

## Being Audited - Life on The Other Side Of The Fence

### Caution!

The following is meant to give you some **ideas**. For example, you will see references to documentation - most of which, by context, is paper documentation. As we all know, there are vast changes taking place every day, from Microsoft's latest "XP" software experiment to 21CFR11 compliant document management software. Some companies are cutting edge - scanners at every PeeCee and a PeeCee at every station and desk. Some companies are still basically paper based. Most are somewhere in between.

This said, take the ideas presented into the context of your company and systems. Some companies have travelers, for example, while others do not. Some companies keep 'work instructions' at each station while other companies have 'work instructions' which are part of the traveler package. And, of course, sometimes OJT (or **education or experience or a combination thereof**) takes the place of specific work instructions.

Also consider **vocabulary**. As an example, some companies call 'work instructions' 'process sheets'.

# Notes

# Being Audited

- A positive and constructive attitude toward auditing can make the exercise enjoyable for both the auditor and the auditee. **Most people enjoy telling you what they know and how good they are at their job.** In addition, without an air of suspicion and distrust, **auditees are likely to confide concerns or suggestions** that are in the company's best interest to address and not simply lay blame.
- In the course of seeking conformance, concerns or nonconformances may become evident, but it is important that everyone involved understand that the intent is to verify / validate conformance. **Conclusions must be based on objective evidence, observation, interview and documents.**
- If auditing is understood as a staff persecution or a 'witch-hunt,' then do not be surprised when (not if, but when) the members of your company respond with suspicion, distrust and even hostility. It is extremely important that management appreciate the purpose and principles of quality system auditing and that the auditors conduct themselves accordingly.
- The results of an audit should indicate whether the quality system is properly implemented and maintained. These results are considered by management for action as necessary.

## Notes

One way to ensure that everyone understands and retains a good perspective on the intent of a management system audit, is to develop an audit mission statement. A two or three sentence statement that captures the positive and constructive intent of your company's audit program can help keep the auditor and auditee on track.

Finally, Quality System audits are **not surprise audits!** They are planned and everyone knows when it will happen, and what elements or departments will be audited. There should be no surprises, as this tends to foster mistrust towards the audit process, and a feeling of "them versus us" between your company and the auditors.

# What is Controlled Documentation?

- A controlled document is a document which, if changed, effects some part of the process or product. These can be 'procedures', process documents, product or part drawings (prints) or other 'similar' documents. Forms are typically controlled documents.
  - Typically there will be one or more list(s) of master documents.
  - If a controlled document is changed, a record of the change has to be made. This means there must be 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 (read **Communicate the changes**).
  - Every employee must know how to check to see if documentation they are using is **the most current version**.

## Notes

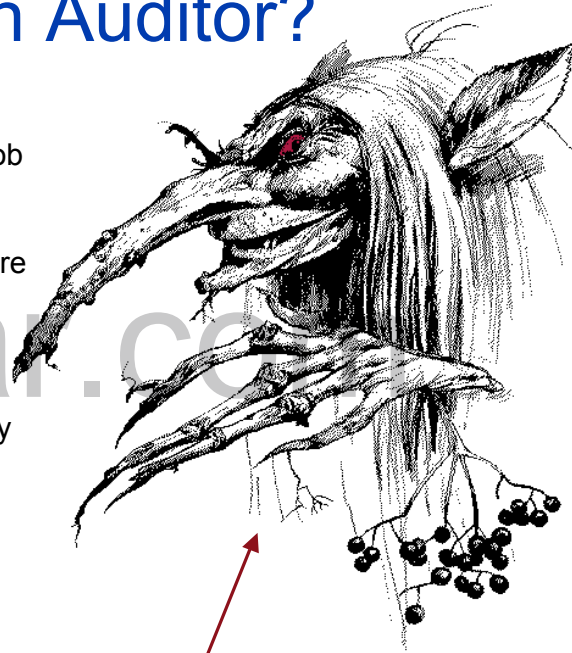
This is something everyone should know with respect to documentation they are responsible for.

Everyone **MUST** understand the basics of what controlled documents are all about.

Everyone should have a basic understanding of what they have to do to effect a change in a document.

# What is an Auditor?

- An auditor is a person. Really! 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 and asking people about their documentation.
- Auditors are just people who ask questions about how you do your job.
- Auditors ask people questions about how they do their job.



**NOT an Auditor!**

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**Auditing and Being Audited**

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## Notes

This really addresses outside auditors, or fears thereof, more than internal audits. I include this slide for those of you who are preparing folks for their 'first' external audit. Many people have a real fear of auditors. Even some who have experienced many audits. For some people it's like taking a test. As we all know, there are some 'good' test takers, and some 'bad' test takers. Ensure that everyone is as 'relaxed' as possible.

At one larger client, during the registration audit, 2 people became so upset whilst being interviewed that they broke down and had to be taken to the local hospital. No kidding. And it wasn't an evil auditor. They were just very scared people. I try to tell folks to remember that they do their jobs every day and since the auditor can only ask questions about what they do, and not what others do, it's an easy test. Heck, they do the same stuff every day for the most part.

This is, of course, easy to tell someone. That doesn't mean they'll take it to heart, but it may help alleviate some apprehension.

# 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 (Examples would be SPC charts and check lists which need to be initialed and dated).
- They will look to make sure everyone is properly trained to do their job.

## Notes

The auditors are looking to see what people are doing and, as stated above, it's pretty simple stuff. After a registration audit, I have heard every time, from many people, the same thing:

“Is that all there is to it?”

If you're prepared, when the 'test' is over - Yes. Yes. Yes. That's all there is to it.

# Who Will Be Audited?

- **Absolutely Everyone** whose job affects quality is subject to the audit. **Which is to say Everyone!**
- 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 plant manager), job duties and responsibilities increase.
  - Corporate Personnel
  - Plant Manager
  - Departmental managers
  - Supervisors
  - Engineers
  - Technical personnel
  - Hourly employees

# Notes

# 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 Motorola GDL 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!**

## Notes

**One very important thing to remember here is to keep the size of the 'gang' as small as possible.** During audits at some companies, 'gangs' tend to develop. You have at least 3 people to begin with, but then someone will drift over and sorta stand there - just to listen in, of course. Then another, and then - well, you get the idea. Next thing you know you have a 'gang'.

Then the questions start. Someone asks something like "Would it be OK if I keep mine in a file drawer...?" The question is from one of the 'listeners' who just 'dropped by to listen'. Next thing you know there's a near riot. People talking to each other, etc.

The situation is often tense enough without disruptions and a 'gang'. Let the auditor do his/her job. **Keep the group small** and keep on the agenda.

# 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'. This is the type of audit the registration audit is!**

## Notes

You can use this slide to explain to your employees what the different types of audits are - assuming you plan to prep everyone. Some companies have been through many, many audits and explanations may not be necessary. But if your company has never gone through a major audit before, you might want to prep them with some 'general' information.



# 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.
- 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.

## Notes

Another 'audit prep' slide.

# 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.

## Notes

These are a few things I like to cover in 'prep' sessions. These help reinforce the idea that this is not all a secret plot to 'Get Them' by management or anyone else. Let them know everything is open and nothing is 'hidden' to be ;'sprung' on them later.

# Things Everyone Must Know

- **Know what documentation affects YOU!**
  - You must know what documentation applies to your job and **know how to check to make sure you are using the 'latest' version**. This should have been explained 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.
- **Know what Training you have had**. If you do not know, **ASK YOUR SUPERVISOR NOW! Don't wait until 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.
- **How do you know if your equipment is in calibration?** Know how to read a calibration label.

# Notes

# Things to Do

- Be patient. **Wait for the auditor to ask a question.**
- **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 exactly! “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.

## Notes

During 'prep' sessions I really like to give these as minimum pointers. Each topic above I have a story for, but I'd really have a long essay on some of them.

One I will include is that sometimes an auditor will ask a question, get an answer, and then just stare at the person. Within 10 to 30 seconds that person will start talking again - about something. About anything. This is because they see the auditor looking at them and since the auditor is not saying anything the auditor must be waiting for more 'information'. It's a very old auditor 'trick'. If they need more 'clarification' wait for them to ask for it. Watch out, or you'll find the auditee rambling on forever.

# 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.

# Notes

# 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 unless the auditor asks you to.** 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!  
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**Auditing and Being Audited**

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# Notes

# Some Typical Questions to Expect

- What is ISO 9001 (or QS 9000)?
- Who is the QS Management Representative?
- What is the quality policy? What does the quality policy mean to you?
- Does your company do a good job meeting the quality policy objectives?
- How do you know whether you are doing your job well or not?
- How do you know what to do? Tell me about your job and your duties. What are your quality responsibilities? Tell me how your job affects the quality of your product.
- What are controlled documents? What documentation do you follow (are you responsible for)? Where is it? How do you know you are using the most recent version? If your documentation says you should do something a specific way and someone else tells you to do it differently, what do you do?
- How do you know if your equipment is in calibration? What do you do if it is not? Can you explain what this calibration label tells you?
- Do you ever have problems come up? How do you handle them?
- When you find nonconforming product, what do you do?

# Notes

# 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 Labeled?

- **Defective Material**

- Is Defective Material Identified and Segregated?
- Is A Defective Material HOLD Area Identified?
- Is DMR Material Dispositioned in a Timely Manner?

# Notes



# Some 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, Organized and Orderly?
- **Baskets, Boxes, Racks, Shelves & Other Containers**
  - Is Each Properly Labeled (Identified)?
  - Are They Where They Are Supposed To Be?

# Notes

Good Luck!



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**Notes**