

# Quality Auditor Review

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## Making a Good Impression

### *Audit Thinking*

An audit system manager recently told me that it was relatively easy to identify quality auditors that had good technical skills for collecting and evaluating data. What was really hard was to find auditors with good people skills (perhaps auditors need to go to 'charm school' ). Even though an auditor is not trying to win a popularity contest, the impressions that the auditor makes with auditee management, interviewees, and escorts can influence the audit and its effectiveness.

The moment an auditor makes contact with the auditee they are making an impression. The impression the auditor makes is a reflection of the auditee's expectations based on prior contact with the audit organization, the auditee's organization culture, and each auditee's background and experiences. The auditor has no way of knowing these things unless he/she does some investigating.

The auditor could start by asking the audit boss (client) what prior contacts have been made with the auditee organization and what was discussed. This could provide a wealth of background information about who is involved, the formal and informal customers, why they want the audit, their concerns, any difficulties encountered when scheduling the audit, communication difficulties with the audit organization, the audit boss's impressions of the auditee personnel, the auditee organization, etc. If an auditor is going to conduct a second party audit he/she could get on the internet (or library) to find out about a company or talk to the buyer in the purchasing department. If it is a public company, auditors can get copies of the quarterly reports. Some companies have web sites that describe the auditee's products and

services. For internal audits, auditors can seek out annual business plans or progress reports. All this information will help auditors better understand what is important to auditee management. It could keep auditors from saying the wrong things when talking to the auditee.

Every time auditors come into contact with an individual from the auditee organization they are representing the audit organization. What auditors say and do will have an effect on what the individual thinks about the auditor and their organization. People are constantly judging the demeanor of others toward them. Auditors must follow a code of ethics to ensure professionalism and consistency, but audit etiquette is also an important factor for good communication and cooperation. Etiquette is a code of behavior that helps people get along with one another. See insert of *Russell's Rules of Etiquette*.

Impressions made by auditors may be the determining factor on whether they are invited back, whether the auditee chooses to do business with the audit organization again, and whether the audit service is recommended to others.



### From the News Desk

The *ISO Lesson Guide* is an easy to understand overview of ISO 9000 in simplified terms. Each element of ISO 9001 is discussed and key management controls are highlighted. The 65 page pocket guide is illustrated with sketches. Purchase for \$6.95 (plus \$1 S&H) from JP Russell

New: See insert for QAR Home Study Program to earn CEUs.

Etiquette is simply a set of good manners

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# The Audit Guy

Dennis Arter

## *The Audit Plan*

**The audit plan is for the specific event.**

If you wish to be successful as an auditor, you need a plan. This is not the same as the Audit Schedule. An audit plan is specific to an audit assignment. It presents the details for accomplishing your assignment. An audit schedule, on the other hand, defines the areas to be audited, over a period of time, and who's going to do those audits. A schedule is like the overall scheme and the plan is for the specific event. The schedule should be prepared by the client (Audit Boss), with input from her auditors and the other managers in the firm. The audit plan should be prepared by the team leader, with guidance from the client and help from the rest of his team members.

When preparing an audit plan, you first need to define the Purpose and Scope of the audit. This defines why and what. Will your audit be compliance only? Are there concerns from manufacturing about the mistakes this supplier has been making lately? Although the Audit Boss will help by providing guidance, these issues should be addressed by the team leader and his team members.

The specific functional areas to be audited within the organization need to also be defined. This is part of the scope. If you think that folks within the Human Resources area will be interviewed, then say so.

After you have defined the purpose and scope, you should identify the performance standards to be used for this upcoming audit. Recall that one of the fundamental principles of quality auditing is to measure performance against requirements. If you don't know what the requirements are, you cannot perform an audit. The client will help you in this respect, but you will probably have to go to the auditee for specific documents. Informally, call them up and ask, "What procedures and other documents do you use for this task?" Make a list.

If the policy in your firm is to use standardized checklist questions, then these need to be defined. Next comes the identification of team members, with Team Leader, Team Members, Observers, etc. identified by name. This is a good time to verify that all these individuals are

qualified.

The last item on your audit plan should be an overall schedule for performing the upcoming audit. When and where will you hold the opening meeting? How long will the fieldwork take? When do you expect to hold the exit meeting? Of course, these are best guesses, but they will help you and your team members, as well as the auditee, to conduct an efficient audit.

# Make Plans

All of this planning information should be captured on one page. Anything longer is counter-productive. After you and your team members agree on the contents of the Plan, give it to the Audit Boss for approval. The act of approval keeps her cut

in on your planning and promotes accountability within the audit program. After she has signed the Audit Plan, it should be sent to the auditee as part of the formal notification of the upcoming audit.

An Audit Plan is not difficult to produce, but it sure helps you to perform better audits. It acts as a communications tool and assures your Audit Boss and your auditees that you haven't forgotten anything.



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# Quality Audit Primer

## *Auditing tips and reminders*



### *Audit Performance:*

### *Evaluating Document Control*

Most all quality systems require some type of document control. Control of documents can be assessed throughout the audit of the quality system (such as in purchasing and marketing departments) but should be checked separately too. Many registrars continually check document controls at every surveillance not so much to trip up the auditee, but to see what has changed and the subsequent follow up to verify that the change was implemented. This is a key area for all auditors to check to see what is new and to follow-up completed corrective actions.

Quality system documents are the documents needed to ensure that quality requirements (customer requirements) are met. Documents normally describe a part of the quality system in some fashion. They may be high level documents that describe policy or lower level documents that provide detail step-by-step instructions. Documents can also be in more a cryptic form such as a checklist, drawing or specification. Auditors must be flexible in accepting various document formats and structures (such as flow charts, photographs) as organizations test out methods to improve the use and effectiveness of documents. The higher the risk of the product or service the stricter the document controls system. Note: see side bar for list of documents.

Documents can be provided in several mediums including paper, electronic, microfilm, scanned documents, and photographs that contain information that must be controlled and updated. Historically, all documents have been on paper, but more organizations are implementing electronic documentation controls due to the ease of controlling the issuing of documents, distribution of documents, and control of changes. In the past (and present), the amount of effort needed to effectively control paper documents has caused people to question the value of such processes. However, there are several reasons to control documents such as a means to verify planned versus actual activities, the documentation of the activity for training purposes, and establishing a base line for improvement. The key for each organization is

to design a document control system that is effective and meets the needs of the organization.

Auditors must verify that the right documents are available to the right people and that obsolete documents have been withdrawn from all points of use. Some documents may be superseded but not yet obsolete (e.g. certain customers may require a prior model).

Documents that do not affect the quality of the product or service need not be controlled unless specifically required by an adopted standard, or regulation, or a customer requirement. A recent, a QS-9000 ruling requires the control of business plans. You may disagree with this ruling, but it is not up to the auditor to bend the rules, an auditor must audit against the requirements (no more, no less). If the rules are wrong or inadequate, they must be changed by the rule makers.

Documents that are not controlled are sometimes called: guidelines, information only, training documents, or simply uncontrolled documents. When you encounter uncontrolled documents you should determine if they are being used: for product/ service acceptability, for control of processes critical to quality, or in some other fashion being used to assure quality. Sometimes you will encounter the gray area where a "guideline" exists for performing a specified process that affects quality and the auditor must decide if the "guideline" is advisory (as the auditee has indicated) or necessary to achieve quality. As a general rule, the higher the risk of the product or service, the more likely the need for controlled documents.

Some document control systems may allow for temporary pen and ink changes. Temporary changes may be observed for emergency changes, typo's, clarification, and minor technique changes. Temporary changes are a result of the high cost and difficulty of up-dating documents. If temporary changes are allowed, changes should be approved by a proper authority. Typically, initials and dates should be marked by each change (similar to making changes to a legal documents such as a

**Documents:**  
 manuals  
 procedures  
 work instr.  
 drawing  
 sketches  
 blue prints  
 flow charts  
 data forms  
 checklists  
 specifications  
 templates  
 customer docs  
 standards  
 models  
 project plans  
 quality plans  
 methods  
 schedules  
 trade practices  
 service stds.  
 PM plans  
 routing cards  
 inspection plans  
 sampling plans  
 tags

# Field Reports:

*The Good.. The Bad.. The Ugly..*

## Spinning the Results

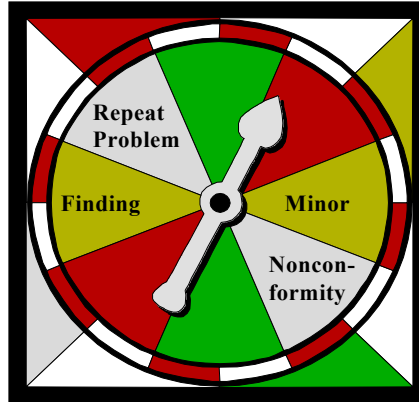
By Dave Kildahl

One of the most frustrating encounters I had in an audit occurred during a follow-up of an internal audit. In the earlier audit, I had reported evidence which showed that three employees were not following procedures in the labeling operation of a medical device firm, a fairly serious situation. Corrective action was going to be consulting with all employees in the department as to: 1) the need for following procedures and 2) what that procedure was suppose to be.

In the follow-up audit three months later, I again found evidence that employees were not following the procedure for the same operation as in the original audit. The counseling had taken place, and was documented. In my report I pointed out that this was the

second instance of the same fault in the system. To my surprise, the supervisor and department manager both objected strenuously to that conclusion, once it came to light that the people involved in the second instance were not the same people involved the first audit. I maintained that people were not the issue, rather, that in two consecutive audits, employees were not following an important procedure. Their firm stance was, "different people, different problem," and I was never able to penetrate that position and get them to look at the process (system) that produced these citations.

I still firmly believe that these two cases were part of a larger system issue, but I have to admit that I still would not be able to overcome that narrow focus on specifics that I encountered in this example. Any thoughts or advice?



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Send stories you would like to share, comments or suggestions to our PO Box or the e-mail address.

## Quality CrossWord

### Across

4. What we hope to exceed
5. Who defines quality
6. "\_\_\_ is fitness for use" Juran
8. Audit opening or closing \_\_\_\_\_.

### Down

1. Requirements
2. Within mental limits
3. It \_\_\_ or it isn't
7. A joiner

Solve the CrossWord and discover the quality quote by Thomas Berry.

Ans: \_\_\_\_\_  
Quality is meeting customers' needs and reasonable expectations.

