

Quality Auditor Review

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Share Best Practices

Audit Thinking

From time to time auditors observe processes that are super efficient and achieve remarkable results. Unfortunately, the auditor's attention is focused on finding the bad stuff (e.g. making observations and identifying nonconformities), not the good stuff. In some situations, reporting the good news may be more important to the organization than identifying what is wrong.

When auditors observe a process that runs very smoothly and is very effective for the situation, they may identify it as a 'Best Practice' (or similar designation such as positive practice or noteworthy achievement). Any observed 'Best Practice' should be reported so that it can be shared with others within the organization. If conducting an audit of a supplier, the auditor may ask if best

By: J.P. Russell

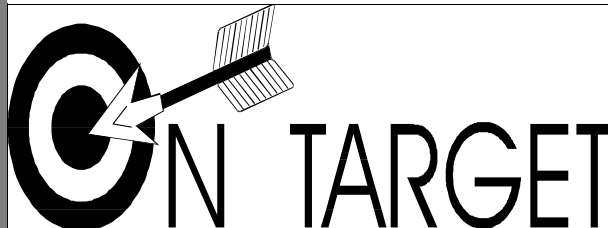
mented by others. Perhaps you have heard of the saying, "You can lead a horse to water but you can't make him drink." The NIH (Not Invented Here) disease and not being able to see the benefits of new processes can be major road blocks to improvement. A study of 10 large firms found that it often took 27 months for best practices to transfer, if at all (Training magazine, 'Knowledge Management Fad,' March 1999, page 37).

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From the News Desk



practices can be shared with the customer organization. The criteria for a best practice would be that the practice: 1) achieves outstanding results with typical consumption of resources, 2) achieves typical results with far fewer resources than what may be considered typical, and 3) achieves outstanding results with far fewer resources.

However, reporting the good news does not mean others will automatically apply the best practice to their situation. Many best practices fall victim to the NIH disease and thus will never be imple-

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The Audit Guy

Dennis Arter

Auditing to Standards

Standards are the norms or criteria against which the performance of an activity is measured. One cannot audit without performance standards.

Performance standards come in four levels. [See Figure 1] At the top are *policy* documents which cannot, and must not, be challenged. These generally come from someplace external to the facility. Examples include corporate policy statements, international and national quality system standards (e.g. ISO 9001 or ANSI/ASQC E4), regulatory standards (e.g. 10CFR50 or cGMP or HACCP), and business sector standards (e.g. CMA's Responsible Care). These standards give broad policy requirements, such as "implement a system of internal audits." They do not give direction on how to accomplish those requirements.

The next level of performance standard is the transition document between policy and procedures. It should be relatively skinny. It is produced locally for the facility and is often called a *manual*. We're not talking about a binder stuffed full of individual procedures.

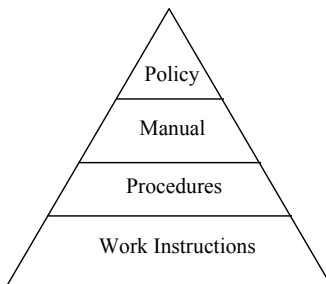


Figure 1: Four Levels

Rather, you need something which describes how the external requirements will be implemented at this particular location. A simple repeat of the top-level requirements is useless. Your manual should be written in a narrative fashion, as if you were talking to your neighbor. 20-30 pages is a good size for a manual.

Next come the procedures. It is here that one finds the step-by-step requirements for the job. Procedures deal with processes. They can be technical, such as welding or painting, or they can be administrative, such as training or evaluating. (Notice that procedures always deal with an action or group of actions.) Procedures must be clear, correct, and effective. As *job performance aids*, they provide direction to a trained individual on the performance of the task. We don't write pro-

cedures for an untrained individual. Procedures can be captured on paper, in a computer, or as a picture on the wall. You will have many procedures available to audit, whether you are performing a process (mini) audit or system (big) audit.

Augmenting procedures are task details. These *work instructions* are used for a specific batch or operation. For example, you may have a *procedure* for electric arc welding in general, and then a *work instruction* for the specific joint. In this case, the *work instruction* would be the drawing. It would state the kind of weld rod to use, the depth of the filler material, and the angle of the joint. *Work instructions* come in many forms. They usually need to be portable, so they can be taken to the job site. That Post-It note sticking on the side of your computer screen could be considered a *work instruction*.

These four levels of documents all have one thing in common: they provide direction on an activity to be accomplished. They are the first element in the Plan-Do-Check-Act cycle. Without requirements, there can be no audit. To perform an *effective* audit, you must use at least two levels. If a procedure is examined all by itself, there is no way of knowing if that procedure is any good. It must be measured against a higher standard of performance, to see if it is accomplishing its in-

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...they provide direction on an activity to be accomplished.

Quality Audit Primer

Auditing tips and reminders



Audit Report:

Audit Conclusions

Audit conventions state that an overall conclusion should be reported as part of the audit report. This can be easily overlooked in light of all the attention placed on reporting the nonconformances or finding statements. An audit conclusion can be as simple as the lead auditor's view of the how the audited area measures up against the purpose and scope of the audit. Some may think of a state of readiness for external compliance audits or customer audits. Others may report the degree of compliance to internal requirements or external standards, such as FAA or 21 CFR 820. A conclusion may express higher levels of achievement by estimating effectiveness of systems and processes compared to organizational objectives. An auditor may report any conclusion based on the evidence and their judgment or understanding of the auditee situation.

At the very minimum, an audit conclusion should be:

- 1). relevant and



- 2). consistent with the observations.

The key to writing an appropriate audit conclusion is to revisit the audit purpose and scope. This will insure that the statement is relevant to the situation. If the audit was conducted to determine the degree of compliance to ANSI/ISO/ASQ Q9001, the conclusion should not be about readiness of starting up the next line.

Example of Audit Purpose:

To determine the degree of compliance to ANSI/ISO/ASQ Q9001 and internal department procedures.

Example of Compliance Conclusion:

The department is in compliance to ANSI/ISO/ASQ Q9001 and internal department

procedures with only a few minor nonconformances reported.

The conclusion should be consistent with observations made during the audit. If there were several significant nonconformities or major findings, it would not be appropriate to state that everything looked fine. If there were no observed nonconformities or findings, it would not be appropriate to state that the area needs a lot of work.

Conclusions are based on objective evidence. The evidence may point out weaknesses or strengths of an organization. If observations included areas for improvement, an audit conclusion may also reflect opportunities for improvement.

Example Improvement Conclusion:

Several areas of improvement were identified during the audit of the warehouse that if addressed, could result in improved effectiveness of the process and increased customer satisfaction.

The conclusion can be enhanced by being more discriminating (descriptive) versus being generalized. Some global statements are vague and may not be true. For example, What if the Engineering Department only received major nonconformities in the area of calibration control of test devices and change control of design documents. A correct but vague audit conclusion would be: The Engineering department has failed to implement procedures and is noncompliant with standards. A more appropriate conclusion may be: The Engineering department has a functioning quality system except for implementation of calibration control of test devices and change control of design documents. If an auditor can point out areas of weakness, it will help auditee management decide where to concentrate their resources. Areas of weakness or strengths can be described as: 1) a quality element or control, 2) an area, department, or process, or 3) deployment of controls (existence of written procedures and implementation of procedures).

Example of Area Conclusion:

...global statements are vague and may not be true.

(Continued on page 5)

Review:

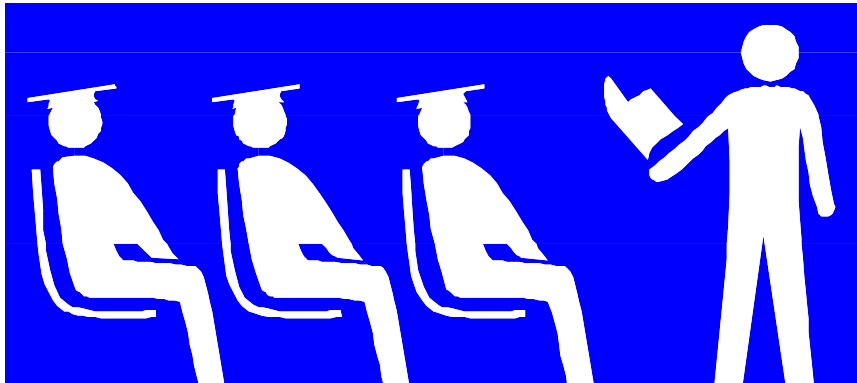
RAB Internal Auditor Training

Review of ANSI - RAB National Accreditation Program Criteria for the Accreditation of a Quality Management Systems **Internal Auditor Training** Course, April 1999.

By: J.P. Russell,

The internal auditor training criteria published by the RAB was very professional and sounds very similar to the 36 hour 5 day quality system lead auditor training criteria. In fact, my major criticism is that the 23 hour internal auditor training is a scaled-down version of the 36 hour course designed to qualify auditors for 3rd Party audit organizations (Registrars). The course provides training in ISO 9001 requirements and auditing as related to ISO 9001 and ISO 10011 standards. As with any education accreditation program, the course provider is required to establish learning objectives and practice good document control

In the same mode as the parent 36 hour course, the internal audit course will be characterized by long days (at least 3 days from 8 A.M. to 6 P.M. by my estimate), will require passing continuous evaluation of students, and passing a final written examination. The formality of the course and continuous evaluation of the students' personal attributes for audit management capabilities and team leader suitability will favor students with professional or management backgrounds.



The course content is very thorough and adequately covers compliance auditing principles and practices. There are the typical self-perpetuating topics related to RAB certification criteria for internal auditors and the importance of registration. Throughout the document there is

constant emphasis on linkage to ISO 9001, ISO 8402 and ISO 10011. The internal auditor trained in accordance with the RAB criteria will be an extension of the Registrar auditor and be able to identify and eliminate potential ISO 9001 or ISO 9002 nonconformities prior to registrar visits. The course will train people to be internal 'ISO Auditors,' though no such title formally exists.

I believe that the most likely customers for this course are in the regulated industries and especially those required by law to maintain an ISO 9000 type quality system. For everybody else, the course is onerous, and too narrowly focused on ISO and compliance philosophies. There is no mention of assessing effectiveness, or value added auditing techniques.

My advice is that if you want the training, go for the full 36 hour quality system lead auditor course. If you want to pay the RAB to formally certify your internal auditors and verify official audit records, go for the 23 hour internal audit training course. If you are seeking the value audits can add beyond verification to external ISO standards, look elsewhere.



Audit Thinking (Continued from page 1)

Similar to audit findings, the auditor should include the benefits of a Best Practice in the statement. The auditor can report the benefits of implementing the best practice as claimed by the user. As with audit findings, people don't take action unless there is a perceived benefit. They must be motivated in some manner.

The audit organization should not stop with simply reporting a best practice in an audit report. Additional techniques and strategies should be used to deploy the best practice to all organizational functions that would benefit from using the new practice. Some ideas are: 1) to follow up Best Practices just like following up corrective actions, 2) issue a special report to upper management, or 3) assign the Best Practice to a team for additional study and deployment. Organizations must create incentives for managers to adopt new processes that will benefit the organization.

It may be by the reporting and sharing of best practices that the auditor may add value and spur on continuous improvement.

**The Audit Guy** (Continued from page 2)

tended purpose. Then you need to get down to some details to see if the process is actually resulting in good stuff. Now, we can do our audit job of providing confidence to management.

Footnote:

A document can be considered to be "a written description of an action to be accomplished." On the other hand, a record is always generated after the event. A record is "a written description of an action that has been accomplished." Auditors use documents as their performance standards. Records are used as one of the many forms of evidence that the action has been accomplished in accordance with the *documented* instructions.



Question: Not counting Alaska, what state in the U.S. is the farthest north?

Ans: The northernmost state in the contiguous US is Minnesota – specifically, 125 sq. mi. of the northern part of Lake of the Woods County.

Audit Conclusions (Continued from page 3)

All areas but purchasing have implemented and maintained satisfactory system controls.

Example of Deployment Conclusion:

The designed system controls are adequate but many of the controls have not been implemented and there are no records to verify compliance.

Another consideration is to state overall consequences of the results of the audit such as:

- ◇ Organization is (or is not) recommended for registration
- ◇ Supplier certification is renewed (or revoked)
- ◇ Operating costs will be reduced (or raised)
- ◇ Negligible (or Significant) risk of a major regulatory citation
- ◇ Customer satisfaction ratings will increase (or decrease)
- ◇ The interval between audits will be increased (or decreased)
- ◇ We will continue (or discontinue) our business relationship
- ◇ A follow-up audit will (or will not) be required to continue operating.

Reporting a grade or percentile score can be considered as part of an audit conclusion, such as an 'A' being an excellent rating or 77% matching required on-going approval levels. A score or grade is normally the result of some type of mathematical calculation based on the response to certain questions. Scoring provides an immediate reference to gauge an organization. However, I have always been skeptical that achieving a certain score is not the same thing as meeting the intent of management controls or compliance to regulations. Organizations may implement unneeded costly controls to achieve higher scores or resist changes to avoid risking a lower score. The question one must answer is: "Do the advantages of scoring overcome the harm it creates?"

Some auditors qualify or issue disclaimers with their conclusion using words such as conditional, provisional, contingent, dependent, or subject to (e.g. provisional registration, conditional certification).

Normally, the overall audit conclusions are reported in a summary, brief, synopsis section, or as pre-matter attached to the detailed audit findings. The conclusion should provide the big picture (key issues of importance) for management. This is when, as the saying goes, the auditor

Field Reports:

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



Unknown Quality Policy

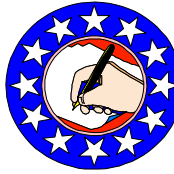
By J.P. Russell

When conducting quality system audits I always ask about the quality policy. The standard states that the policy shall be understood, implemented, and maintained at all levels. Making known the quality policy such that everyone will remember it can be a difficult task. The idea that everyone should know that their organization is committed to providing quality products and services, makes sense to me. I do not expect people to recite the quality policy verbatim, but I do want them to have the right focus. Organizations have used banners, buttons, meetings, contests and all sorts of techniques to make the quality policy known.

One particular company was having difficulty getting out the word to all the employees. When I interviewed the operators about the quality policy they answered: to do your best, to work harder, the customer is always right, etc. In short, the company was not successful in communicating the quality policy to the people in operations.

On a return audit, I again went around and asked

operators about the company quality policy. To my surprise I received many of the same answers such as: get to work on time, tell the boss, etc. When I discussed this problem with management they said a nonconformity cannot be issued because they have proof that everyone knows the quality policy. The proof was that before anyone could get their pay check last Friday, they had to sign a statement saying they read and understood the quality policy. The company had a signed statement from all employees.



I thought this was a clever tactic and very convincing except for the fact that there was no corroboration that any of the operators knew the quality policy.



J.P. Russell is an ASQ CQA, and RAB Quality System Lead Auditor.

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Quality CrossWord

Across

- 1. Easy to understand
- 3. Schemes
- 5. Fresh groceries or work
- 7. Better than great

used more than once in the quote

Down

- 2. Carried out
- 4. Desirable outputs
- 6. Healthy

Note: Quote used with permission

Solve the CrossWord and discover the quality quote.

Ans: Simple, well executed strategies produce excellent results. By: Darryl L.Sink

