Costs
  - Re-audit Frequency
  - Dispute Resolution

Implementation I

Organizational Inertia

Denial

Annoyance

Grudging Compliance

Getting Involved

The Stark Terror of Audits

Acceptance of 'New' Systems

Implementation II

Roll Out - Communication

The General Employee Population

Managers & Supervisors

Executive Management

Implementation III

Implementing the Plan

- Internal Audits
  - Importance Of Internal Audits
  - Considering a Third Party
  - Beginning The Audits
- Registrar Communications and Involvement
- Documentation Systems and the Details
- Milestone Tracking
- Steering Committee Decisions and Involvement

Implementation IV

Nonconformance and Corrective Action Systems

System Nonconformances

Procedural Nonconformances

Escorts

Selection

Training

Recognizing Problem (Failure) Areas

The Registration Audit

What to Expect

An ATTITUDE

Escorts at Ready

Executive Management at Ready

Managers at Ready

General Employee Population at Ready

Contesting a Finding

The Registration Audit

Post-Audit

Review of Findings

Revising Plans and Lessons Learned

Focus on Predicted Problem Areas

Training Considerations

Resource Allocation

Technology Concerns and the Future

R U FIN?

Ensuring Continued Compliance

Internal Audits

Management Reviews

Registrar ‘Check-Ups’

General Registration Path

- Assess your situation (Pre-assessment)
  - May be by registrar or consultant
  - Also called Gap Analysis
- Define a plan with time line & begin
- Interview and choose registrar
- Documentation processes
- Manage transitional activities
- Registrar document review
- Registrar pre-assessment
- Corrective actions
- Registration audit
- **Implementation timeframe: 3 months to 2 years**

Failure Modes

- Can’t explain systems and/or documentation
- Lack of documentation
- No or inadequate document control
- Poor record keeping and systems
- Lack of management involvement
- Personnel not following documentation
- Poor communication and/or training

Critical Success Factors

- Dedicated ‘Company Knowledgebase’

  (Co-ordinator and/or Management Representative)
- Pre-assessment (document and interview)
- Involved, supportive top management
- Receptive culture
- Focus on business rather than functional areas
- Prioritise processes based on customer needs, anticipated benefits, and potential for success

A Word About Registrars....

- Choose several registrars and interview them each in-house
- Determine their man-day fees and hours (some cite 6 hours as a ‘man-day’)
- What is included in their ‘expenses’?
- Negotiate/bargain for your best deal
- Determine their ‘Scope of Authority’
- Are their auditors on contract or are they hired as Full-Time employees?

Now - Practically Speaking, How Do We Start?

- Appoint a Champion

  This person will be your company 'Knowledge Base'. Begin 'Document Identification and Mapping'

- Where are you at now?

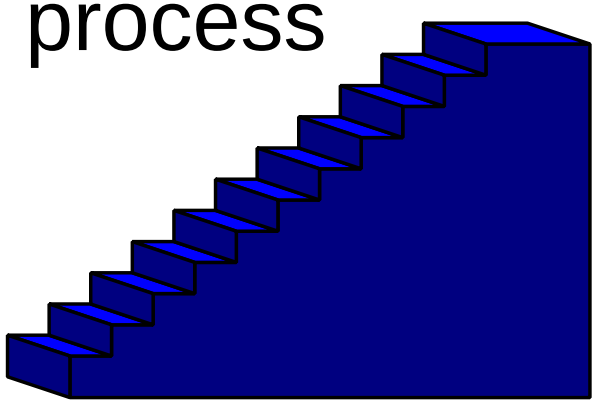
  The Champion should do a self analysis of the company, begin to develop an implementation plan and should begin to contact registrars.

- Call a Meeting!!!

  Do a roll-out! Bring everyone together and explain the basics of ISO and what it means to each person and to the business. Give 'Marching Orders'!

How to Start - Part 2

- The Champion should start flow charting and understanding the 20 master systems and a quality manual should be *started*
- Individuals should begin listing and flow charting their jobs
- Do you need a Piano Teacher?
- This is a step by step building process
- The Champion orchestrates



A Word to the Wise...

- Your quality systems manual is one of your most important documents
- 'Canned' texts will have to be tailored
- Best way is to take the QS 9000 text and tailor it as you develop your internal systems for each QS element
- DO NOT try to write your quality manual and then write procedures to support it

How to Start - Part 3

- Do another self assessment when you have everyone's input
- If you think you're ready, arrange for the registrar's document review
- Next will come pre-assessment by the registrar
- Registration audit

** It can take up to 2 to 3 months to get your certificate after your registration audit

Documentation Mapping

A Necessity

Document Mapping

- There are ‘levels’ of documentation. In general terms we have the description of documentation in levels or tiers. As we learned earlier there are typically 4 tiers of documentation in an organisation (excluding Ad Hoc documents - I call these Tier 5 documents).
- The top tiers normally guide the content and focus of the bottom tiers. In short, each successive lower tier is DEPENDENT upon the upper tier which defines it. This is said to be a ‘Flow Down’ of requirements.
- Higher level documents normally cite lower level documents. These citations are important as they form a ‘trail’ which can be followed. The top level documents tend to be general and to some extent vague while the lower level documents provide increasing detail.
- Many times the reverse also happens - lower level documents cite higher level documents internally. There is controversy as to whether this is ‘good’ practice. In any case, **requirements** do **NOT** flow up.
- Document mapping is more important now than ever as mature companies shift towards interdisciplinary (cross-functional) communication and operation. The old way was for departments to ‘pass off’ to another department. The new way causes everyone to be involved. In short, the rise of the importance of TEAMs requires documentation to be more integrated and consistent - and thus the need for control is greater. This is also the reason for the ‘review’ requirement.

Company Xyz Procedure QC-122

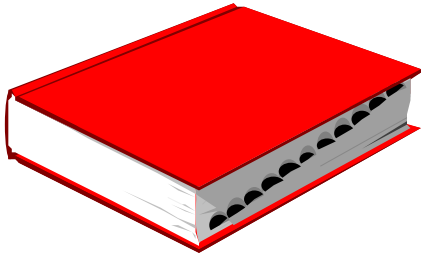
- Document mapping HAS to be done with Company Xyz's QC-122 Document Control Procedure in mind.
- This procedure will have to be rewritten to account for the document control database Mr. X spec'd out and is implementing.
- My expectations are for Ms. Y and Mr. X (and the person we are getting to help them) to be mapping with QC-122 at their side so that they can be drafting the revision as they do their work. QC-122 will be the description of the results of the mapping process.
- A matrix of document types should be added as an appendix or otherwise as a part of QC-122

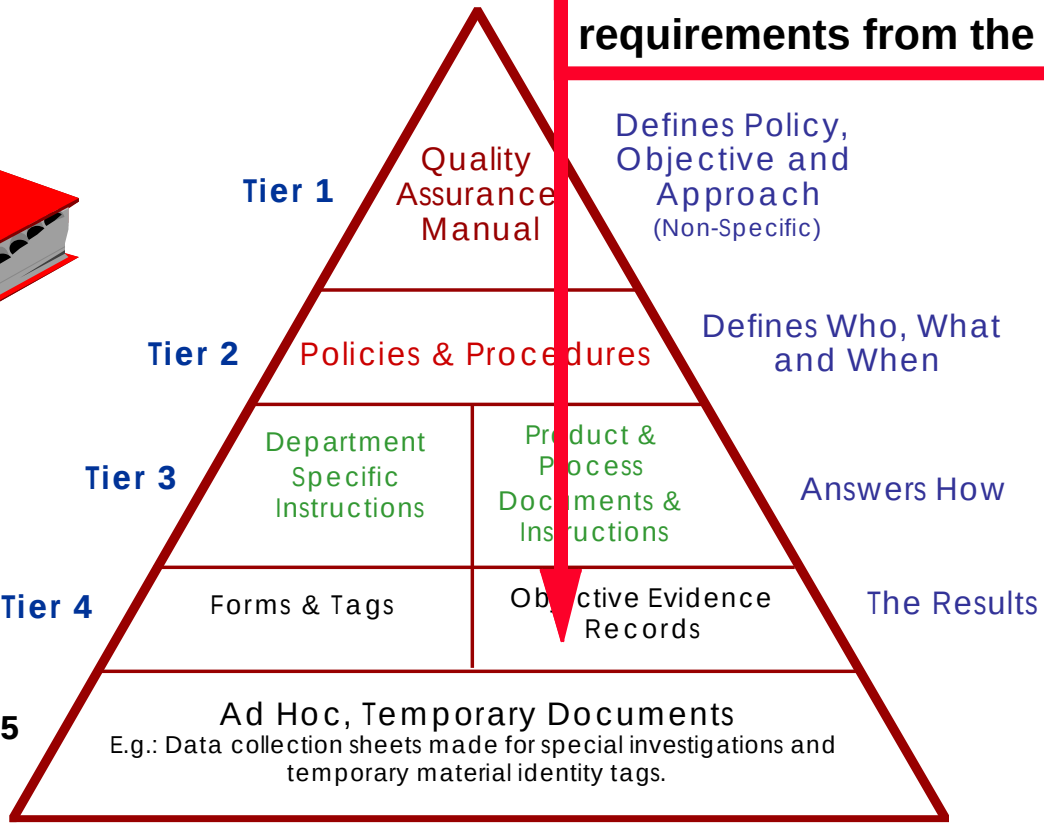
Why the Stress on Documentation?

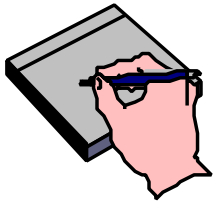
- The majority of failures in both QS and ISO 9000 registration efforts has been, and continues to be, element 4.5.
- Discontinuity is easy to discover in the documentation. Even Quality Manuals have been shown to have invalid links.
- Auditors will focus on the continuity and flow of documentation. Inconsistencies will keep your facility from passing the registration audit.

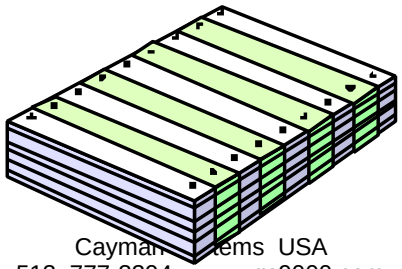
Typical Documentation Tiers

We ensure flow down of requirements from the top down









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Mapping Aspects

- Mapping starts at the top with the QA Systems Manual.
- When you map documents, you normally ‘verify’ links between documents (where one document cites another within it). The first thing to verify is that the cited document exists.
- A second aspect of mapping is to verify that the content of the citation is relative. This is to say that the links should ‘make sense’. If a citation in one document says something like “The audit will be performed in accordance with procedure ABC-1234” and procedure ABC-1234 is titled ‘Calibration of Pressure Gages’, it is evident that the link is **NOT Valid**! It does not make sense!
- After verifying that the linked document both exists and that the links are ‘relative’ and make sense, the document is mapped to the matrix relative to the mapping project. In this case the matrix is QS 9000 line items against the document ‘class’.

Document Tiers & Classes

- It is uncommon to find 'Pure' documents. That is to say, it is not very often you find a document which one can clearly define as 'only' Tier I or Tier II or Tier III. In almost all cases there is some cross over. A good example is a Tier III document which becomes a Tier IV document. In this case we have a document which is a Tier III Procedure with some places which which will eventually be filled with data - which will then make it a Record (Tier IV).
- The idea of a defined border and thus a pure document is fine, but is seldom actually seen. Normally the closest you will come is with the Quality Systems Manual. A QSM will normally be the 'purest' document you will find within any given system.
- Purity is to some degree a function of company size. A company with only 20 to 50 employees with simple processes will generally have little need for 'pure' structure. The necessity of structure in very large companies necessitates a more defined documentation structure in large part due to necessary overall complexity.
- Also consider the idea of document classes. Classes may include production documents, engineering documents, Human Resources documents, maintenance documents, etc. From this we should understand *there are usually several classes of documents in any given tier*.
- Document classes are related to document tiers. In most companies there are multiple document 'classes'. These classes are always Tier II or lower.

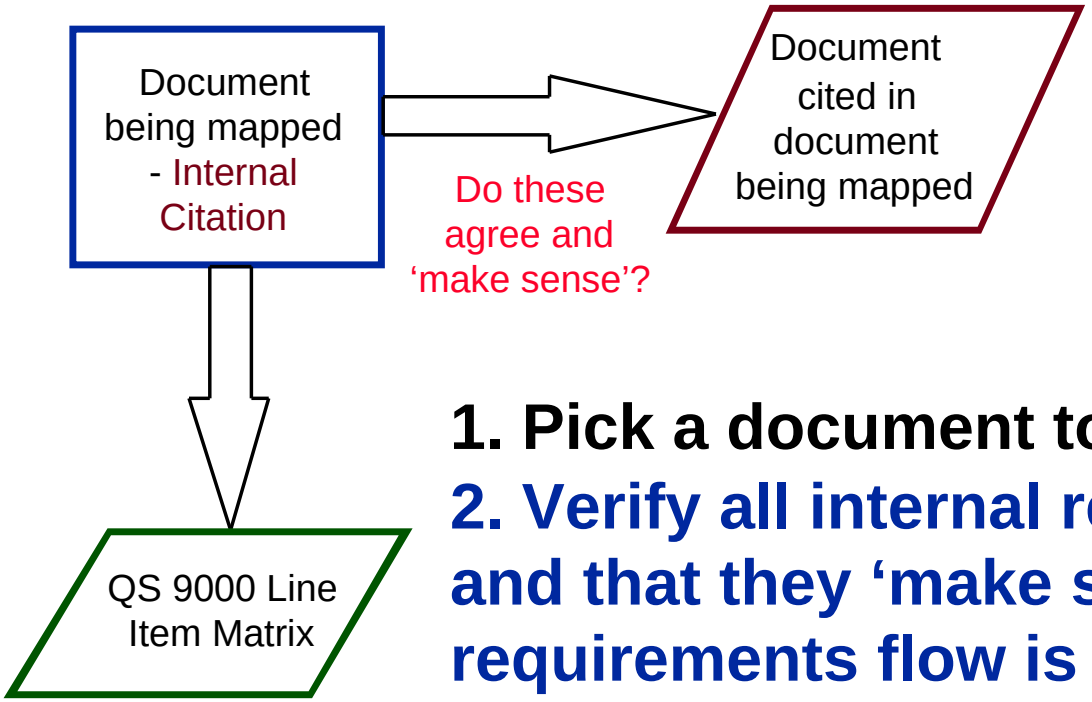
Requirements Flow Down

1. A Flow Down requirement does NOT have to be specified by a reference. A Policy, for example, normally states something shall happen or be complied with. An example is a policy which states: “All employees shall comply with ESD policies and procedures” implies these exist without referencing them. This is definitely a flow down requirement.
2. It’s a good idea to provide references, but often this is not possible. In the case of corporate policies, for example, there may be many locations which are expected to comply. We comply by providing ‘local’ documentation which fulfils the corporate policy requirements.

Flow Up vs Flow Down

- Not all documents have flow down requirements
- Flow downs are normal
- Flow downs generally reference lower level documents, but references are not mandatory
- Flow Ups are seldom found
- Flow Ups are dangerous mistakes
- Use a Flow Up when you believe it is necessary for clarity and/or understanding

Mapping - Two Aspects



Map from top down.
The corporate Quality Systems Manual on down to local Tier IV's

1. Pick a document to map.

2. Verify all internal references are valid and that they 'make sense' and that the requirements flow is always down

3. Enter the document number (the one being mapped) in the appropriate column and row of the QS 9000 Line Item Matrix.

4. Examine matrix for redundancy.

QS 9000 Line Item Matrix Mapping

After verifying internal links for existence and continuity, one maps the document to the requirements matrix while checking for redundancy.

Matrix Class (Document Type) Listing is Descending Tier Hierarchy

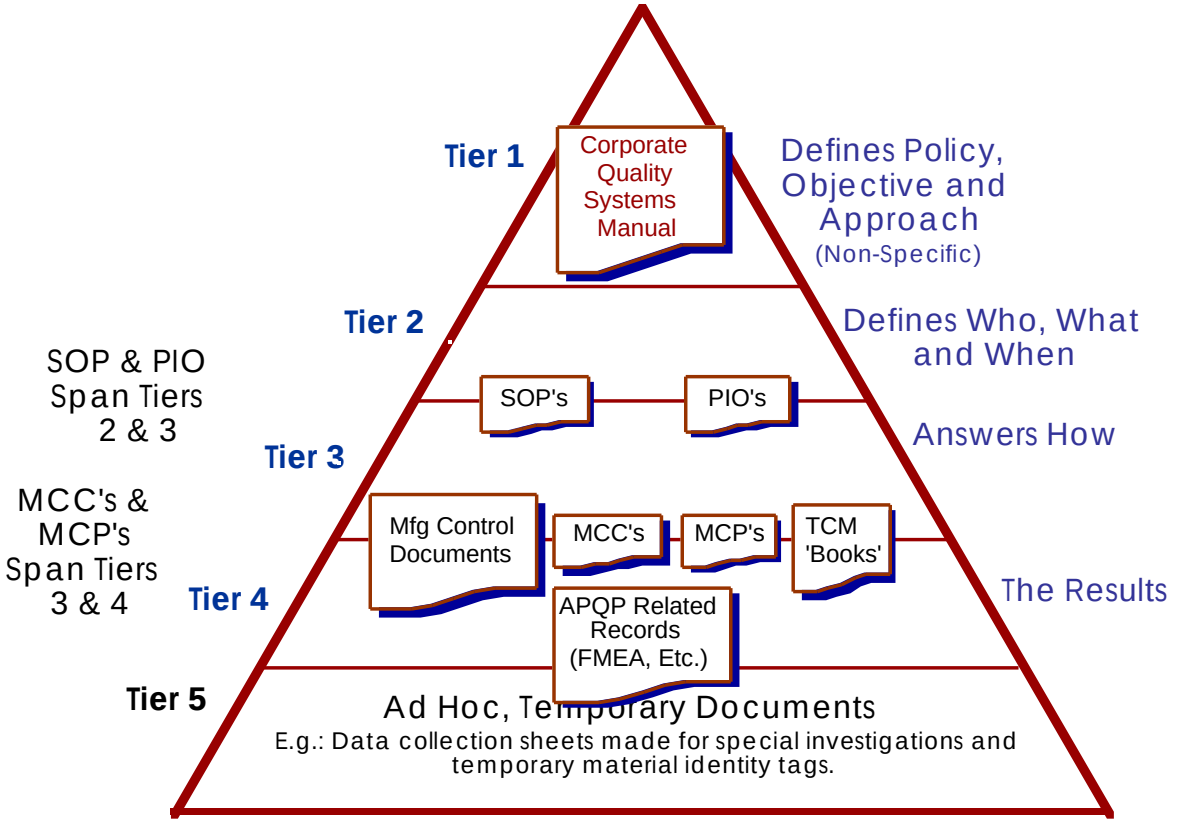
Requirement	QS 9000	QA Man.	AIAG Ref.	Corp SOP	PIO	12MRM-
Analysis and Use of Company-Level Data	4.1.5	X		SOP 4-15, SOP 8-13		
Customer Satisfaction & Customer Complaints	4.1.6	X				
Quality System	4.2					
General	4.2.1	X		SOP 4-9		
Quality System Procedures	4.2.2	X				
Quality Planning (per APQP & CP)	4.2.3	X	APQP	SOP 4-15		
Use Of Cross Functional Teams (per APQP & CP)	4.2.3	X				
Feasibility Reviews (per APQP & CP)	4.2.3	X				
Control Plans (Prototype, Pre-Launch & Production)	4.2.3	X				
PFMEA (per PFM&EA Ref. Manual)	4.2.3	X				12MRM96619A
Key/Critical/Special Characteristics	4.2.3	X				
Contract Review	4.3			SOP 3-47		
General	4.3.1	X				12MRM95827A

Summary

Mapping internal documents IS:

- Verify internal reference documents exist and that the names and numbers 'make sense'
- Verify that the link subject matter makes sense and that requirements flow down
- Find where the document fits in the QS 9000 line item matrix
- Examine matrix for redundancy

Partial Documentation Structure



Conclusion

- The document mapping effort is extremely important.
- It MUST include communication with corporate not only in regard to Quality Systems Manual inconsistencies, but at all documentation levels where there is a system, team and/or documentation interface requirement.
- It must be detailed and precise. ***All*** inconsistencies must be addressed!

QS 9000

The Specifics

Quality System Requirements

- Quality Policy
- Quality Manual
- Procedures
- Work Instructions
- Other Documentation
- Internal Auditing

The Elements of QS 9000

The QS 9000 document is divided into 3 sections

1. ISO 9000 Based Requirements
2. Sector Specific Requirements
3. Customer Specific Requirements

'Reference' Manuals Cited Within QS 9000

APQP - Advanced Product Quality Planning

PPAP - Production Part Approval Process

MSA - Measurement Systems Analysis

FMEA - Failure Mode and Effects Analysis

SPC - Statistical Process Control

Semiconductor Supplement

Tooling and Equipment Supplement

List of Main QS Elements

4.1	Management Responsibility
4.2	Quality System
4.3	Contract Review
4.4	Design Control
4.5	Document and Data Control
4.6	Purchasing
4.7	Control of Customer-Supplied Product
4.8	Product Identification and Traceability
4.9	Process Control
4.10	Inspection and Testing
4.11	Control of Inspection, Measuring and Test Equipment
4.12	Inspection and Test Status
4.13	Control of Non-Conforming Product
4.14	Corrective and Preventive Action
4.15	Handling Storage Packaging Preservation and Delivery
4.16	Control of Quality Records
4.17	Internal Quality Audits
4.18	Training
4.19	Servicing
4.20	Statistical Techniques

4.1 Management Responsibility

Requirement	QS 9000	ISO 9001	QA Man.	Procedure	WI
Management Responsibility	4.1	4.1			
Quality Policy	4.1.1	4.1.1			
Organization	4.1.2	4.1.2			
Responsibility & Authority	4.1.2.1	4.1.2.1			
Resources and Trained Personnel	4.1.2.2	4.1.2.2			
Mgmt. Representative (Quality System Responsibility)	4.1.2.3	4.1.2.3			
Organizational Interfaces	4.1.2.3				
Management Review	4.1.3	4.1.3			
Business Plan	4.1.4				
Analysis and Use of Company-Level Data	4.1.5				
Customer Satisfaction & Customer Complaints	4.1.6				

4.1 Management Responsibility

- Management Responsibility is applicable to every company registering to QS 9000. It can be one of the most difficult to achieve when management fails to support and involve themselves in the effort.
- A major key is having a 'formalized' agenda and keeping meeting minutes.
- QS 9000 is NOT something management can simply delegate to employees and/or a consultant.

4.2 Quality System

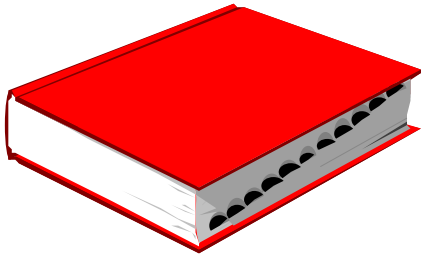
Requirement	QS 9000	ISO 9001	QA Man.	Procedure	WI
Quality System	4.2	4.2			
General	4.2.1	4.2.1			
Quality System Procedures	4.2.2	4.2.2			
Quality Planning	4.2.3	4.2.3			
Use Of Cross Functional Teams	4.2.3				
Feasibility Reviews	4.2.3				
Control Plans (Prototype, Pre-Launch & Production)	4.2.3				
PFMEA (per PFM&EA Ref. Manual)	4.2.3				
Key/Critical/Special Characteristics	4.2.3				

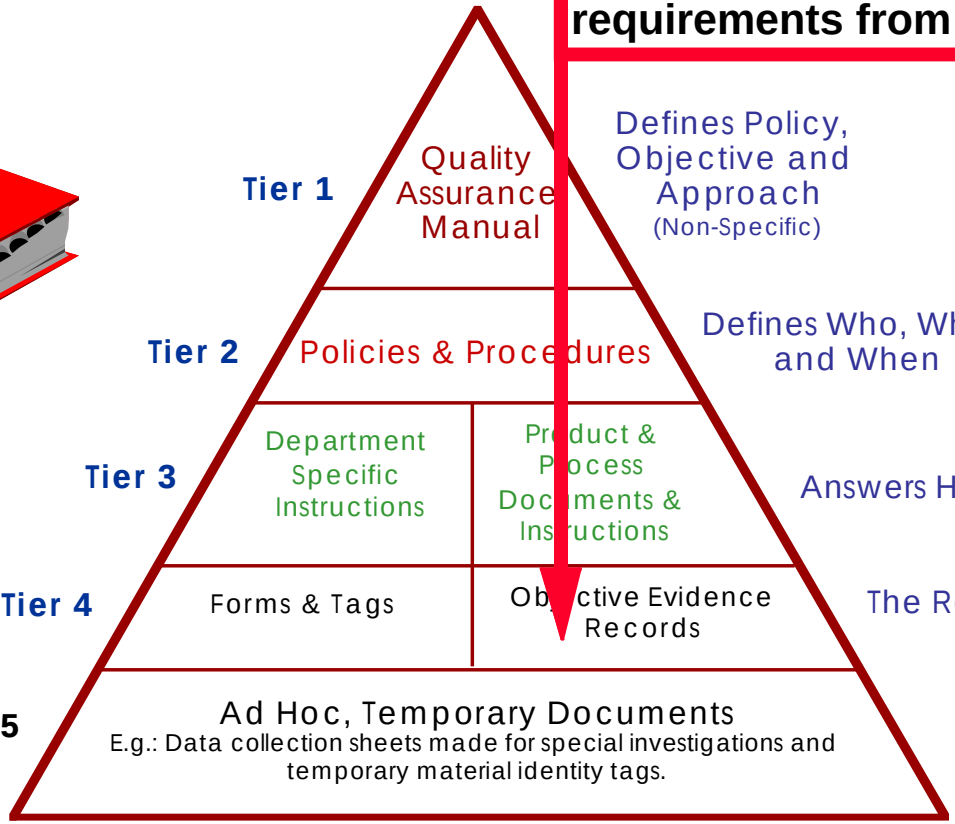
4.2 Quality System

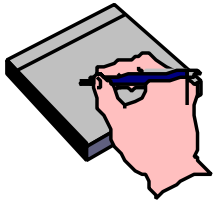
- This element requires that your quality related systems be defined within company documentation.
- Requires ‘Documented’ Procedures
- You will have to define how you ‘Plan’ for quality - this involves APQP and the design process.

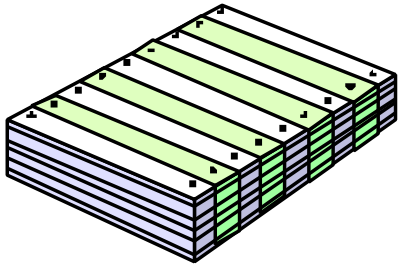
QS 9000 Document Structure

We ensure flow down of requirements from the top down









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4.3 Contract Review

Requirement	QS 9000	ISO 9001	QA Man.	Procedure	WI
Contract Review	4.3	4.3			
General	4.3.1	4.3.1			
Review	4.3.2	4.3.2			
Amendment To Contract	4.3.3	4.3.3			
Records	4.3.4	4.3.4			

4.3 Contract Review

- This element requires contracts to be reviewed for a number of concerns and issues.
- The intent is to ensure everyone agrees on terms and requirements
- Amendment to contract is of particular auditor interest, although it is generally just a re-entry into the defined review flow

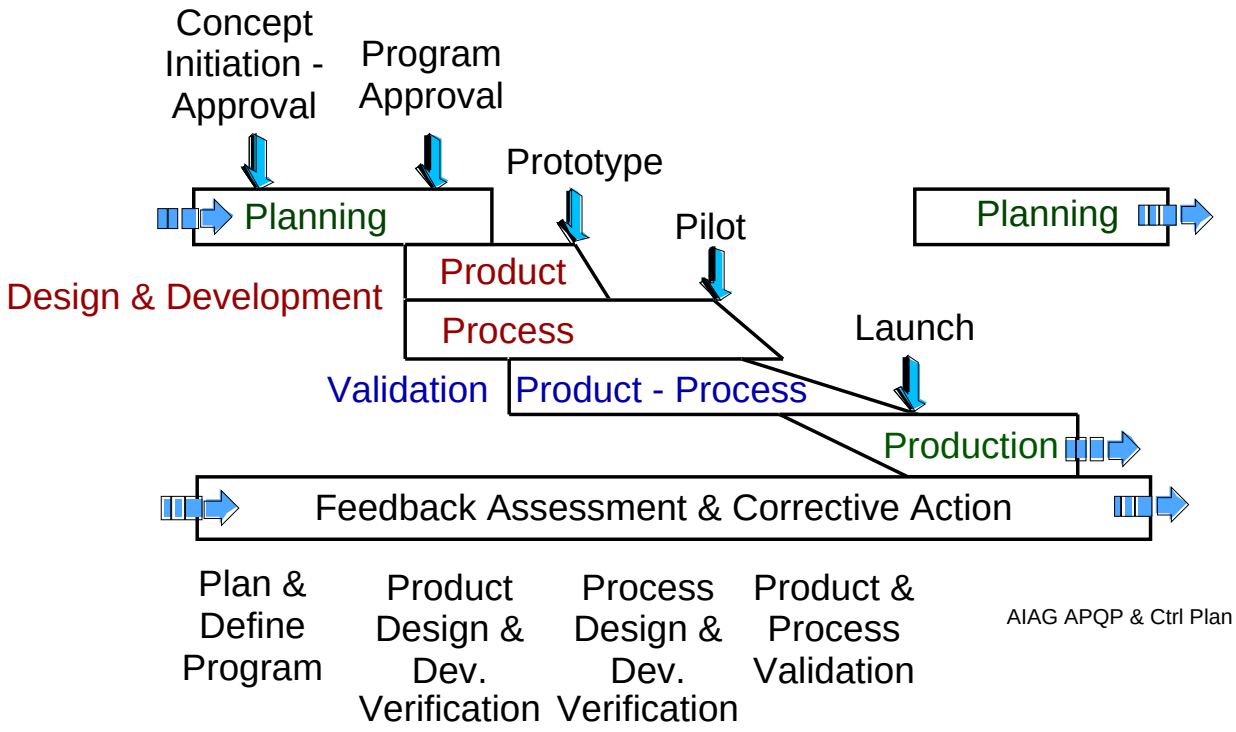
4.4 Design Control

Requirement	QS 9000	ISO 9001	QA Man.	Procedure	WI
Design Control	4.4	4.4			
General	4.4.1	4.4.1			
Design & Development Planning/Tests	4.4.2	4.4.2			
Design & Development Activity Required Skills	4.4.2				
Organizational & Technical Interfaces	4.4.3	4.4.3			
Design Input	4.4.4	4.4.4			
Design Input (Add'l Requirements)	4.4.4				
Design Output	4.4.5	4.4.5			
Design Output (Add'l Requirements)	4.4.5				
Design Review	4.4.6	4.4.6			
Design Verification	4.4.7	4.4.7			
Design Validation	4.4.8	4.4.8			
Design Changes	4.4.9	4.4.9			
Design Changes (Add'l Requirements per PPAP)	4.4.9				

4.4 Design Control

- Can you define Inputs and Outputs?
- What is the difference between Verification and Validation?
- What is the difference between Product Verification and Validation versus Process Verification and Validation?

Advanced Product Quality Planning



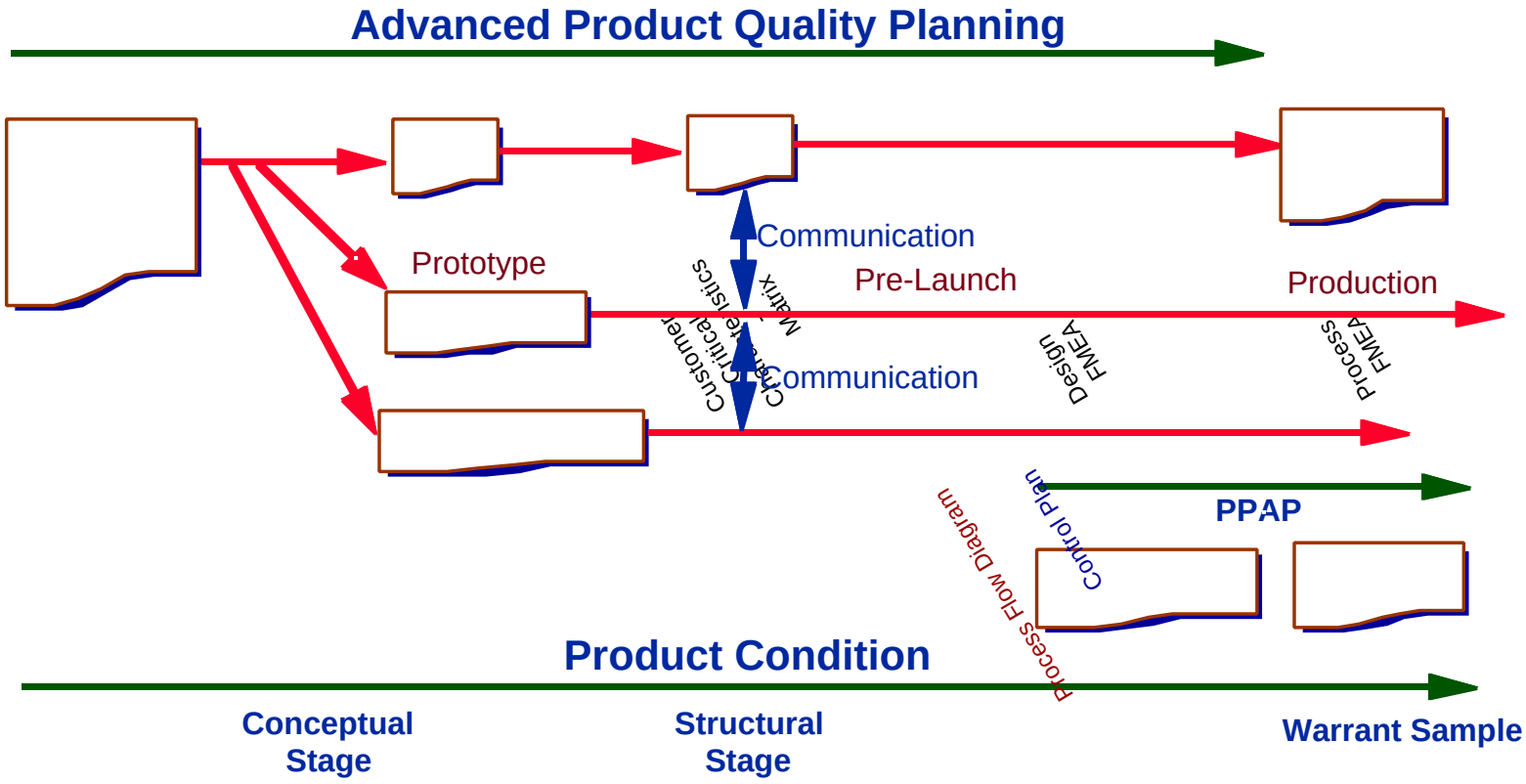
AIAG APQP & Ctrl Plan Reference Guide, Page 5

- A structured method of defining the steps (process) necessary to assure that a product satisfies the customer
- The goal of APQP is to facilitate communication with everyone involved to ensure that all required steps are completed on time.
- Effective APQP depends upon top management commitment and support to assure that customer satisfaction is achieved

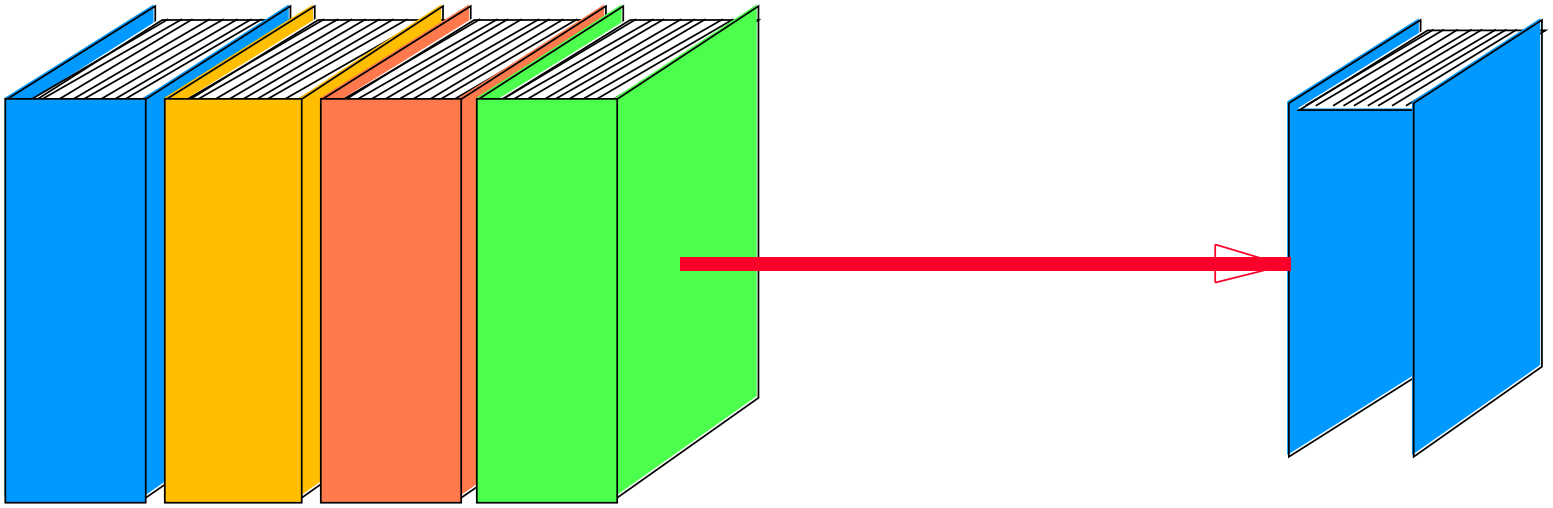
What Is APQP?

- APQP is ‘defined’ process for a product development ‘system’ for Ford, GM, Chrysler and their suppliers.
- APQP is an attempt to provide a common path and synchronization of product development activities.
- APQP is an attempt to ensure communication both within a company and between a company and their customer.

The Base Process Sequence



PPAP



APQP Launch Binders

PPAP Submission

The End Product of APQP!

4.5 Document and Data Control

Requirement	QS 9000	ISO 9001	QA Man.	Procedure	WI
Document, Data & Specification Control	4.5	4.5			
General	4.5.1	4.5.1			
Reference Documents	4.5.1				
Document Identification for Special Characteristics	4.5.1				
Document and Data Approval & Issue	4.5.2	4.5.2			
Engineering Specifications	4.5.2				
Document & Data Changes & Modifications	4.5.3	4.5.3			

4.5 Document and Data Control

- This requires that ‘quality related’ documentation be controlled.
- Data (quality related forms) must also be defined and controlled.
- ‘Documents of External Origin’
- Manufacturing documentation
- Company procedures

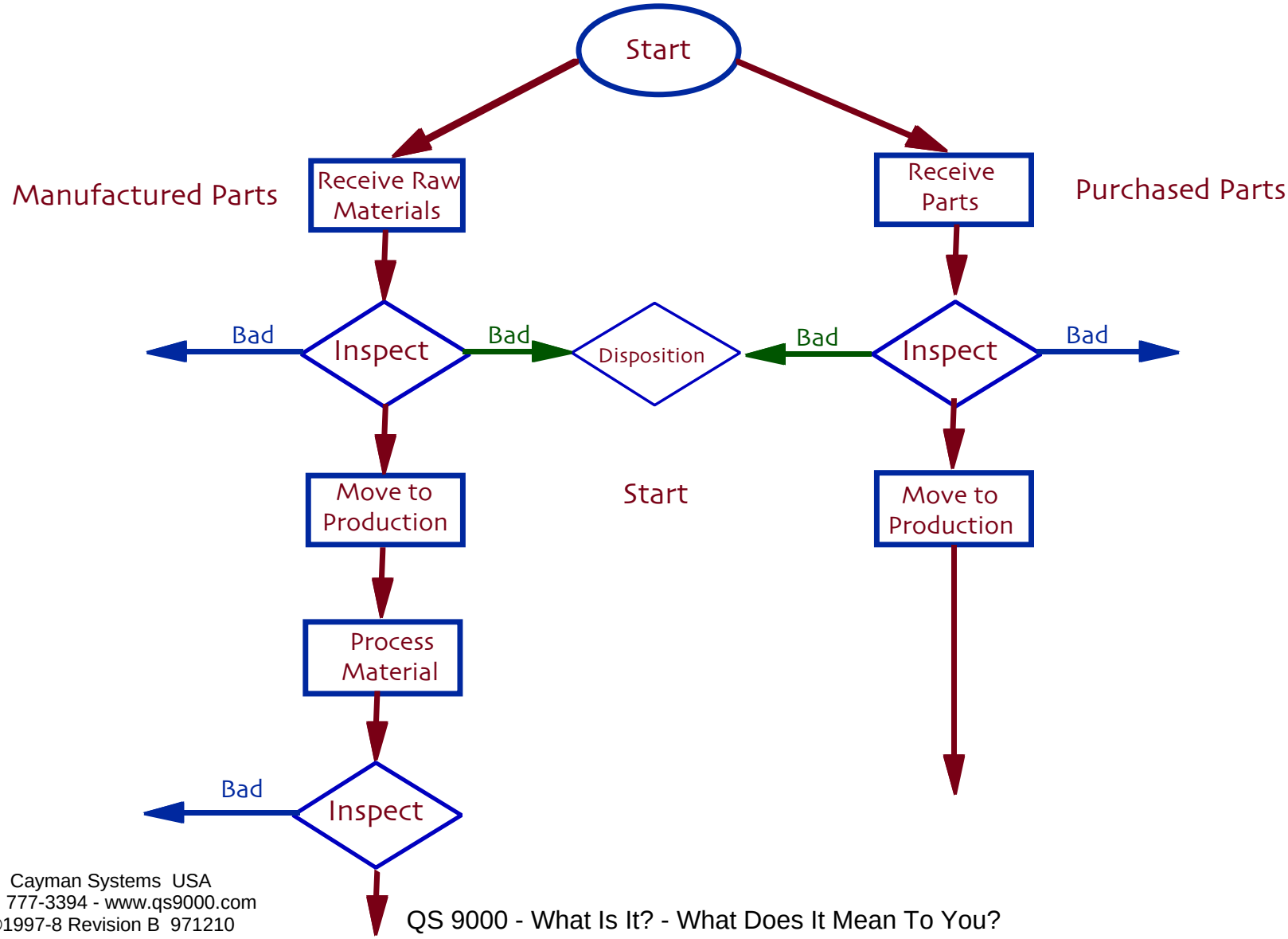
What is Documentation?

- Documentation is much talked about. There are different types. At Company GDL, for example, there are PIOs. Corporate has SOPs and maintains a Quality Systems Manual. There is process documentation in the manufacturing areas.
- Everyone uses documentation outside of work. If you buy something (like a clock), there are instructions in the box. That is documentation.
- Think of documentation as instructions. Documentation explains how to do things.
- The auditor's job is to make sure everyone is 'Following Instructions'. The instructions are your documentation.

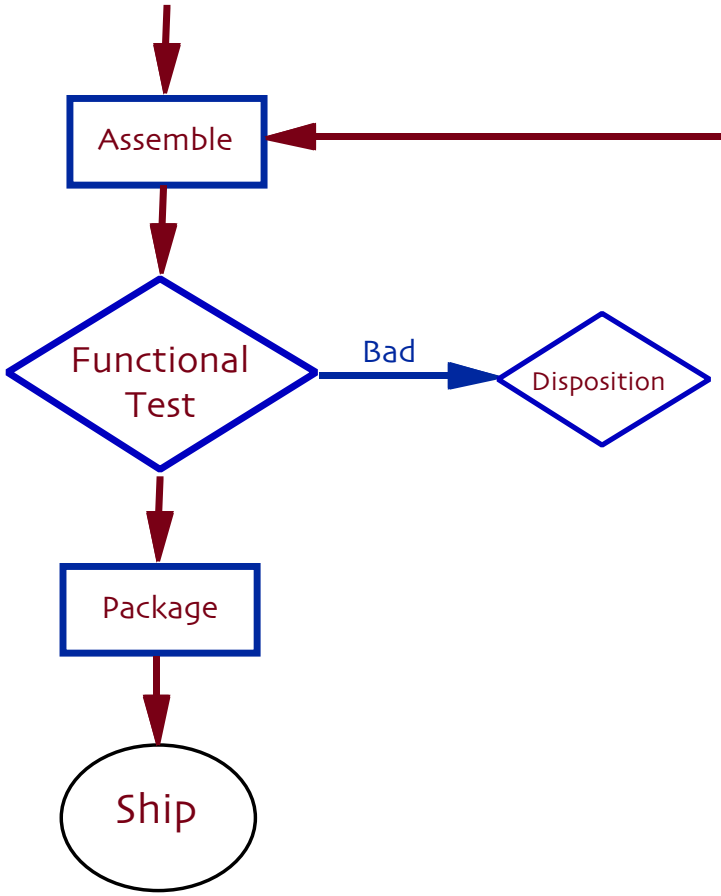
What is Controlled Documentation?

- If a controlled document is changed, a record of the change has to be made. This means we must have a History of All Changes.
- If a document is changed, people who use it must know about the change. This means there has to be a distribution list or other effective way to let everyone who uses it know the document has changed.
- Every employee must know how to check to see if documentation they are using is the most current version.
- 'Controlled' documents include Quality Records, outside specifications, drawings, etc., including QS 9000 *and* the Interpretations...

Flow Chart Example



Flow Chart Example



How To Use The Flow Chart

- Use to define what steps are occurring in a process
- Use as a check list to collect data on where problems occur
- Use to help determine who should be involved by identifying all the work areas and responsibilities in a process
- Use as a job aid to remind people about process the process and related standards
- Use the ‘ideal process’ flow chart data to communicate proposals (changes)

Flow Chart Tips

- If a process step or box has two output arrows, consider whether a decision box is needed
- Remember that the people closest to the work know it best. Make sure people are involved in developing the flow chart
- Software packages make flow chart production easy.

4.6 Purchasing

Requirement	QS 9000	ISO 9001	QA Man.	Procedure	WI
Purchasing (Control Of Purchases)	4.6	4.6			
General/Responsibility	4.6.1	4.6.1			
Approved Material for Ongoing Production	4.6.1				
Supplier Assessment (Evaluation of Sub-Contractors)	4.6.2	4.6.2			
Supplier Development	4.6.2				
Scheduling Subcontractors	4.6.2				
Purchasing Data	4.6.3	4.6.3			
Restricted Substances	4.6.3				
Verification of Purchased Product	4.6.4	4.6.4			
Supplier Verification at Sub-Contractor's Premises	4.6.4.1	4.6.4.1			
Customer Verification of Sub-Contracted Product	4.6.4.2	4.6.4.2			

4.6 Purchasing

- This element requires a company to review suppliers of product and process related material and services.
- Should be considered during APQP.
- Can you explain how purchasing knows what to put on each purchase order?

4.7 Customer Supplied Product

Requirement	QS 9000	ISO 9001	QA Man.	Procedure	WI
Purchaser (Customer) Supplied Product	4.7	4.7			

4.7 Customer Supplied Product

- This requirement originally was aimed at materials utilized in the manufacture of product, items such as molds and dies, and special gages and fixtures.
- This has been extended to include transportation containers and related items. The main thrust is that customer supplied items must be tracked and taken care of.

4.8 Product Identification and Traceability

Requirement	QS 9000	ISO 9001	QA Man.	Procedure	WI
Product Identification and Traceability	4.8	4.8			

4.8 Product Identification and Traceability

- The extent of identification and traceability is company and product dependent/specific. The expectation is that you have a system to identify and track items in conformance with customer requirements and industry standards.

4.9 Process Control

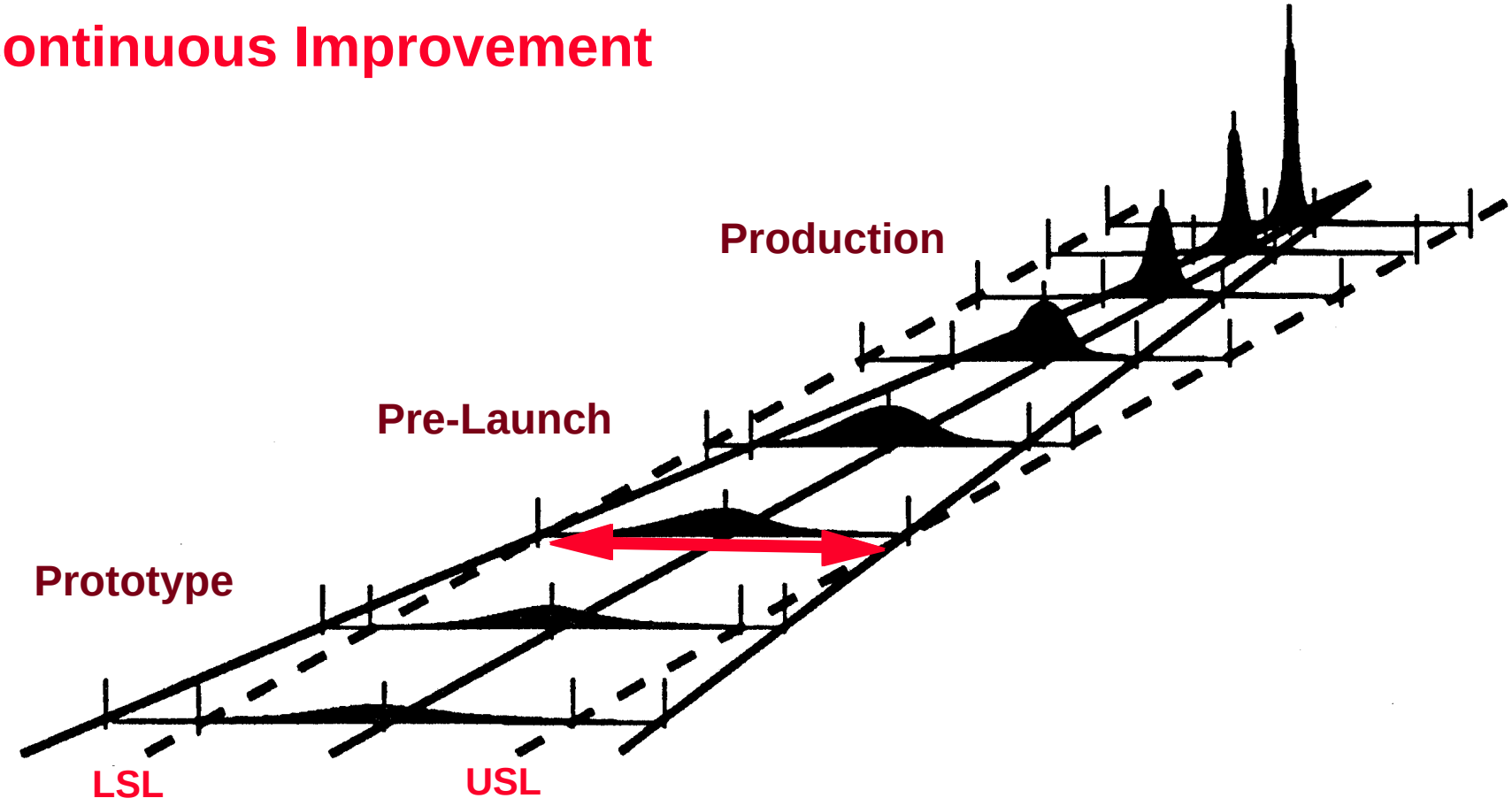
Requirement	QS 9000	ISO 9001	QA Man.	Procedure	WI
Process Control	4.9	4.9			
Government Safety and Environmental Regulations	4.9				
Designation of Special Characteristics	4.9				
Tooling & Equipment (Preventative) Maintenance	4.9				
General	4.9.1				
Written Work/Process Instructions	4.9.1				
Process Parameter Monitoring	4.9.1				
Preliminary Process Capability Requirements	4.9.2				
On-Going Process Performance Requirements	4.9.3				
Modified Beginning/On-Going Capability Requirements	4.9.4				
Verification of Job Set-Ups	4.9.5				
Process Changes/Change Control	4.9.6				
Appearance Items	4.9.7				

4.9 Process Control

- This element requires that your ‘processes’ be controlled. Evidence is from the following list. Things to consider may include on-time pick-up and delivery as well as no damage to the conveyed goods.
- APQP Items
  - Control plan
  - Process FMEA
  - Inspection and/or Test Points
  - Operator Instructions
  - Training
- Preventive and Predictive Maintenance
- Ongoing Training
- Transportation

The Target & Goal

Continuous Improvement



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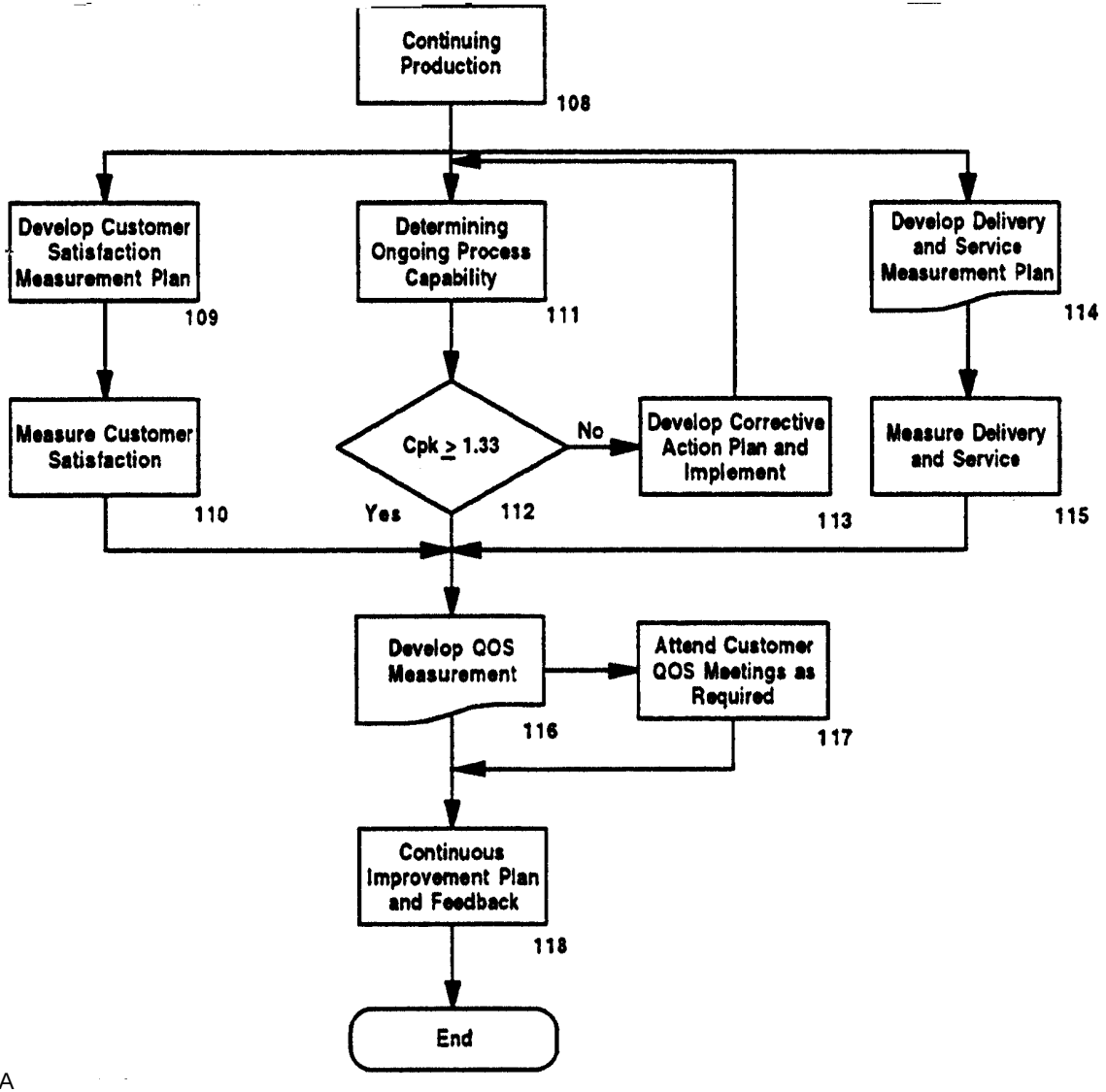
Continuing Production



4.10 Inspection and Testing

Requirement	QS 9000	ISO 9001	QA Man.	Procedure	WI
Inspection and Tests	4.10	4.10			
General	4.10.1	4.10.1			
Acceptance Criteria	4.10.1				
Accredited Laboratories	4.10.1				
Receiving Inspection & Testing	4.10.2	4.10.2			
Incoming Product Quality	4.10.2				
In-process Inspection & Testing	4.10.3	4.10.3			
Final Inspection & Testing	4.10.4	4.10.4			
Layout Inspection & Functional Testing	4.10.4				
Inspection & Test Records	4.10.5	4.10.5			

4.10 Inspection and Testing

- This element is addressed during the APQP phase of development. As your control plan develops (along with your PFMEA), inspection and test points are determined, defined and documented.
- In short, this entire element says you will 1.) follow the ‘plan’ defined by your control plan and PFMEA *and* 2) that during APQP you will set up your inspection and test requirements with consideration to and of this QS 9000 element.

4.11 Control of Inspection, Measuring and Test Equipment

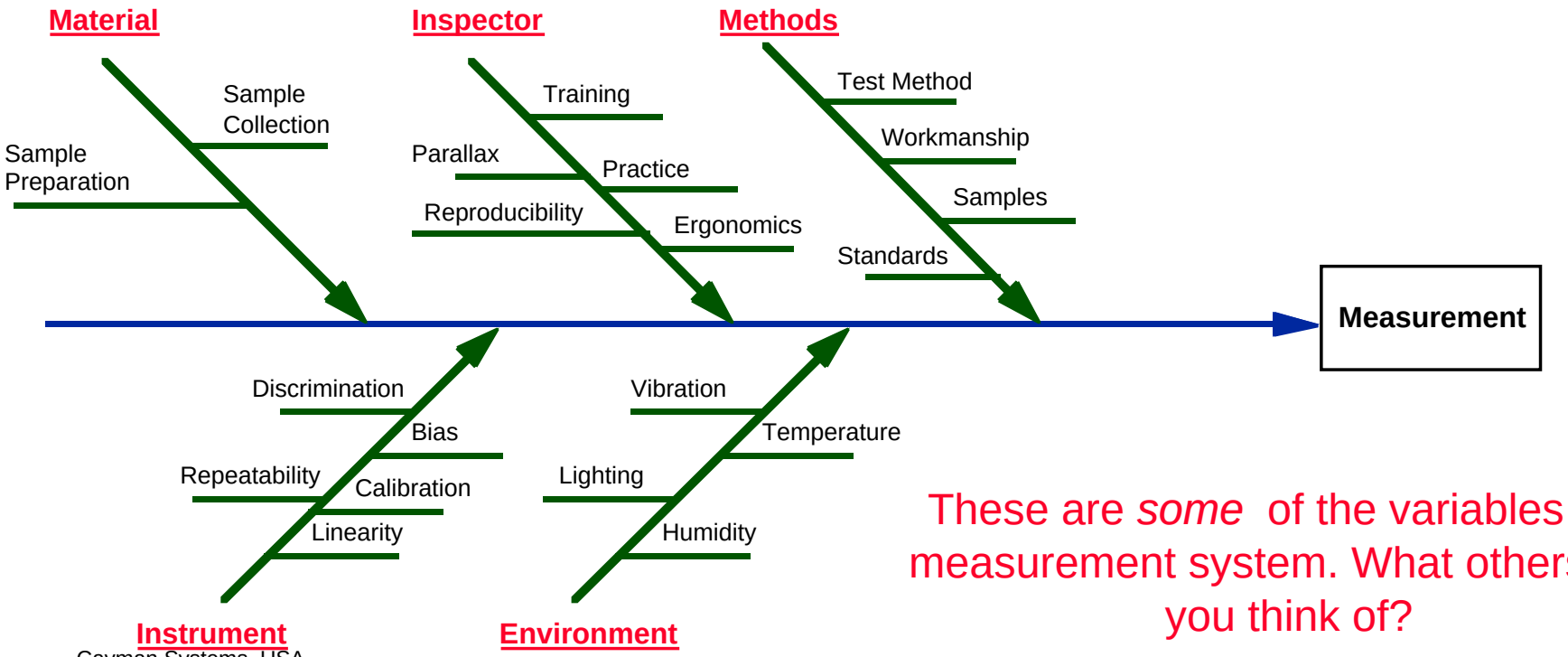
Requirement	QS 9000	ISO 9001	QA Man.	Procedure	WI
Inspection, Measuring and Test Equipment	4.11	4.11			
General	4.11.1	4.11.1			
Control Procedure	4.11.2	4.11.2			
Records	4.11.3				
Gage R&R Studies (Measurement Systems Analysis)	4.11.4				

4.11 Control of Inspection, Measuring and Test Equipment

- Requires you to not only keep things calibrated, but also requires you to demonstrate you understand measurement systems including properties.
- Gage R&R is included here, but really applies only to M&TE identified on the control plan.

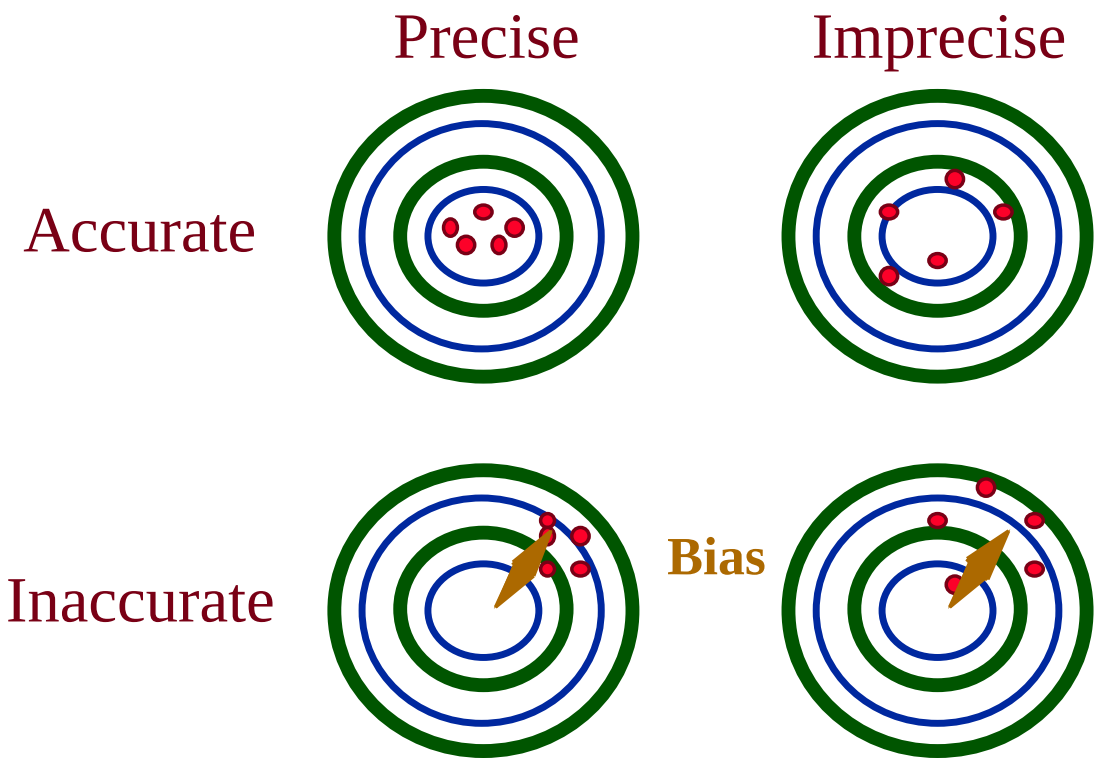
Measurement Systems Analysis Plan Ensures Gage:

- Linearity
- Accuracy
- Repeatability
- Reproducibility
- Correlation for duplicate gages
- Gages may be needed prior to gage sign-off at subcontractor plant or any in-house pilot runs



These are *some* of the variables in a measurement system. What others can you think of?

Measurement Bias & Repeatability



You can correct for Bias

You can NOT correct for Imprecision

4.12 Inspection and Test Status

Requirement	QS 9000	ISO 9001	QA Man.	Procedure	WI
Inspection and Test Status (Indication Of)	4.12	4.12			
Product Location	4.12				
Supplemental Verification	4.12				

4.12 Inspection and Test Status

- This relates to how you identify product during the manufacturing phase to ensure that no operations, inspections and/or tests are missed.
- QS 9000 gives no guidance on how to do this but during APQP this should be defined with consideration to/of Element 4.10 of QS 9000.

4.13 Control of Nonconforming Product

Requirement	QS 9000	ISO 9001	QA Man.	Procedure	WI
Control of Nonconforming Product	4.13	4.13			
General	4.13.1	4.13.1			
Suspect Product	4.13.1				
Nonconformity Review & Disposition	4.13.2	4.13.2			
Control of Reworked Product	4.13.3				
Deviations (Eng. Approved Product Authorization)	4.13.4				

4.13 Control of Nonconforming Product

- This element is to ensure no ‘bad’ material is used in production and that ‘bad’ finished product is not shipped
- This element requires a system which addresses ‘bad’ stuff and defines how ‘bad’ material and/or product is ‘processed’ (including specific disposition systems)

4.14 Corrective and Preventive Action

Requirement	QS 9000	ISO 9001	QA Man.	Procedure	WI
Corrective and Preventive Action	4.14	4.14			
General	4.14.1	4.14.1			
Problem Solving Methods	4.14.1				
Corrective Action	4.14.2	4.14.2			
Returned Product Test/Analysis	4.14.2				
Recurring Defect Prevention (Prevention Action)	4.14.3	4.14.3			

4.14 Corrective and Preventive Action

- This element requires you to address problems identified by the Nonconformance System by a documented methodology and that you show proof that your corrective measures are effective at eliminating the problem
- The goal is Preventive Action and Continuous Improvement

4.15 Handling, Storage, Packaging, Preservation and Delivery

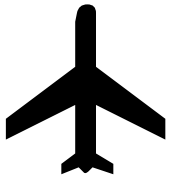
Requirement	QS 9000	ISO 9001	QA Man.	Procedure	WI
Handling Storage, Packaging and Delivery	4.15	4.15			
General	4.15.1	4.15.1			
Handling	4.15.2	4.15.2			
Storage	4.15.3	4.15.3			
Inventory	4.15.3				
Packaging	4.15.4	4.15.4			
Customer Packaging Standards	4.15.4				
Labeling	4.15.4				
Preservation	4.15.5	4.15.5			
Delivery	4.15.6	4.15.6			
Supplier Delivery Performance Monitoring	4.15.6				
Production Scheduling	4.15.6				
Shipment Notification System	4.15.6				

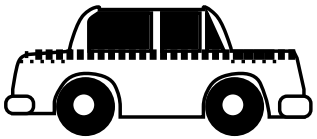
4.15 Handling, Storage, Packaging, Preservation and Delivery

- This element is rather wide. Most should be addressed during the APQP phase of a project.
- Includes internal storage.
- Requires identification and understanding of customer packaging requirements.
- Requires objective evidence of on-time delivery.
- ‘Production scheduling shall be order driven’.
- Shipment notification system (ASN’s), unless waived (in writing).

Packaging Standards

- From customer
- From experience
- Developed during prototype or pre-launch runs





Delivery and Service

- Continues the supplier - customer partnership in problem solving and continuous improvement
- Replacement parts and services are important
- Leads to possible price reduction from:
  - Inventory cost reduction
  - Process cost reduction
  - Cost of quality reduction
  - Reference QS 9000 Element 4.15

4.16 Control of Quality Records

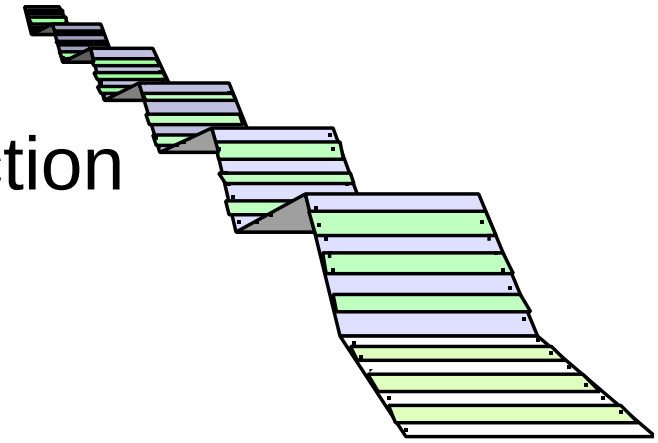
Requirement	QS 9000	ISO 9001	QA Man.	Procedure	WI
Quality Records	4.16	4.16			
Records Retention	4.16				
Superseded Parts	4.16				

4.16 Control of Quality Records

- This element is most important. It requires that ‘quality related data’ be defined and controlled. Each company has to decide and document what theirs are.
- Disposition also has to be addressed.
- It is advised that you have a specific list (or matrix) of your quality records.

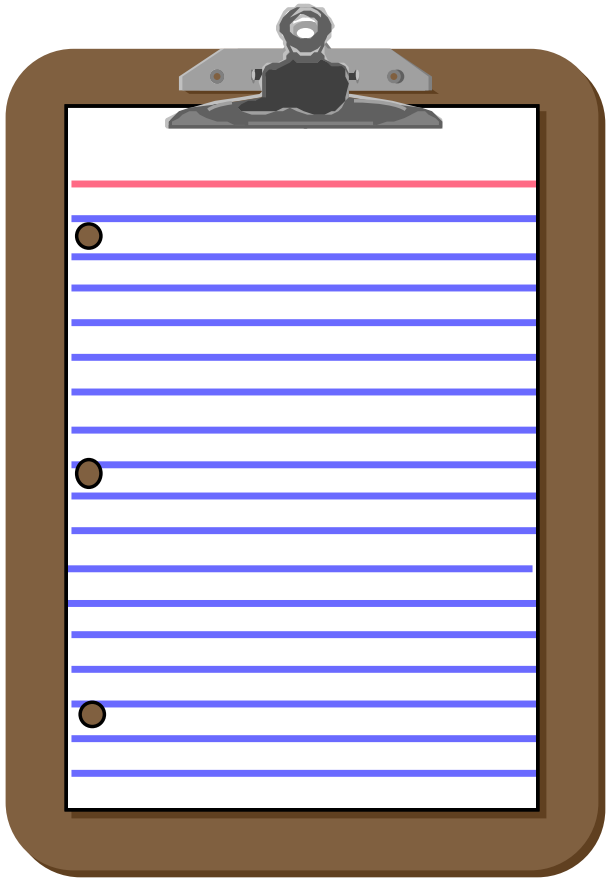
Typical Types of Records

- Contract Review
- Purchasing
- Identification and Traceability
- Process Control
- Inspection and Test
- Control of Measurement and Test Equipment
- Non-conforming Product
- Corrective and Preventive Action
- Internal Quality Audits
- Training



Records Management Activities

- Management of Active records
- Records creation (forms)
- Design of records system
  - Retention schedule
  - Vital records protection
- Development of records procedures
  - Indexing
  - Filing
  - Access
  - Disposition



4.17 Internal Quality Audits

Requirement	QS 9000	ISO 9001	QA Man.	Procedure	WI
Internal Quality Audits	4.17	4.17			
Inclusion of Working Environment	4.17				

4.17 Internal Quality Audits

- This element requires that at least once a year your company audit its self against its internal documentation. This can be done by company employees
- This is in addition to the registrar's annual 'visit'
- Internal audits can be 'farmed out' (they do not have to be performed by company personnel)

4.18 Training

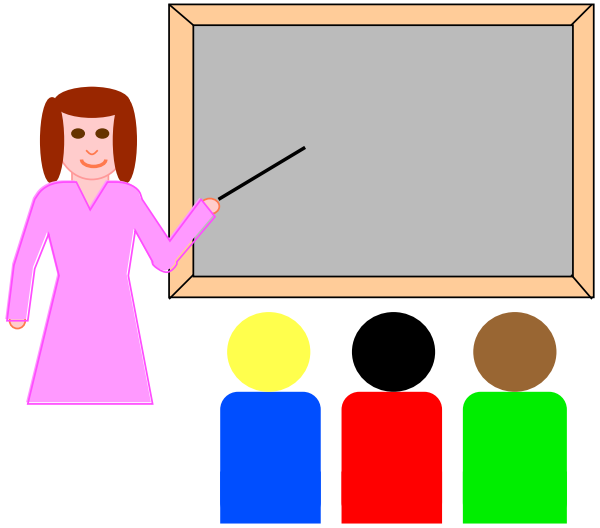
Requirement	QS 9000	ISO 9001	QA Man.	Procedure	WI
Training	4.18	4.18			
Training as a Strategic Issue	4.18				

4.18 Training

- ‘Training as a Strategic Issue’
- Training effectiveness shall be periodically evaluated.
- This includes on-the-job as well as all other training issues.
- Records must be kept and will undoubtedly be examined during the registration audit.

Training

- Customer needs and expectations
- On-The-Job Training
- Working as a Team
- Group process skills
- Development skills
- APQP
- FMEA
- PPAP



4.19 Servicing

Requirement	QS 9000	ISO 9001	QA Man.	Procedure	WI
Servicing	4.19	4.19			
Feedback of Information from Service	4.19				

4.19 Servicing

- This element was aimed at manufacturers who provide services to their customers in setting up and/or maintaining product including doing so by documented procedures, if appropriate.
- QS has bastardized it to include “Feedback of Information form Service” where ‘service’ means dealership service department and assembly plant feedback.

4.20 Statistical Techniques

Requirement	QS 9000	ISO 9001	QA Man.	Procedure	WI
SPC & Statistical Techniques	4.20	4.20			
Identification of Need	4.20.1	4.20.1			
Procedures	4.20.2	4.20.2			
Selection of Statistical Tools	4.20.2				
Knowledge of Basic Statistical Concepts	4.20.2				

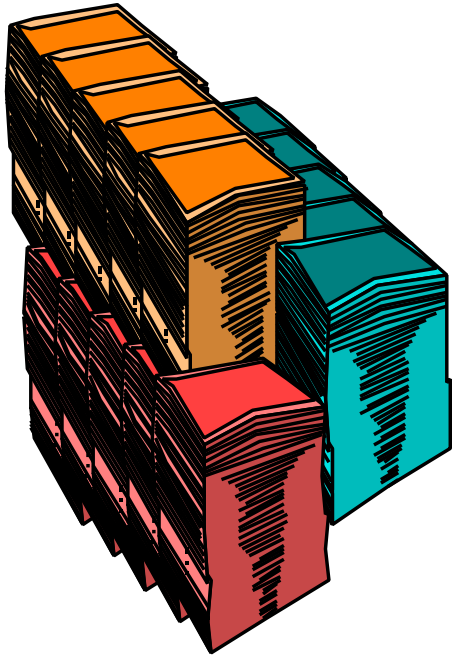
4.20 Statistical Techniques

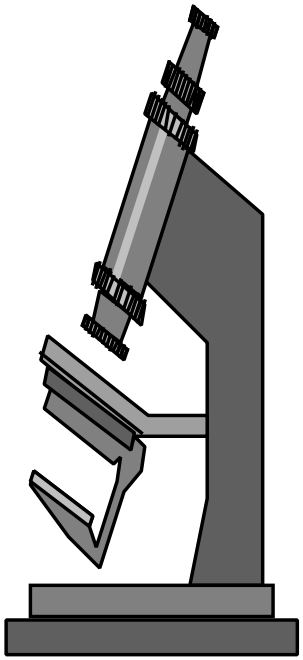
- This element title does NOT say SPC - it says Statistical Techniques.
- Not limited to production line.
- Metrology
- Shipping
- Maintenance
- Many other opportunities.

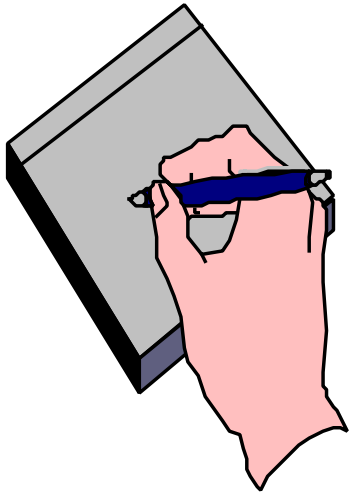
Basic Definitions

Statistics:

the science of collecting, analyzing, interpreting and presenting data.







A ***Statistic*** is a single characteristic taken from this process.

Universe, Populations & Samples

Universe:
the collection of all elements

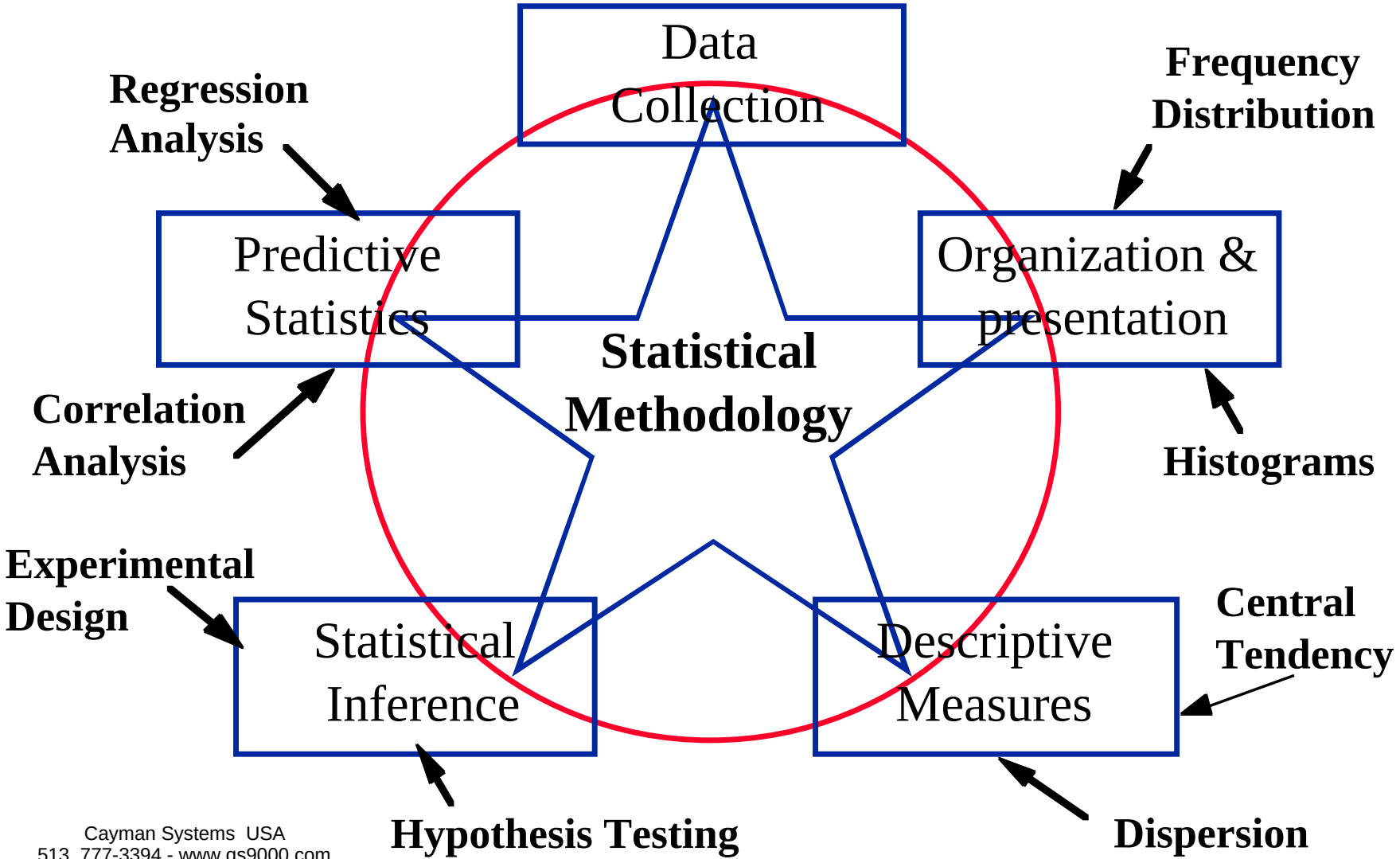
Population:
the set of objects of interest

Sample:
a subset of objects taken from the population

Random Sample:
all possible samples of the same size have an equal chance of occurring.

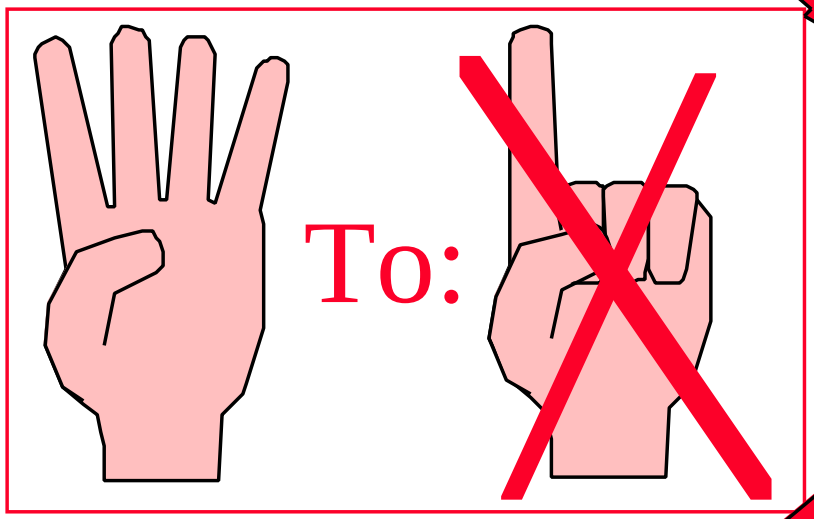
Statistical Methodology

Statistical methods are procedures for drawing conclusions about populations utilizing information provided by random samples.



Classification of Statistics:

◆***Descriptive statistics:*** the methodology of efficiently collecting, organizing, and describing data.



◆***Inductive Statistics:*** the process of drawing conclusions about unknown characteristics of a population usually based from a sample taken from the population

◆***Predictive Statistics:*** the process of predicting future values based on historical data.

Tomorrow we will produce 5000 parts, based off of last weeks production of : 5250; 5500; 4500; 4750; 5000

Four Levels of Measurements

- **Nominal:** Objects are classified into simple attributable categories with no quantitative difference between them, (Yes/No, Good/Bad).
- **Ordinal:** Objects are able to be arranged, ranked, or ordered into a meaningful attributable arrangement with no real measurement. (Yellow/ Blue/Green, Square/Round/Triangle)
- **Interval:** observations are able to be ranked into exact differences between any two observations, measurements with no natural origin or zero, 80 degrees is not twice as hot as 40 degrees. A one unit scale change corresponds to a one unit change on the object being studied.
- **Ratio:** contains all the properties of interval but has a natural origin. Having a natural origin allows 25 to be half of 50.

Note that each successive level has all the properties of the previous.

Section II: Sector Specific Requirements

QS 9000 - Section II Sector Specific Requirements from QS 9000					
Production Part Approval Process					
General	1.1				
Engineering Change Validation	1.2				
Continuous Improvement					
General	2.1				
Quality & Productivity Improvements	2.2				
Techniques for Continuous Improvement	2.3				
Manufacturing Capabilities					
Facilities, Equipment, and Process Planning & Effectiveness	3.1				
Mistake Proofing	3.2				
Tool Design & Fabrication	3.3				
Tooling Management	3.4				

Section III: Customer Specific Requirements

	QS 9000 - Section III Customer Specific Requirements from QS 9000				
Chrysler					
Significant Characteristics					
Annual Layout					
Internal Quality Audits					
Design Validation/Production Verification (Yearly)					
Corrective Action Plan (Chrysler 7D elements)					
Packaging, Shipping and Labeling					
Process Sign-Off					

Section III: Customer Specific Requirements

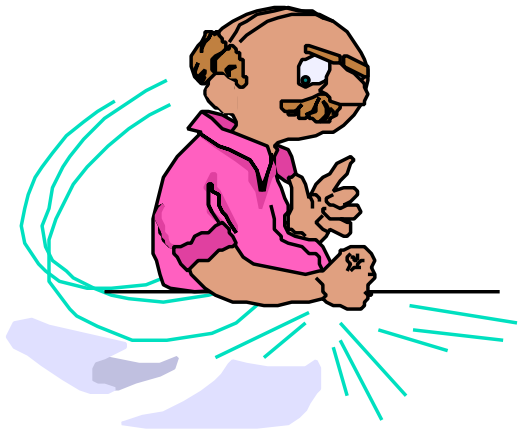
QS 9000 - Section III Customer Specific Requirements from QS 9000					
Ford					
Control Plans & FMEAs					
Shipping Container Label					
Equipment Standard Parts					
Critical Characteristics					
Set-Up Verification					
Control Item Fasteners					
Heat Treating					
Process & Design Changes for Supplier Responsible Designs					
Supplier Modification of Control Item Requirements					
Engineering Specification (ES) Test Performance Requirements					
System Design Specification					
Ongoing Process Monitoring					
Prototype Part Quality Initiatives					
QOS					
Qualification & Acceptance Criteria for Materials					

Section III: Customer Specific Requirements

	QS 9000 - Section III Customer Specific Requirements from QS 9000				
General Motors					
General Procedures & Other Requirements					
GM 9000 Documents					
GP11 - Pre-Prototype and Prototype Requirements					
GP6 - Supplier Submission of Match Check Material					
GP9 - Run @ Rate					
GP10 - Supplier Test Facilities					
GP4 - Pre-production/Pilot Material Shippiong					
GM1805QN - Key Characteristic Designation System					
GP8 - Continuous Improvement					
GP5 - Problem Reporting & Resolution (PR/R) Procedure					
GM Supplier C4 Information					
GM1724 - Shipping/Parts Identification Label Standard					
GP7 - Component Verification & Traceability					
GM1731 - Traceability Requirements					
GM1737 - Part & Component Bar Codes ECV/VCVS					
GM1738 - Packaging & Identification Requirements					
GM1797 - Shipping and Delivery Performance					

QS 9000 Reminders

- Does NOT define quality
- Is NOT a one-time process
- Is NOT easy
- Requires commitment
- Requires resources



Teams

- What is a team?

  Two or more individuals who co-ordinate activities to accomplish a common task or goal.

- Maintaining Focus

  A separate team for each product or project.

Facilitation

- Team leaders are in a tough spot. Most are managers who have been given new roles as their departments have evolved into functional and cross-functional teams. Unfortunately, the skills that helped them be successful as managers don't necessarily apply in a team environment. In particular, a team leader often must facilitate decision making, rather than making the decision alone. Team leaders are still responsible for achieving results, yet now they are supposed to empower, not manage, others. To be successful in this new environment, team leaders need a new set of skills to channel the team's energy toward the achievement of its goals.
- Through practice and feedback, team leaders must learn the skills they need to effectively maximize a team's energy, thinking, and resources. This helps empower teams as they meet to move forward on issues, solve problems, and make decisions.

Team Effectiveness

- Teams are proliferating in American business because of their ability to achieve quality results quickly and effectively. Because of the push to "get the job done," however, most teams don't take the time to develop clear agreements about their team charter, the way they work together, or their internal processes. At the very least, this lack of alignment creates stress in individuals and teams. At its worst, team members may unknowingly be working at cross-purposes, undercutting the productivity of the team as a whole.
- Building Team Effectiveness engages team members in a focused discussion about their work as a team and how the team achieves success. Gaining clarity and commitment regarding the team's purpose, partnership, and productivity yields better team relationships and enhanced team results.

Performance Needs

- Build commitment to your team purpose and partnership by reviewing issues critical to their development
- Develop guidelines for team productivity by addressing norms for decision making and limits of authority
- Create a collective vision of what your team can become in the next year
- Build an action plan to move them toward sustained team effectiveness.

Application

- Team members must "get on the same page" regarding areas critical to performance
- Teams must revisit their missions and their role to ensure continued high performance
- New teams can avoid the usual confusion of a "team start-up," enabling them to solidify more quickly into a focused and unified work group.

Team Structures

Two Types of Team Structures

	Natural Work Group	Task Team
Membership	Work area or unit. Representatives from support groups on as-needed basis.	Representatives who have key information or are stakeholders.
Member Selection	Participation is mandatory.	Assigned by steering committee or uper management.
Project Identification	Assigned by management or identified by team and within its authority.	Assigned by or mnegotiated with steering committee or upper management.
Team Life Span	Ongoing.	Disbands when task is finished.
Leadership	Leader appointed by management.	Leadership shared or delegated by members.

Team Organization

- **Cross-functional**
  - Engineering (Typically the leader)
  - Quality Assurance
  - Purchasing
  - Manufacturing Engineering
  - Material Control
  - Sales/Marketing
  - Etc.
- Participation appropriate for phase being conducted
- Resources - Team defines 'Needs'
- *Should* involve customer or subcontractor participation (not always feasible)

Team-to-Team Communication

- Manage using a process
- Understanding of 'How We Work As A Team'
- Should have a Focus Person & Distributed Minutes
- Customer teams
- Internal teams
- Supplier teams
- Sub-Teams

Define Team Intention & Scope

- Select team members and functions
- Define roles and responsibilities
- Identify **external** customer needs, expectations and requirements
- Identify **internal** customer needs, expectations and requirements
- Complete preliminary feasibility study
- Identify costs, timing and constraints
- Identify documentation process and method
- Develop program plan (if project is a go) or other intended plan

Successful Teams

- Are management directed and focused
- Build their own identity
- Are accountable and use measurements
- Have corporate champions
- Fit into the organisation
- Are cross-functional

Some teams just "Do Not Work"

Basic Team Rules

- Determine if there should be a meeting
- Decide who should attend
- Provide advance notices
- Maintain meeting minutes or records
- Establish ground rules
- Provide and Follow an agenda
- Evaluate meetings
- Allow NO interruptions

More Team Ground Rules

- Ground Rules are an aid to “self-management”
- Team must develop their own ground rules
- Once developed, everyone must live by them
- They can modify or enhance the rules as they continue to meet

Team Meeting Responsibilities

- Clarify
- Participate
- Listen
- Summarize
- Stay on track
- Manage time
- Test for consensus
- Evaluate meeting process

Decision Criteria / Model

- One person makes the decision
- One person consults the group, then makes the final decision
- Team or group makes decision based upon majority rule or consensus

Finale

Customer Satisfaction

- Improve Product
- Improve Performance

- Increase Business
- Increase Profits

Wrap-Up

- **How To Begin**
  - Examine your commitment
  - Examine your reasons
  - Define your resources
  - Further your education
- **Not a panacea, cannot neglect...**
  - Marketing 101
  - Competitive Strategy 101
  - Human Resources 101
  - Project Management 101

Future ‘Specification’ Trends

- Trend towards international agreements in business and trade (e.g.: NAFTA & GATT)
- ISO 14000: Documented environmental quality system
- Occupational Safety and Health
- Federal Transportation Agencies

Additional Resources

Tune your browser to http://www.qs9000.com

- National ISO Support Group

  (616) 891-9114

- Society of Automotive Engineers

  (412) 776-4841

- American Society for Quality

  (Formerly the ASQC)

  (800) 248-1946

- Society of Manufacturing Engineers

  (800) 733-4763