



SUBJECT	On Being Audited	REV	12-8-09
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If you work for an organization involved with meeting a quality system standard, spec or government regulation, sooner or later you will be on the receiving end of a quality system audit. The auditor might be one who works for:

- your organization (an internal auditor),
- an outside “Registrar” (a certification auditor),
- a customer (a supplier auditor), or
- a government agency (often referred to by names not used in polite company because, unlike the other auditors, they typically arrive unannounced.)

Sometimes, being audited is upsetting and it does not go well. Other times it isn't upsetting and you come through with flying colors. The difference is really simple. If you are prepared, you will do well. If you are not prepared, you won't.

The good news is you will be prepared if you know:

- what the auditor will do,
- how the auditor will do it,
- what the auditor will expect of you, and
- how you should respond.

The other good news is that:

- if you are prepared, there will be no bad news, and
- if you are not in a management position, the guidance in this bulletin is possibly all you will need.

What does an auditor do?

An auditor must answer three questions:

1. Do the quality system “controls” (that is, your manual, procedures, work instructions, standard practices etc.) require you to do all the things that the quality standards, rules and regulations require?
2. Does the organization follow the system and its related controls?
3. Does the system work? In other words, does it deliver the results that Management wants? (For example, is it realizing the Quality Policy? Is it achieving the metrics - the numbers- set by Management?)



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How does the auditor do it?

The auditor looks for **objective evidence**. These are the hard facts – not opinions - that support the answers to those three questions. An auditor gets that evidence in three ways:

1. **Observation** - It comes from what the auditor sees.
 - Does the system paperwork include everything it is supposed to? (Does it say what you do?)
 - Does the organization perform activities the way the paperwork requires? (Do you do what it says?)

2. **Examination of records** – Records provide a history of what was done in the past. Many of these records come from forms you fill out such as, inspection records, test reports, records of reviews, etc.

3. **Inquiry** – The auditor makes verbal inquiries (asks questions) of a sampling of people at all levels of an organization. But the auditor is not auditing people: he/she is auditing the **system**, to learn if it provides all the information, tools, equipment, training and instructions people need to get their jobs done. The questions are not meant to test **you**. You will neither pass nor fail. You won't get "a grade".

Typical auditor inquiries

Auditors ask open-ended questions. They cannot be answered with a simple Yes or No. Open-ended questions provide much more information. “How do you perform that activity?” results in a lot more information than “Do you perform that activity?”

Here are some questions auditors ask.

- Would you give me a "birds eye view" of your job?
- Please tell me/show me how you do that.
- How do you know what to do and how to do it?
- What training did you get?
- What procedures, work instructions, flow charts or other documents do you use?
- How can you tell if they are the correct/latest revision?
- Where would you go or whom would you ask to find out?
- What do you need to start your work?
- What do you do when you receive something that isn't right (nonconforming)?
- What must you do to check it before you start or how do you know it's OK?
- What do you deliver to the next person in line?



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- What do they expect to get from you and how do you know if they are satisfied?
- Who checks your work and how is it done?
- How do you know you did your work correctly?
- What inspections or tests are made? Show me any instructions you use for that.
- Who signs off, checks or stamps the results? Show me.
- What forms do you fill out? Show me some completed ones.
- What reports do you have to prepare? Show me some.
- To whom do you deliver the completed forms/reports?
- What do you do if you make a part that isn't right?
- What do you do when something goes wrong?
- How do you know you are doing a good job?
- How do you measure your success?
- How does your supervisor measure your success?
- Who is the organization's Management Representative?
- What does the company's Quality Policy mean to you?
- What company quality objectives – measures or metrics or target numbers - do you relate to the most?
- What gets measured in your department or for your job?
- What has the company done to improve how this job is done?
- How do they involve you?
- What have you done on your own to improve how the job is done?
- If you were boss, what changes or improvements would you make to your job and why?

What can you do to come through it with flying colors?

Before the audit – Ask yourself these questions

1. Have I reviewed the typical audit questions? Am I satisfied I can answer them easily. (You can often find the answers in the procedures for your job, in the training you received for the job, in some document that the company gives or makes available to you, or directly from your supervisor.)
2. Have I reviewed any procedures, work instructions, travelers, etc. I must follow?
 - Are they the correct, current versions I must follow?
 - If I am permitted to have any obsolete documents at my work place, am I certain they are clearly marked as such? If not, have I **REMOVED THEM**?
 - Do they reflect how I actually perform the work?
3. Is my work area neat, clean and orderly? (*A place for everything and everything in its place. We never get a second chance to make a first impression.*)
4. Are my tools & equipment in good working order?
 - Is the equipment I use to inspect/test product at any stage of production in current calibration?
 - If preventive maintenance (PM) is require on machines I use, has it been done and recorded?



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5. Have I referred any questions or problems I may have about any of this to my supervisor or to our Management Representative?

During the audit

- Listen carefully to the auditor’s questions and answer them to the best of your ability. Tell the facts as you know them. If you don’t know the answer to a question, say so. If the auditor wants more information, he/she will ask.
- If you are not sure you understand a question (audit terms and audit language can be a bit strange), say so. Or, you might want to try repeating the question back in your own words. " *I think you are asking me.....Is that correct?*"
- If the auditor asks you to describe how you do your job or perform a certain activity and if there are procedures, instructions, flow charts, drawings, travelers, etc. that apply to your job, feel free to use them as a discussion guide. " *Here, Mr./Ms. Auditor, let me show you what the procedure says.*" You are not usually expected to commit the contents of these documents to memory. Procedures are tools and are put there for your use, so use them as you would any other tool.
- If you disagree with something the auditor says and are unable to convince him/her to come around to your point of view, you can say something like, " *I'm not sure I agree with that. I'll have to think on it a while.*"
- Don't be afraid to show your confidence in yourself. It tells the auditor that you are in control. That's one of the things a good auditor likes to see. Besides, who knows more about your job than you do?
- Relax. Relax. Relax. Experienced auditors are friendly, respectful and will do everything to put you at ease.

Above all, remember

1. Good auditors do not ask trick questions or try to trip you up. His/her job is not to catch you doing things wrong. The auditor is not there to audit **you** but to audit the **system** that you work in.
2. Most problems are not the fault of the worker (you) but of the system you work in. W. Edwards Deming, one of the most respected quality experts of the 20th century, said, " *In my experience, most troubles and most possibilities for improvement add up to proportions something like this: **94% belong to the system (the responsibility of management)** and 6% are attributed to special causes.*"
3. The measure of a good audit is not the number of problems the auditor can find – auditors do not get paid based on the number of “write-ups” - but on the thoroughness of the audit itself. Think of an auditor in much the same way as you would your doctor. Both of you are happiest when, after a thorough examination, the



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doctor gives you a clean bill of health. Unlike the doctor, however, the auditor is not permitted to provide or recommend solutions toward improving the health of the quality system.

If you found this guidance helpful, feel free to share it with others in your organization.

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