Quality Auditor Review

Apr.-June. 1998 Volume 2 Issue 2

Audit for Effectiveness & Suitability

Audit Thinking

By: J.P. Russell

Most organizations want and need... input to their improvement process

Some auditors believe very strongly that they cannot or will not audit for effectiveness or suitability. However, most organizations want and need to know if their processes/ systems are not suitable and/or not effective as input to their improvement process.

What is meant by auditing for effectiveness and/or suitability? When testing for suitability, I think of: "is it fit for use or is it adapted to a use or purpose consistent with organizational needs/ objectives?" When testing for effectiveness, I think of: "does it work, and does it achieve organizational goals, and is it an efficient (capable) process/ system?" Both terms are abstract and more information is needed to understand the meaning for proper application.

Beyond compliance and conformance there are four things we can test for during the quality audit. The "keep it simple" list is:

1. Is the activity getting the results desired?
For Example: The unit has been behind schedule for the last quarter. The number of rooms cleaned per day per maid is down 10% from last year.

2. Are resources (people, equipment, money) being used wisely? Are they cost effective?
For Example: The auditor noticed that there was an excessive amount of old machinery in the bone-yard. The observation was reported to enable management to write off the machinery (so as not to inflate the value of the company) and/or reclaim the scrap value of the old machinery.

3. Are people able to do it right the first time?
For Example: Is the process capable (in statistical control using customer requirement parameters) so it will be done right the first time, minimize rework, and operate at the lowest cost?

4. Have the right processes and controls been selected?
For Example: The auditor found that clause 19 had been misinterpreted and incorrectly applied to the Hotel reception desk making that part of the quality system not suitable.

More formal and possibly pedantic definitions for effective and suitable are:

Effective: The process or system is achieving the planned goals/ results in a capable manner with optimum use of resources.

Note: The word 'efficient' was not used because many confuse efficient with minimum use of resources compared to optimum use of resources. The other danger is that a timely, accurate, and low cost process may be considered efficient, but the same process may not be capable.

Suitable: The chosen (adapted) process or system and associated controls are consistent with internal and external requirements/ needs.

The credibility of the assessment is based on the auditor's experience and background, and the audit organization's reputation. When auditing for effectiveness and identification of improvement opportunities auditors should have

From the News Desk

RAB Announces Draft Internal Auditor Criteria for Training and Certification Programs. Free copies of the draft criteria are available for public view from the RAB. Call 800.248.1946 and ask for item number B0902.

inside...

The Audit Guy

Dennis Arter

The Audit Team

For the majority of audits it is best to have more than one person on the audit team.

Those assigned the task of performing a specific audit are called an audit team. This team is composed of one or more persons qualified to carry out the audit assignment. They report to the client (audit boss).

For the majority of audits, it is best to have more than one person on the audit team. This allows for balance and differing perspectives. It is also more productive, allowing more stuff to be audited. Teams are composed of leaders, members, and others.

When you have more than one person on the team, someone has to be in charge. This person is called the "team leader" or "lead auditor." In most organizations, these two terms mean the same thing. Sometimes, however, lead auditor can refer to a title or rank. In the third-party registration field, an RAB-certified Quality Systems Lead Auditor has more experience (and a higher salary) than a Quality Systems Auditor.

The audit team also has "team members" or "auditors." Along with the team leader, these folks do the work. They prepare checklists, conduct interviews, review records, and contribute to the written report. Normally, these are the only two categories on a team: leaders and members.

In some organizations, there is a third (and sometimes fourth and even fifth) category of membership on the audit team. These are the technical specialists, observers, and auditors-in-training. Except for those in training, they have no reporting relationship to the audit group. They are asked to participate because of their specialized knowledge or their association with another interested party. For example, a microbiologist may be needed for an audit of the food processing bacteriological monitoring program. Or an Indian Tribe representative may be asked to watch an audit of dam construction activities.

Audit team leaders, members, specialists, and trainees must all be qualified to do their tasks. (Observers just watch the audit. Except for a request to remain silent and not interfere with the other team members, they really need no training or qualification.) To be qualified, you must a) have a technical understanding of the activities assigned to you, and b) know how to perform your portion of the audit.

Technical understanding can be gained by watching the activity as it is performed. It can be gained by studying the procedures and manufacturer's technical manuals. You can also have someone from the audited organization talk to you and explain the processes. Often, we need to use a combination of all three approaches.

Audit knowledge can be gained from reading books. (My book on auditing is quite popular.) It can come from attending a training class. It can also come from on-the-job training under the watchful eye of other qualified auditors. Again, all three approaches are useful.

To demonstrate this technical and audit qualification to others, every person on the team (except for perhaps observers) should have a piece of paper that states they are qualified for the audit assignment. Usually, the client (audit boss) signs the certification papers of the audit team leaders. These certificates remain valid throughout the year and should be renewed annually. The rest of the team (auditors, technical specialists, and trainees) receive signed qualification certificates from the team leader. These certificates are only valid for the duration of the audit, after which they expire. There is no standard curriculum for the certification of either team leaders or team members, so it should be specified in the local written procedure for auditing.

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Dennis has been an independent quality assurance consultant since 1984. His primary service is instruction in the field of management auditing for a wide variety of clients, including government, manufacturing, energy, research, aerospace, and food processing. He is an ASQ Fellow and active in the Quality Audit Division. His home page is at http://home.earthlink.net/~auditguy/ *or he may be reached*

Quality Audit Primer

Auditing tips and reminders

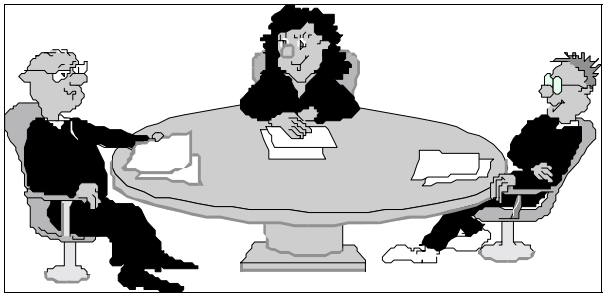
Audit Performance:

Classification of Observations

During the quality audit, the auditor makes observations. The observations make up the objective evidence (data) needed to verify such things as compliance and effectiveness of the activities under review.

Next, the evidence that was collected before and during the audit must be examined (analyzed). First, the auditor must identify data that cannot be considered objective evidence. Actually the auditor is testing the data for objectivity all along but it is a good idea to make one more sweep. It is not unusual for some data to be thrown out or reverified prior to reporting the final results to the auditee. This applies to both data that support conformance to requirements as well as data that support a nonconformity.

The data may be recorded on a checklist, in a log (record of auditor's observations), a photograph, notes on blank forms, and references to auditee documents and records (*Data Collection Plan* article in QAR Vol 1, Issue 3, discussed the *things* to look for to collect objective evidence).



Datum is considered objective evidence if can be proved true (per ISO 10011 definition) and is free of bias. It can be proved true if it is traceable (to verify) or reproducible (another auditor would collect the same datum).

An audit report is a report of the status of an area by exception. Auditors normally only report the nonconformances and not the objective evidence that verifies conformance and effectiveness (except for outstanding results). How the auditor sorts the data is influenced by the style (format) used to report the results. Most auditors report the results either in the form of nonconformity statements (violation of a specified requirement) or finding statements (an audit conclusion stating a system weakness). Audit results reported in the form of nonconformities is a very effective tool for implementing a quality system and to check compliance to a particular standard or contract. Organizations looking to improve effectiveness and identify areas for improvement may choose to report results as finding statements.

One of the main differences in objective evidence between the two styles of reporting is the collection of performance data to assess effectiveness of the quality system. For example: Increased levels of rework or unattended customer service telephone lines may not be important objective evidence for a compliance audit, but is very likely to be of interest to management if performance and effectiveness is being assessed.

The next step is to sort the data based on importance (significance) and relevance. Is it relevant to the organization being audited? Does it violate a requirement/ objective?

Importance can be judged based on 1) repeat occurrences (quantitative data), and 2) one time occurrences that have high risk or a performance level judged to be unacceptable (qualitative data). However, observing repeat occurrences does not necessarily make the evidence important, there should also be consequences (rework, loss of certification, increase costs, lost customer, etc.). Qualitative data comes into play regarding safety, environmental, and wrongdoing (e.g. not wearing protective equipment, dumping hazardous waste, stealing, lying, etc.).

Data may fit into other classifications such as concerns, observations, quality improvement points, positive practices, noteworthy achievements and notes. The reporting of data that does not relate to a nonconformity, or finding, is at the discretion of the auditor with approval from the client. The lead auditor must

How the auditor sorts the data is influenced by the style used to report the results.

Field Reports:

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

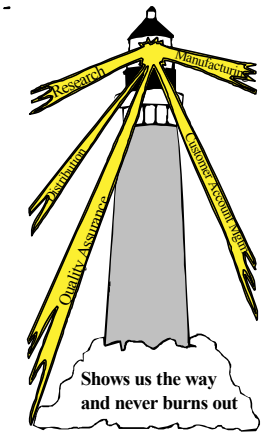
A Revolving Door of Quality

By Candy Ruggiero

Pasteur Merieux Connaught, USA, an international manufacturer of vaccines in Swifter, PA, has evolved a system of spreading quality principles throughout the population of the company.

After being registered to ISO 9001 in July, 1996, we formed a team of internal ISO auditors. This team is cross-functional with representatives from various departments such as research, Quality Assurance, Manufacturing, Distribution, Information Systems, Quality Control, Customer Account Management, and Engineering.

Team members are nominated either by individuals or by the department manager/director for a two year commitment. The members of this voluntary team (some having no previous auditing experience) are trained in the ISO standards and are given basic auditing skills. Team members complete an average of one audit per quarter each year. Due to the cyclical nature (2 year time frame) of the audit team, experienced auditors are teamed up with new auditors who will then become the experienced auditors the following year.



The following benefits from this revolving auditor program have been noted:

⇒ No additional full-time resources are required to fulfill the ISO requirement of internal auditing.

⇒ New resources are added to the cGMP Audit program. Some joint ISO/cGMP audits are conducted and findings are communicated to the Compliance Department.

⇒ The skills learned are taken back to the auditor's own job which increases quality awareness and enhances compliance in the regulatory areas.

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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

3. His or hers
5. Quality lust?
8. In full measure
9. Own

used more than once in the quote

Down

1. Fixes before occurrence
2. Promptly
3. Non descriptive items
4. Follows state of or human
6#. Fro's opposite
7#. Completed

Solve the CrossWord and discover

Ans: To desire to have things done quickly prevents their being done thoroughly.