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A FORMULA FOR CONTINUED IMPROVEMENT: AUDIT FOLLOW-UP

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A FORMULA FOR CONTINUED IMPROVEMENT: AUDIT FOLLOW-UP(1)

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ABSTRACT

In his book Management Audits, Allan J. Sayle states, "QA standards stipulate that corrective action, required as a result of performing an audit, be followed up and closed out. There would, indeed, be little point in performing audits, requiring corrective action, or having a QA system at all if the auditee knows that the auditor will never verify that the corrective action has been efficaciously implemented."(3)

The QA auditor has an obligation to include follow-up in the overall audit planning. All too often the auditor will go to great lengths to plan and perform an audit only to have a recurring finding in the next audit. The proposed corrective action was only promissory and was not designed to stop the problem from recurring or to identify its root cause. Auditors do a disservice to the overall QA program and particularly to the customer when they fail to follow up and verify that an audit corrective action has been effectively implemented.

In this paper, the techniques used by the quality assurance auditors at the Pacific Northwest Laboratory (PNL) will be presented. Although PNL is a research and development laboratory, the techniques outlined in this paper could be applied to any industry conducting quality assurance audits. Most important, they provide a formula for continued improvement by assuring that audit follow-up is timely, meaningful, and permanent.

INTRODUCTION

You are no exception as you sit across the table from the two imposing persons who are reviewing your audit records with a fine-toothed comb. Your temples are throbbing. Your mouth is dry. You wonder if they notice the droplet of sweat, resembling a tear, on your cheek. You have done everything

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(1)This paper was originally presented to the 43rd Annual Quality Congress at Toronto, Ontario, Canada on May 10, 1989 and subsequently published by The American Society for Quality Control in the proceedings from that Congress.
(2)Pacific Northwest Laboratory is operated for the U.S. Department of Energy by Battelle Memorial Institute.
(3) Sayle, Allan J. Management Audits, Quality Press, 1985, p. 170.

you could to prepare for this extrinsic audit, but something tells you an item is out of place. As you probe the far reaches of your memory, one of the auditors asks, "Have you performed any follow-up to this audit finding?" The words hit you like a north wind off Lake Michigan in February. The sound of an audit follow-up falling through the cracks is very quiet until someone else finds it, and then it is deafening. In your haste to prepare for this audit, you forgot to follow up on one of your own. Does this sound familiar?

TEXT

In a tutorial presented at the Forty-Second Annual Quality Congress in Dallas, Texas, Bernie C. Carpenter asked the question, "Follow-up, corrective action over?"(4) Before the quality assurance auditor can answer that question, a system must be in place that will begin the follow-up process. A company's QA audit program should dictate some requirement for providing a response to an audit deficiency. For the purpose of this paper, the audit deficiency will be called a "finding."

TRACKING SYSTEMS

When the audit report is issued, the auditee will generally have a set period of time (at PNL, 30 days) in which to provide a written response to the finding. How can the auditor assure that the response will be provided on the date it is due? Before you ever send out your report, enter the response due date on something you will look at on a daily basis; e.g., a desk calendar, a yellow self-stick note, an automated tracking system or some other device for jarring your memory. Back up your reminder by also giving your secretary a note for the status or "tickle" file.

In the auditing organization at PNL, we use several systems for assuring that audit responses are provided in a timely manner. At the time the audit finding is recorded in the audit report, we write in the date a response is due and immediately enter the date on a desk planning calendar. This begins the first of many phases in our audit follow-up system. The information is also recorded in the "Audit Status Log," which is maintained to provide monthly audit information to upper management. Two more reminders are also employed: a note to the section secretary for the status file and an entry in the "Daily Organizer" in the computer.

The "Daily Organizer" is essentially an automated tracking system. We use the software that came with the IBM Personal System/2 Model 30. (Similar pc-based reminder programs are available for other makes of computers.) Checking the organizer on a daily basis, at the time the computer is put on line, becomes a habit. Besides providing the auditor with meeting information, milestones, etc., it forecasts what audit responses are due for the day and in the days to come. If a response is received on or before the due date, it will be entered in the status log. If a response is overdue by

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(4)Carpenter, Bernie C., "Planning The Audit", 1988 ASQC Quality Congress Transactions, 1988 ASQC Milwaukee, p. 213.

more than ten days, a delinquency notification is issued requesting a response within five working days, and this is also tracked.

Perhaps all these systems seem to be overkill for tracking a simple audit response, but they have proved effective for the audit group at PNL. I know of one company which has an "Automated Action Tracking System" (AATS) that uses a big mainframe computer to track audit responses. Every two weeks, a 40-page AATS list is published. The auditor, the action party (usually the auditee), and the action party's manager receive a copy of the list. Due dates and past due dates are highlighted. Closeout and interim action dates are also included. To some degree the system works, but it has some drawbacks. When an input sheet is submitted for closeouts, date changes, or action party names, it must get to the data entry clerk before the deadline or the changes will not be reflected on the list for that reporting period. The action party screams. The action party's manager screams. The auditor screams. Based on the level of distribution for that list, poor timing, which is out of the auditor's control, can create a very ugly scene.

A tracking system should be simple, user friendly, reliable and credible. Once you have that, **use it.** Use what works for you. In the nuclear business, the standard says I have to follow up to verify that corrective action has been accomplished as scheduled.(5) It doesn't tell me what system I have to use to track scheduled actions. Our present system works for us.

RESPONSE REVIEW AND EVALUATION

Once the response is received, the lead auditor will evaluate it for responsiveness to such issues as the following:

- Has the root cause of each finding been identified and the impact of the finding upon completed work been evaluated?
- Have other areas/items that might have similar problems been examined?
- Have actions been taken to correct those problems?
- Has action been taken to prevent recurrences?
- Has the person(s) responsible for implementing the corrective action plan and the completion date for each item been identified?

This evaluation should be completed as soon as possible after receiving the response, usually within ten working days. If these issues are not addressed in sufficient detail to allow the auditor to evaluate the

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(5) ANSI/ASME NQA-1-1986 Edition, Quality Assurance Program Requirements for Nuclear Facilities. American Society of Mechanical Engineers, Supplement 18S-1

reasonableness of the proposed corrective action, the response is unacceptable.

A key problem with audit responses is the failure of the auditee to adequately determine the root cause. Audit responses in the past have identified only symptoms of the real problem. The following are examples:

- Employee error - employee has been consoled.
- Engineering has been contacted about a possible drawing change.
- If production volumes increase, instructions will be provided.
- Operator told not to use so much force; Operator will retire next year.
- No corrective action required because the cause of the deficiency is unknown.

Responses must provide the basic reason for the deficiency. Corrective action should not go for the "quick fix," but rather should target long-term cures to prevent recurrence. A less-than-adequate determination of the root cause will ultimately yield a less-than-adequate corrective action proposal. Compare the following responses with the previous "quick fix" responses:

- Employee error. Investigation indicates that the employee had not been trained on the new equipment since he was on vacation during the time the training was given. The employee has been removed from the line until the equipment manufacturer can provide formal training. In the interim, the employee will be assigned to work under the supervision of a senior operator to become familiar with the equipment and will receive on-the-job-training (OJT). In the future, training will be offered on two separate occasions to accommodate those individuals who may be on vacation, ill, etc., and to preclude recurrence of this problem. Further investigation indicates that work performed by this operator while he was operating the equipment has not been jeopardized. The manufacturer will be available to conduct the required training at our facility the last week of next month; this schedule will coincide with our latest group of new or transferred employees.
- Our analysis of the finding that the operator was using a 5-ft. "cheater bar" to tighten down a leaky, 3-in. valve is that the operator lacks recent training. In the past we have excluded from formal training any operators who would be retiring within a six-month period. This was viewed as a cost savings. A review of the "trend" database has shown similar deficiencies over the past several months. All operators will receive periodic training regardless of their impending retirement date. All valves that have been maintained by this operator will be repacked and reworked to assure operability. The training will be conducted immediately. Valve rework will be completed within the next thirty days.

As the lead auditor evaluates the audit response, consideration should be given to the timeliness of the proposed corrective action and whether or not the response is realistic. The timeliness of the proposed corrective action will depend on the complexity and exigency of implementing the corrective action. For example, if the finding identifies the need to provide statistical process control training to two staff members whose daily activity has an effect on product quality, it would not be timely to say the training would be provided three years from now. This is especially true if the training was minimal and not technically overwhelming. On the other hand, it may not be realistic to expect the training would be accomplished in only a couple of hours. You must evaluate the response. Seek other resources and ask if the proposed corrective action is realistic and timely. Don't let the auditee fail. You are providing a service. It is possible to provide a caveat without providing a recommendation, compromising your independence, or reassigning responsibility.

Once the lead auditor has evaluated the proposed corrective action in the response and found it to be acceptable, he or she should get concurrence from management. With this step accomplished, the auditor should then go back to the tracking system and enter the date on which the corrective action will be completed. This step will help to provide input to any audit planning and scheduling which may result from the corrective action (i.e., a follow-up audit or a re-audit). It will also assure that the finding will be closed in a timely manner. The prompt, expeditious closeout of an audit finding will enhance your credibility as a quality professional and, hopefully, will satisfy your customer.

Whether accepting or rejecting an audit response, courtesy dictates that auditors provide a written acknowledgement. If you are accepting the response, thank the auditee for the timeliness and responsiveness of his proposed corrective action. Let the auditee know that you will be tracking the completion date for follow-up and that you will be contacting him before the milestone to verify the completed action. If you are rejecting the response, tact and diplomacy should be the bywords. If the corrective action in the audit response is not satisfactory, it will be necessary to contact the auditee, provide a justification for the rejected response, and provide a date for the revised response to be reevaluated. Here again, the tracking system plays a key role in assuring that the date is met.

VERIFICATION

Mr. Sayle's words ring true when we get to the verification aspect of the corrective action. "There would, indeed, be little point in performing audits, requiring corrective action, or having a QA system at all if the auditee knows that the auditor will never verify that the corrective action has been efficaciously implemented."(6) The main purpose of a follow-up is to verify that the audited organization has implemented the approved corrective action, that it was implemented in accordance with the approved schedule, and that its provisions are being met.

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(6)(Sayle, "Management Audits", 170)

Truly effective corrective action is achieved if, and only if, the identified problem never occurs again. One's past auditing experience may suggest that that result is not always achieved. Action implemented as promised does not always guarantee that the problem will not recur.

Each audit finding should be scheduled for at least one "formal" verification of the corrective action to assure that the problem has actually ceased to exist. Timing will play a considerable role in this verification effort; you should wait long enough to allow objective evidence on the results of the corrective action to accumulate. This may be stated as an effective date plus some agreed-upon grace period.

FOLLOW-UP ACTIVITY

How the follow-up verification is actually conducted may be a matter of procedure, personal preference on the part of the auditor, or manpower constraints. Perhaps the least demanding in the manpower arena is the surveillance. Although this term may sound a bit surreptitious, surveillance is defined as "the act of monitoring or observing to verify whether an item or activity conforms to specified requirements."(7) The surveillance is generally performed by one individual dedicated solely to that purpose. It does not require the formalities of a follow-up audit.

The follow-up audit on the other hand will follow a protocol very much like the original audit. It will have been planned, placed on a schedule, and formally announced by letter with the attached audit plan. The advantage in performing the follow-up audit lies in a few areas. First, your scope will be limited. You will only have to audit those elements for which corrective action was requested in the original audit through the audit finding. Second, because the scope will be limited, your checklist will also be limited. You need only include checklist items that will measure the implementation and effectiveness of the corrective action. The following could be used as follow-up checklist questions:

- Has the corrective action been completed?
  -procedure authored and issued
- Was the corrective action completed according to the promised schedule?
  -milestone dates met; reality reflected
- Do the affected personnel understand the corrective action and the role they play in it?
  -additional training/orientation completed
- Are current activities consistent with the corrective action?
  -overall QA program is being effectively implemented and the procedures are being followed.

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(7) ANSI/ASME NQA-1-1986, Supplement S-1 Terms and Definitions

Objective evidence should, in most cases, accompany those questions that can be answered in the affirmative. Finally, your time investment will be kept to a minimum.

The last method of follow-up would be the re-audit. A re-audit comprises everything that was performed during the original audit. A re-audit is usually the result of an audit that identified a total system or program breakdown. In other words, things were so bad the auditor could not proceed with the audit. Such situations are rare and usually evolve into a "Stop Work" order (which is even rarer). Put another way, the re-audit is a method of last choice.

For findings not requiring significant corrective action, two more methods may be considered:

- a review of newly approved, newly issued or revised quality-affecting documents (i.e., QA manuals, technical procedures, test plans, training records, etc.)

- verification of that activity during the next regularly scheduled audit. This course allows for a conditional, or interim, acceptance and recognizes the auditee's attempts to rationalize deviation as being acceptable, but still places the burden of responsibility on the auditee for demonstrating satisfactory implementation at that time.

As each new audit is performed, previous findings must be incorporated into the checklist and used to determine whether or not earlier identified problems are showing signs of recurrence.

CLOSEOUT

The lead auditor is responsible for closing out audit findings when the implementation of the completed corrective action has been verified. When all the objective evidence has been gathered, analyzed and accepted, the lead auditor should complete the close-out section of the audit report or finding form and provide justification.

Before any letters are written, the close-out date should be entered into the audit status log indicating that the finding has been accepted and closed. This will provide the closing link in your follow-up formula. Close-out is acknowledged by a formal letter directed to the auditee, summarizing the follow-up methodology and results, and stating that the finding is in fact closed. If a separate finding form is used, attach the signed, closed-out copy of the form to your letter.

CONCLUSION

With any formula, you have to make sure you have the appropriate mixture of elements to achieve success. This is no less true of a formula for continued improvement. For audit follow-up, you must have a working, user-friendly system for tracking the responses to the audit findings. Once the response is received, it must be evaluated for timeliness of corrective

action implementation, and during the verification, the implementation itself must be evaluated for effectiveness. Having accomplished all these elements, the closeout can be issued and the follow-up is complete. The result is a formula for continued improvement that can be represented in the following way:

$$Fu = Tr\ [R\ (E+CA) + (E+I)\ V]$$

Fu = Follow-up
Tr = Tracking
R = Responses
E = Evaluation
CA = Corrective Action
I = Implementation
V = Verification

Follow-up equals tracking responses, evaluating corrective action, and verifying its implementation.

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