Improving the Effectiveness of Internal Auditing
Steps to Quality Management System Success

Authored by Richard Strouse, Lead Auditor, Quality Registration Division

Internal auditing, when effectively implemented, can arguably be considered the most important tool in the quality system “tool box.” It is the primary continual monitoring process of a company's Quality Management System (QMS). The output from internal auditing is critical to the growth of the QMS – identification of system ineffectiveness, corrective action and ultimately continual improvement.

However, when internal auditing is poorly deployed, its ineffectiveness leads to increased, non value-added costs, many hours of wasted resources and an eventual, inevitable QMS breakdown.

So, what sets effective internal auditing systems apart from the ineffective, poorly executed auditing systems? How do you know if your internal audit system is effective at all?

First and foremost, it starts with the **commitment of Senior Management**. Without their approval, support and encouragement, the internal audit process is doomed for failure, and worse, time and money wasted. After ten years of conducting third party audits, I’ve surmised that the difference between the most and the least effective QM systems was how strong management supported the auditing process. Management must buy into the fact that the internal audit process is just as critical and important an activity as any other process within the QMS.

When scheduled audits are routinely put off for other pressing issues, the message that management sends is clear – it’s a low priority that is done only because it’s a necessary evil. It’s remarkable that some companies that have been ISO registered for ten years or more still fail to demonstrate the QMS maturity one would expect. In these cases, it always comes back to management understanding and supporting the internal audit process and its powerful value. Ironically, these same organizations can't understand why, over time, their QMS fails!

Consequently, the company that understands and supports its internal audit system keeps its QMS edge sharp. These auditors have acquired the skill to identify system effectiveness rather than compliance alone. These companies have progressed to understanding the subtlety of continual improvement, and they no longer think in terms of short term gain and hitting home runs.

How? It's simple. The more committed Senior Management is to the success of its quality management system, the better and more effective that system is likely to be. However, this is only the first block of the quality system foundation.

What happens, for instance, when Senior Management demonstrates – even encourages – quality management system participation and continual improvement yet customer satisfaction feedback paints a contrary, non-favorable picture? In other words, what must be done if customer concerns climb yet internal audits are not recognizing and capturing the cause(s)? What are the grounds for this disconnect?

Actually, there could be many possible reasons. However, in almost all cases the root cause of why companies that continually fail to effectively identify and eliminate QMS nonconformances points to an ineffective, underdeveloped internal audit process.

The following lists some of the most common pitfalls to poor and ineffective internal auditing deployment:

Pitfall #1: *Not understanding the definition of, and not basing audits on, status and importance.*

What is **status**? What is **importance**? Both can be interpreted differently, yet most often it's simply misunderstanding their intent.

Status can be defined as how a particular department, discipline, facility or process is performing against established policies, goals, objectives and expectations. For example, what are the performance indicators for an area/group/department reflecting? What does the history of performance indicate? Have they been the result of root cause corrective actions? Are they recurring? Have there been changes in process, equipment, personnel or management? Has the area/department been restructured or reorganized? These are just a few examples of some types of indicators used for justifying the basis of status. If the performance history of a department, process or group is meeting established expectations then its status can be considered healthy. Remember, everything needs to be considered on a case-by-case basis and appropriate according to the size and type of the organization. The Management Representative or the process owner of internal audits ultimately makes that determination.

Importance is an entirely different aspect, yet is directly linked to status. Assume, hypothetically, that a final inspection process has been performing as expected, i.e., no escapes of nonconforming products with goals and objectives consistently meeting expectations. Therefore, one could ascertain that the status of the final inspection process is operating as expected and all is well. However, its importance still remains critical. Even if the final inspection department shows a good track record, it is still a critical process. If nonconforming product escapes, the customer is the next one in line to receive it. Hence, although the final inspection department metrics indicate a clean status with no "escapes," the importance of this function still remains crucial.

Therefore, concentrate on the areas that are critical - *importance*. Increase the internal audit focus on areas that are root cause or otherwise not performing to expectation - *status*. This is especially true when companies implement new departments, processes or initiatives (i.e., Lean Manufacturing, Six Sigma projects, etc.). During these situations, time is usually a major concern to get things up and operating as soon as possible. Auditing the general implementation and functionality of any newly implemented system, area or process, then becomes an importance (its status will unfold as it is monitored and measured).

When scheduling internal audits, consider other aspects such as: What's been the past performance history? Are there new employees, equipment or management? How effective is the training system? What do past audit results indicate? How critical is that area?

Truly effective audit schedules concentrate where potential, not just the obvious, shortcomings or weaknesses lie. Utilizing control plans along with related design and/or process Failure Mode Effect Analysis (FMEA) can also be helpful as a guide to aid in identifying critical areas. The key is to develop the audit schedule so that the focus is on the areas that are or could potentially be a root cause for nonconforming situations and the areas critical for maintaining product conformity. The audit schedule is a living document and should be revised as appropriate. The individual responsible for scheduling audits should be fully aware of: management review output data; customer, internal and supplier concerns; and, organizational infrastructure changes.

Pitfall #2: *Ineffective internal audit scheduling.*

If status and importance aren't properly understood then this pitfall is sure to follow. Audit schedules must reflect the reality of the QMS. A third party auditor is expecting to see an internal audit schedule that is demonstrating reaction to whatever the key performance indicators within the organization are reflecting. Going back to status and importance, processes falling below expectations should be getting internal audit attention. Processes meeting or exceeding expectations do not necessitate audit focus.

When a third party auditor examines an audit schedule that never changes, is never revised, that neatly lists each process just once with all processes given equal weight, that appears more like a decorative pattern on a calendar rather than a thoroughly developed living document. The design of the audit schedule provides clues as to whether the internal audit process is understood and being utilized to its fullest potential.

Perhaps the worst practice is when a company takes the "Grand Daddy" audit approach. This tactic generally involves scheduling a full system audit of the entire QMS just once or twice a year.

There is so much ineffectiveness and inefficiency with this practice that it's easier to just list the few positive aspects. Aside from the fact that status and importance consideration are virtually non-existent, it is also statistically unsound. It is not possible for management to conduct an effective management review of the QMS based on the sample of one or two grand system audits. Conducting only two full system audits is the equivalent to sitting down at Thanksgiving, eating the entire meal, and then not eating again until Easter. No one, of course, could eat just two huge meals twice in one year and expect to be suitably nourished. It's the same when developing the internal audit schedule – audits should be spread out so that audit activity is "digestible" to the organization, not overwhelming it.

Full system audits pose other problems, as well. It absolutely places strain on all resources involved – auditors and auditees alike - and it's also a major disruption to the operation. When such an endeavor is undertaken, audit focus tends to get lost under the enormity of the task. Full system audits do not allow the auditor to concentrate on the specific aspects of the process. Thus, since the scope of a full system audit is so wide the inconspicuous, subtle nonconformances that may exist could easily be overlooked.

Therefore, when developing the audit schedule give consideration to:

1. Focusing on the "climate" changes within the QMS (i.e., keeping abreast of customer feedback, new employees, new equipment and/or processes, quality initiatives, new departments, root cause areas of concern, etc.).

2. Executing short duration, highly concentrated audits in lieu of long, drawn out audits that tend to lose focus. Consider 30-60 minute weekly audits instead of auditing on a monthly or quarterly basis. This method is much easier to manage, takes less time,

increases focus and is much less disruptive.

3. Utilizing a wide variety of trained internal auditors. In fact, some of the best auditors are new employees or the employees that have no clue of the area, the function or the process they are auditing. These individuals therefore ask the uncomplicated questions and are not satisfied until they understand the answers provided. These are the types of auditors that ask the "why" question at least five times which almost always leads to revealing the underlying root causes.

4. Using a checklist only as a guide and ensure it is a process based approach. Otherwise, if the checklist becomes the basis of the audit it can get stale in a short period of time. Admittedly, checklists are great for first time auditors to generate an audit trail. Just be careful not to rely on them solely, since they tend to keep the blinders on and generally do not allow the auditor to think outside the box.

5. Rotating auditors to keep the system fresh. Spread them around. Take advantage of new thoughts, perspectives and ideas. Share the audit results among the entire organization as a lessons learned exercise – one person's corrective action could be someone else's preventive action.

6. Consider scheduling other activities, such as: corrective action effectiveness validation; customer website examination to ensure customer specific requirements are current; and, assessing company statutory and regulatory requirements, if applicable.

Pitfall #3: *Internal auditors not effectively utilized.*

Auditing is an acquired skill just like playing a musical instrument, cooking or golf. The more it's practiced, the better one becomes at it. Simply put, the more one audits, the better and more comfortable they become auditing. Honed auditing skills shortly follow. It's a wasted opportunity when a company invests time and money to train their audit team yet uses them on a minimal basis. Consequently, it's equally beneficial for the auditee to be engaged in the audit process often, as well. The more one is exposed to being audited the less intrusive and threatening the process becomes.

Pitfall #4: *The internal audit/corrective action process is not timely.*

Many audit schedules I've assessed allows the internal audit team a wide time allowance to complete a scheduled audit. Typically, if an auditor is given a month to complete an audit then it will be a month (or more) before that audit is complete. You know the saying, "Give an inch – take a mile". Effective audits are scheduled for specific days, and at the most, specific weeks. Any allowance more than that only dilutes the effectiveness and importance of the system. Even worse, when corrective action responses are given equal relaxation, the timeframe between initial audit schedule, deployment, finding and response can be spread out so far that its impact gets completely nullified.

Pitfall #5: *Internal audits do not reflect a process based approach.*

When the ISO 9001:2000 standard was released much emphasis was placed on the requirement of conducting audits using the process approach. The intent was to incorporate audit focus towards assessing process effectiveness, including interface activities with other processes, rather than focus on element and clause compliance alone.

Unlike third party auditors, many companies did not pursue formal ISO 9001:2000 training and hence never fully grasped the intent and understood process based approach auditing. As a result, this creates a disconnect between the third party auditor and the organization as some companies still do not fully understand: their process inputs and outputs; process sequences and interfaces; and, process monitoring and measuring.

Organizations that are still struggling with the process approach concept are highly encouraged to pursue formal training or consulting assistance.

The bottom line is that internal auditing is a cornerstone of the QMS – a vital tool to identify and improve the effectiveness of the Quality Management System. With the advent of the process based approach to auditing and process layered audits, its value and importance is significantly raised. Management reviews simply cannot be effective without effective internal auditing and reporting.

The pitfalls mentioned in this article represent only some, not all, ineffective auditing practices. If an internal audit system is disciplined to the point that it is supported by senior management, carried out as scheduled and coupled with effective corrective and preventive action in a timely manner (as required by the standard), then the benefits will justly be realized – through continual improvement and customer satisfaction.

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