



Quality Auditing Services White Paper:

Preparing Your Team for a Third Party Audit

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<http://www.quality-auditing.com>

How to help prepare your team

Getting ready for an Quality Management Systems audit can be nerve wracking. Some employees do not know what to expect from an audit. Even though they may have had lots of practice with internal audits, it just isn't the same as a third party or customer audit. To help prepare your team for an audit, QAS has prepared the following guidelines. Remember the purpose of an audit is to gather objective evidence to verify that your company complies with the requirements of ISO 9001:2000, TS 16949, ISO 13485 or AS9100. It is a fact finding event not a fault finding one.

For Management / Supervisory personnel:

If you are not already, become familiar with the procedures, work instructions, control plans in the department and know where they are located. In addition, a walk through the area to make sure it is clean and neat. At the same time, check the area to ensure that there are no "uncontrolled documents". Take down those handy little notes that direct people what to do that are posted but not controlled. Or better yet, incorporate the directions on the sticky notes into the work instructions. Also, review any work instructions or prints to make sure there are not handwritten changes that have not officially gone through the document control process. In addition, verify that operators are performing work to standard work, routers, control plans, travelers, etc. When reviewing operator instructions / manufacturing instructions, pay close attention to inspection frequency and criteria. It is a good idea to double check to make sure that current operations are performing to the required inspection frequency and criteria. In addition, review measuring equipment to ensure are properly calibrated. Review any applicable past corrective actions that the third party auditor has previously issued to make sure that the corrective actions are still in place.

For all employees:

When you are being audited, answer all questions that the auditor asks you fully and honestly. It is importance to be cooperative. If you do not understand the question that the auditor has asked –it is ok to ask the

auditor to rephrase the question. Sometimes auditors speak in “auditor speak”, and talk in terms that you may not understand. If you are not the right person to answer a question – do not guess; tell the auditor who the right person is to answer the question if you know.

This may be the first time the auditor has been in the building, they are learning a lot about your company. They may not be familiar to company specific terminology so he/she may ask you for clarification. Remember that the auditor is auditing the Quality Management System (QMS), not you. Any failures will be of the QMS, not you personally. Be cooperative with the auditor – acting like you are too busy to be audited is a sure fire way to make sure that the auditor spends more time with you.

Examples of questions that the auditor may ask:

- Walk me through the process? Tell me what you do?
- How have you been trained for this job? How do you know what to do?
- If something goes wrong – what do you do? Who do you notify?
- What do you do with non-conforming (bad) product?
- What kind of records do you keep? How Long? Where?
- What are the objectives/ goals for this area?
- Can you tell me what your Quality Policy is?

What is the guides role in the audit?

Typically the guide that follows the auditor through the areas is the Quality Management System representative. They should be very knowledgeable about the area that is being audited and the Quality Management System. They should take good notes for the audit; the guide may find issues that the auditor hasn't, and could be corrected later. In addition, the guide will be available to clarify any issues that arise during the audit. However, the role of the guide is not to answer questions for the auditee.

Overview

Remember, the audit is an opportunity to make corrections and improvements to the Quality Management System.

For additional information contact Quality Auditing Services at mjones@quality-auditing.com.

US Call 419-277-0354
www.quality-auditing.com

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