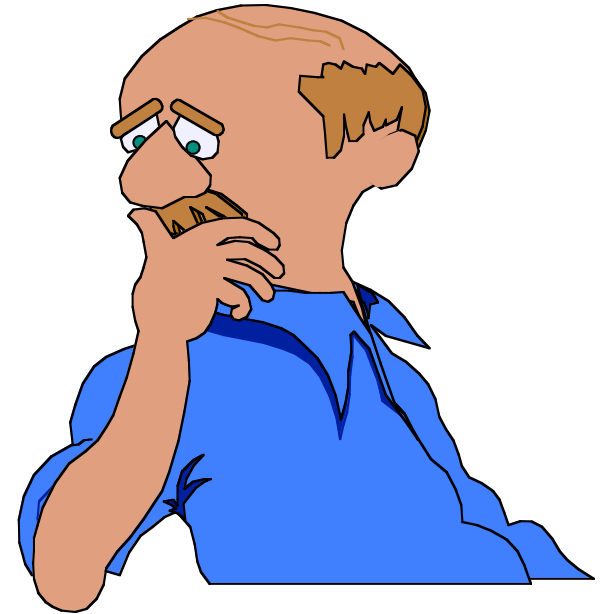


# ISO 9001 Awareness Information

# We've Done This Before...

Why will this be  
different?



# Basic Responsibilities

- Know your job duties!
- Know your documentation!
- Do you job correctly!

# The Basics

## Say What You Do

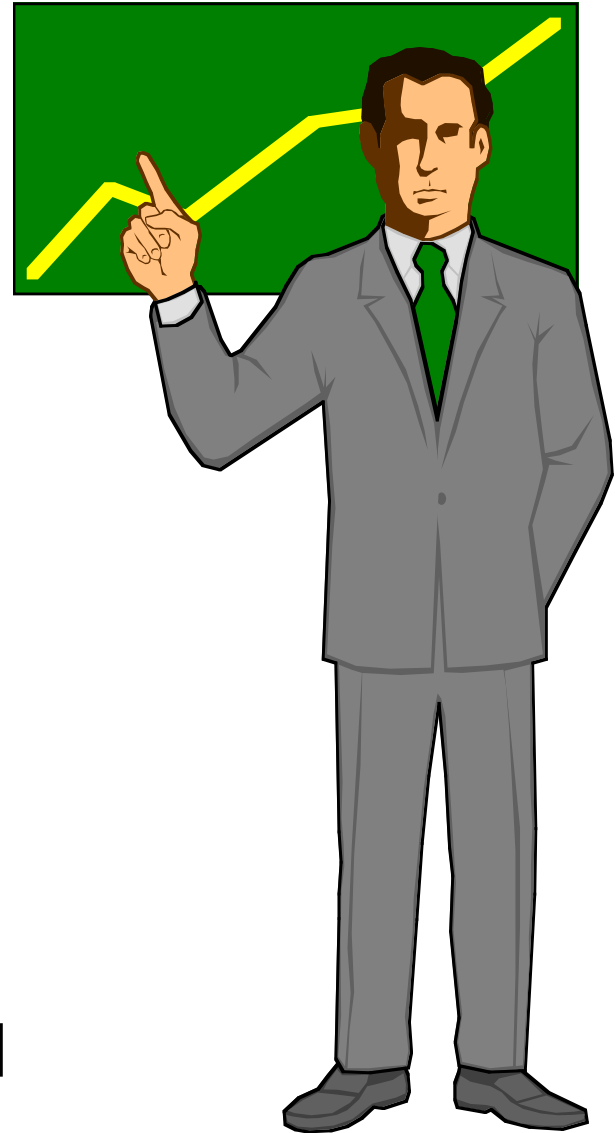
This means document your systems so you will consistently do the job the same way every time. We must make sure we have appropriate documentation.

## Do What You Say

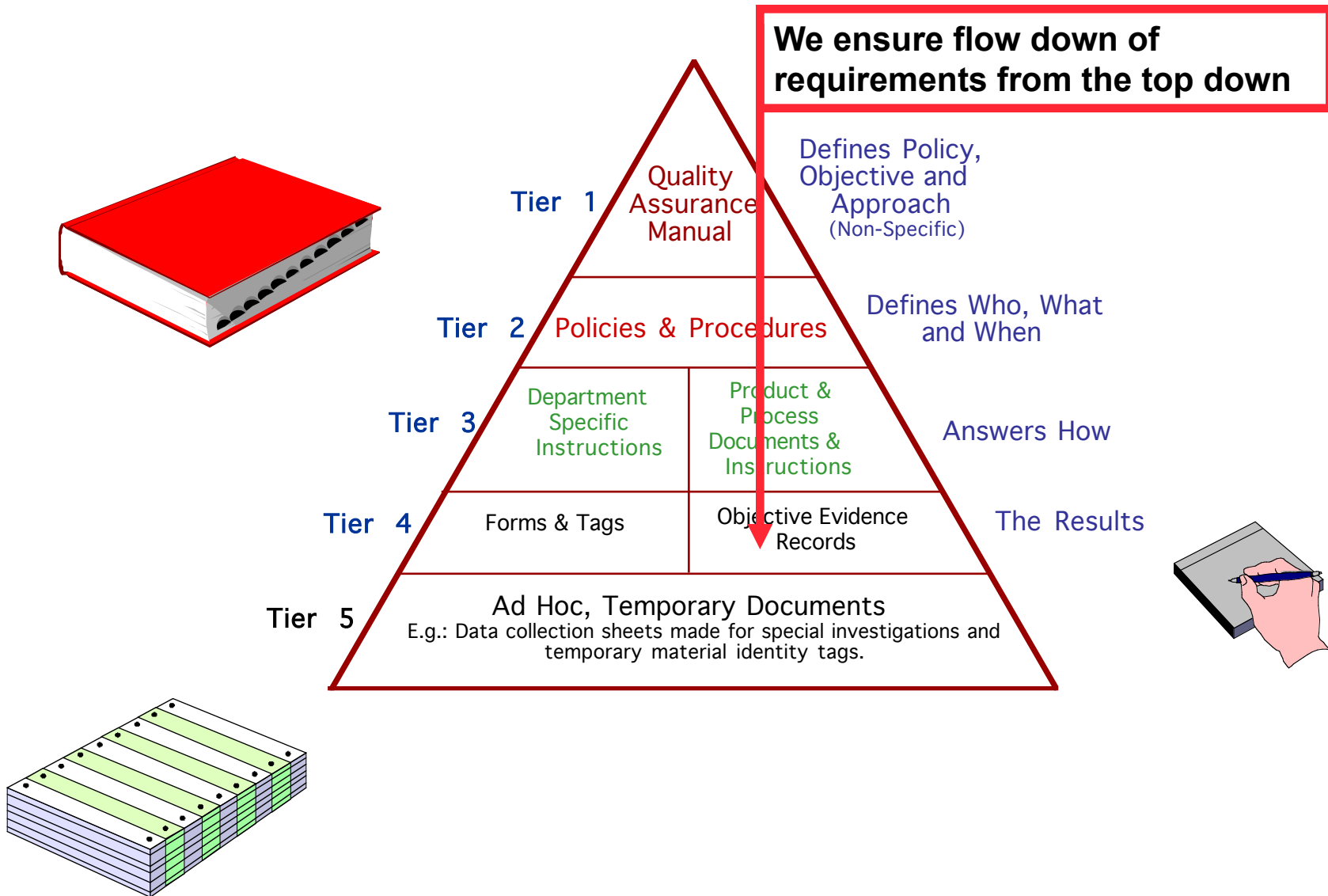
This is what the auditors want to see. Objective evidence that what you say you are doing in your documentation is what you are doing in practice.

# Payback

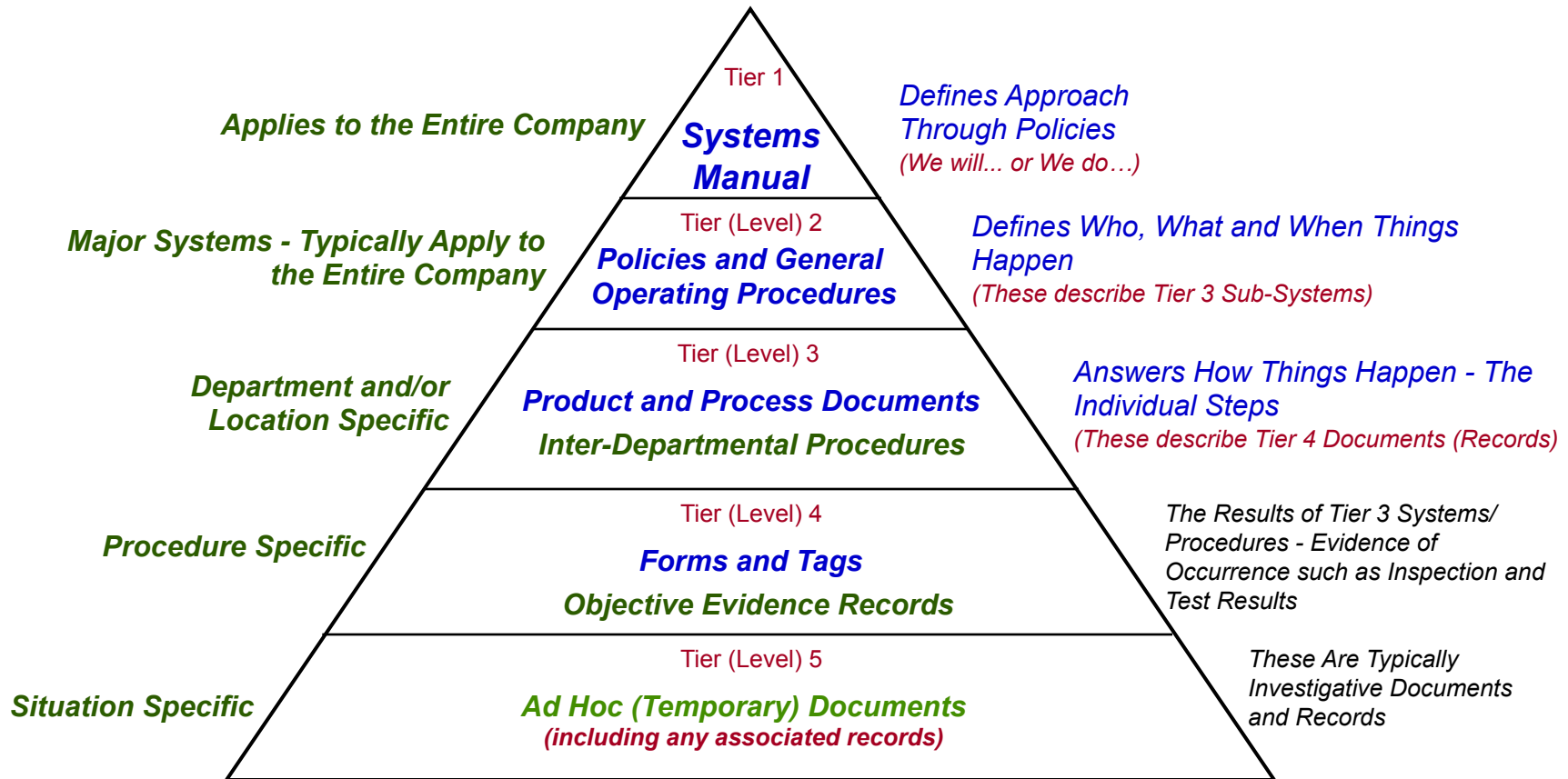
- Companies **minimize deficiencies** in supply and support of products and services.
- Companies **identify problem areas** and address them quicker.
- Companies **identify customer needs** more accurately.
- Companies **become more consistent** in their product and services.



# Typical Documentation Tiers



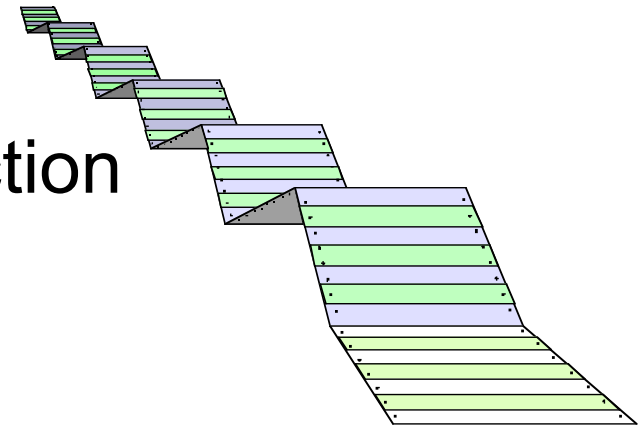
# Documentation Structure



**The 'Standard' Document Pyramid**

# Typical Types of Records

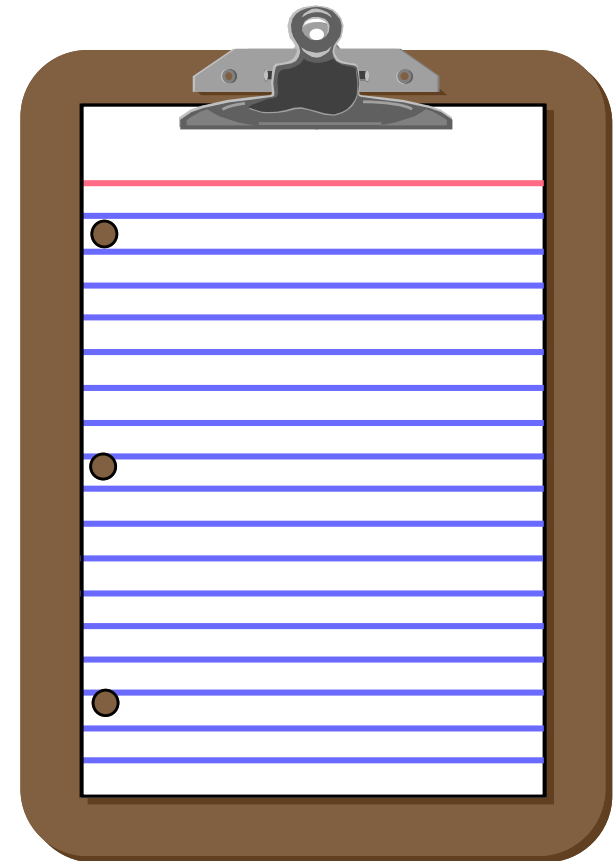
- Contract Review
- Purchasing
- Identification and Traceability
- Process Control
- Inspection and Test
- Control of Measurement and Test Equipment
- Non-conforming Product
- Corrective and Preventive Action
- Internal Quality Audits
- Training





# 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



# Preparation

- To prepare for the audit you should be reviewing your area for problems.
- Start at one corner of the room and sweep through it.
- Have an way to identify what you have looked at.
- Be ready to identify and explain every piece of paper in your area whether on walls, in drawers or in open files (including 3 ringed binders).

# Preparation 2

- Review all the questions in this presentation.
- If there are any questions you cannot answer, **FIND** the answer - ask someone who knows!
- If you find what you believe is a problem, notify the appropriate person.

# 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 be audited by the company which registers your company. That company is your **Registrar**.



# What Is An Audit?

- An Audit is a check to ensure that what a business says it does is actually what it is doing.
- In ISO 9000 and ISO 9001 an audit is meant to validate that a company ‘Says what it does and Does what is says’. For the most part this is a verification and validation of written procedures, policies and related documentation.



# What is Documentation?

- Documentation is much talked about. There are different types. There is the Systems Manual and there are "Level 2's" 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'**.

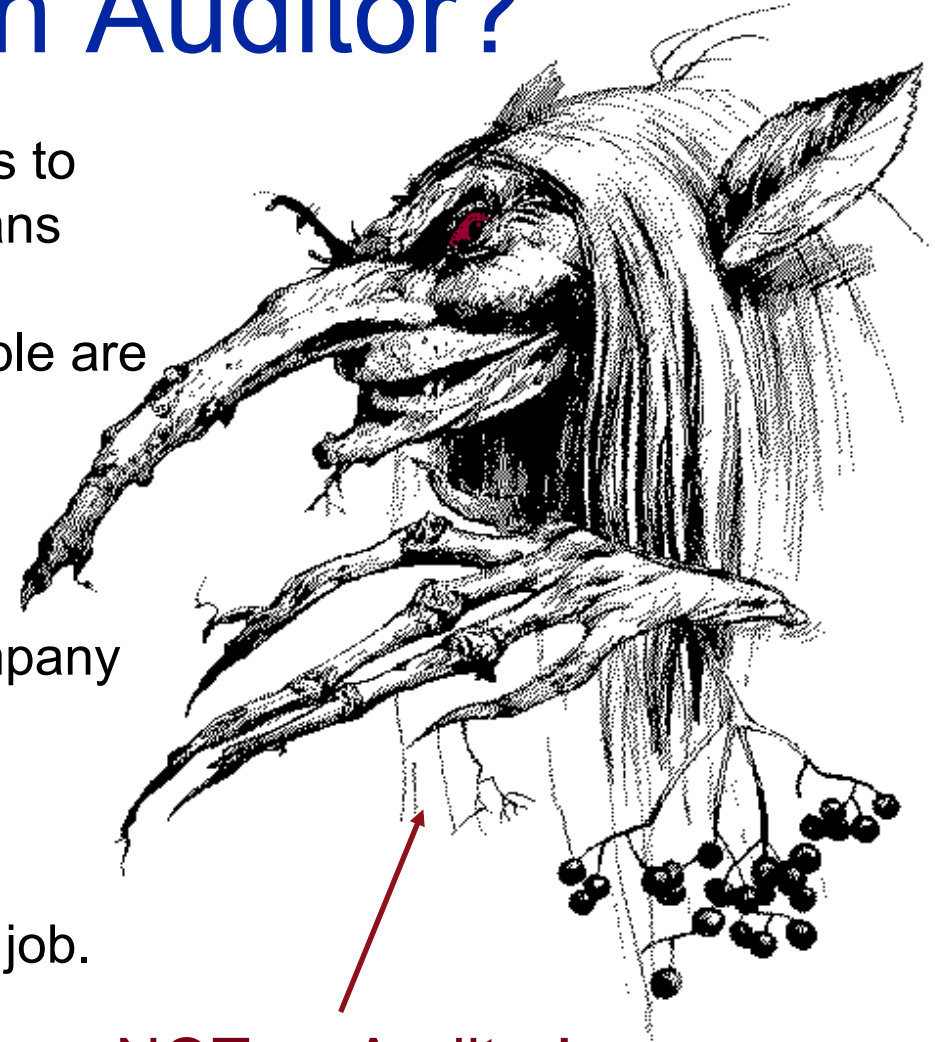
# What is Controlled Documentation?

- A controlled document is typically one that is Revision sensitive - BUT - Not always!!
- 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.



# What is an Auditor?

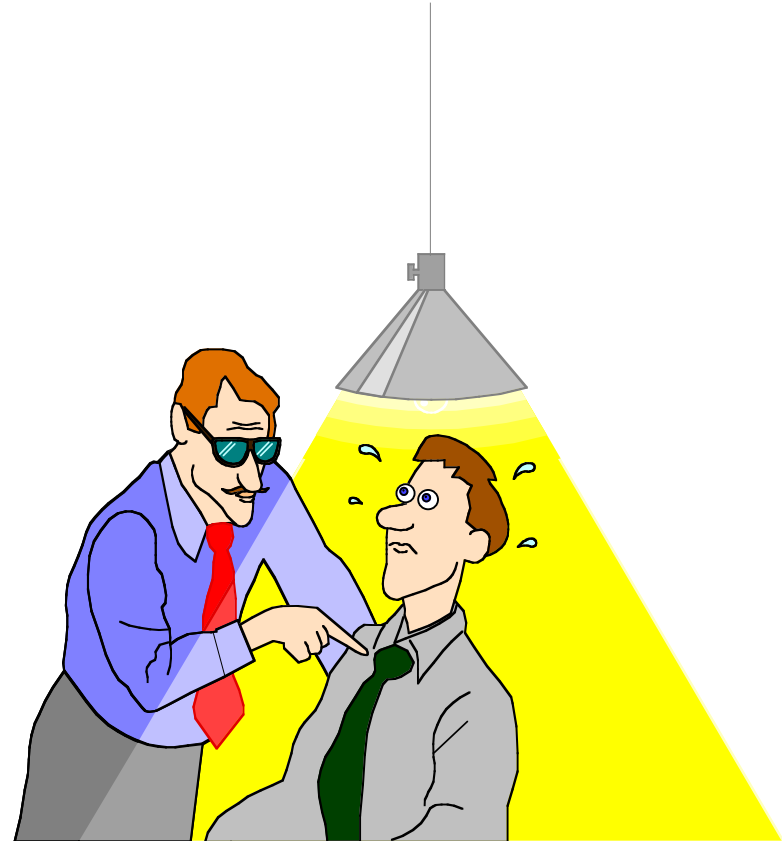
- An auditor is a person. Their job is to validate documentation. This means they look at documentation (instructions) and make sure people are following the documentation.
- Auditors go from company to company validating documentation.
- Auditors are just people who ask questions about how you do your job.



**NOT an Auditor!**

# Auditors Are Not!!!

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



# The Reason 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 specialize 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.

# Reasons for Audits 2

- 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.

# What Will The Auditors Do?

- The auditors will look at written procedures and policies (verification).
- The auditors will then look at and ask how people in the company do things. They will look to make sure each person is following written procedures and policies (this is called **validation**).
- They will look at records to ensure everyone is properly completing paperwork (examples would be process related documentation and 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

Associates

# 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 Gunderlin 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 and/or Manager** - The area supervisor or other person directly responsible for the area will be present.

- Remember - **YOU ARE NOT ALONE!**

# Types of Audits

- **Internal Audit**

An audit of internal systems and/or procedures. An internal audit is most often performed by people who 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'. Your registrar audit is a third party audit.



# 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. Many registrars (for example, LRQA does **\*NOT\*** require this) 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 MANAGER **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 answer a question for another person.** (Some auditors will \*test\* people for this) 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 escort with the auditor must take the lead from this point.
- **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.

# 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 beyond the question asked.** 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.
- **Right NOW!!!** If there is any documentation which you are using that you think or know is not correct, contact your supervisor immediately!

# Some Questions to Expect

- What is ISO 9001?
- 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 **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?
- What do you do if your machine jams or malfunctions?

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

# Supervisors 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 Labeled?

- **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 Your 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**

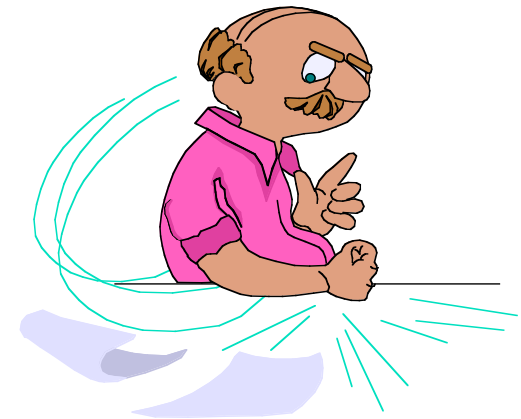
Is Each Properly Labeled (Identified)?

Are They Where They Are Supposed To Be?



# ISO 9001 Reminders

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



# Do **You** Have Questions?

- If any of this presentation confuses you, talk to your **manager** and ask him/her your question(s).
- The **ISO 9001 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!**