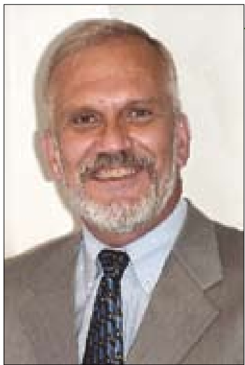

by Ron Ball

An Internal Compliance Audit Program Can Be a Powerful Management Tool

Managers are better able to focus their compliance resources and programs when they can identify the areas that require strengthening.

An internal compliance audit program is a powerful management tool for finding and fixing potential compliance exposures in your operations. Just one of the advantages it offers managers is that it gives them the capability to identify the areas that require strengthening, and helps them to better focus their compliance resources and programs. In this article we will discuss key elements of an effective audit program and some potential pitfalls to avoid.

Considerable variability exists in regulatory requirements related to compliance auditing. Some regulatory bodies establish specific requirements for conducting audits in a specified frequency. Other agencies do not have specific requirements, but believe internal auditing programs are desirable activities, and have established guidance and policies that encourage companies to implement internal audit programs. While I think it is safe to say that all regulatory agencies would agree that internal compliance auditing programs are useful, there are a number of agencies that have not publicly communicated an expectation to perform internal compliance audits. For instance, the OSHA PSM standard, 29 CFR, section 1910.119 (o) (1) requires a compliance audit, and specifies a frequency of every three years. FDA device regulations, in 21 CFR, section 820.22, require quality audits, but do not establish an audit frequency. FDA audit requirements for drug manufacturers are not so specific. FDA encourages firms to perform audits, but there is no specific requirement stated in 21 CFR 210 & 211. CDER policy is not to ask to see the results of internal audits. It is more a means of encouraging firms to conduct them.

Good auditors are developed, not born. Auditing is an acquired skill, and comes both from industry experience and professional auditor training.

It is important for business owners to establish the appropriate "tone" for internal audits. Firms that use the audit process as a learning opportunity for managers and employees alike, and foster open and free dialogue about problems and potential solutions are on the road to success. These same firms see areas of non-compliance uncovered during audits as opportunities for improvement. Conversely, firms that send in the audit team to poke around looking for problems, and then use this information as a means to punish or embarrass facility managers, are likely to find these same managers unwilling to volunteer information or ask questions about potential compliance issues that concern them.

Once these types of internal walls go up, the value of the internal audit in finding and fixing potential problems vanishes. In establishing the tone for audits, it is also important to maintain some balance. Too often auditors bore in on the negative aspects, and fail to see the positive things sites do to maintain compliance. Finding examples of things done well to manage compliance, and communicating these examples to the rest of the organization, is just as important as finding and fixing problems.

A further influence on audit programs is the auditors themselves. This, in our opinion, can be the most difficult aspect to get right. A key pitfall to avoid is putting people in audit roles that either bring or develop a strong cop-like mentality. There is a big difference between someone who is good at conducting audits and someone who likes to audit. We often find that people who enjoy a steady diet of auditing are likely to have gravitated into the regulatory cop mentality. Individuals who are good at auditing are people who see the process as one that can be likened to assembling a jigsaw puzzle. They take the bits of data gathered during the audit process and assemble a picture of the site's compliance activities, looking at the whole picture, not just the negative elements. Good auditors recognize that a steady diet of auditing is a recipe for achieving "audit burnout."

We recommend that people in audit roles have additional job responsibilities, such as training or site assistance type activities, that allows them to feel they contribute to the business and are not just there to point out problems. Another important aspect to remember is that good auditors are developed, not born. Auditing is an acquired skill that results both from industry experience and professional auditor training. In addition to having a solid experience base in medical gases, we highly recommend that your internal auditors have training in how to audit and how to manage the audit process.

Third-Party Audit: When The Doctor Comes to Call

Business owners and managers in large and small companies alike find that third-party audits are a valuable management tool. In larger firms, with dedicated internal resources, third-party audits offer a different perspective on their internal compliance activities, as well as their compliance measurement tools. These outside audit events help companies identify opportunities to improve safety and FDA compliance, which may only be apparent to a "fresh set of eyes." These same audits also help validate what elements of their compliance program are working well.

In smaller firms, with no or part-time compliance resources, third-party audits help business owners ensure that their organization is in step with industry compliance requirements. Business owners can compare third-party audits to an annual compliance health check performed by a doctor. The audit alerts them to potential problems, and at the same time, lowers their anxiety when the government inspector comes to call.

Elements of Audit

As to the audit process itself, there are three basic elements: *planning and preparation*, *conducting the audit*, and *reporting and follow-up*. Each of these plays an important role in a successful audit program. In planning your audit process the first consideration is to select the type of audit. There are three different types available:

- Firms can elect to have site managers do a self audit of their facility. We recommend that some sort of check list or audit form be used to guide this process. The pitfall with self assessments is that some local managers may lack adequate objectivity in reviewing their own operation, and/or may be unwilling to voluntarily identify potential deficiencies.

- The second audit type is an internal audit, in which the auditor does not have line responsibility for operations at the site being audited. Here the auditor usually has more objectivity; however, in small firms this could still be an issue. We recommend that an audit tool that guides the process be developed to ensure a thorough audit.
- We also recommend that a set of guidelines be developed that establishes what constitutes acceptable compliance to a requirement. Having specific guidelines minimizes arguments between site managers and the audit team over what is acceptable compliance.

For this reason the B&R self-audit program includes an auditor guideline that provides detailed guidance in determining compliance. The third type of audit is a third party assessment. In addition to offering the highest level of objectivity, third party auditors can provide feedback on relevant industry best practices. During our customer audits we routinely are able to offer suggestions for alternative methods to comply with a requirement that may have the potential to save customers both time and money, compared to their current method.

During internal or third party audits, it is vital to have site management involved in the audit process. Audit processes that are only a review of paperwork, and which do not involve interviewing operations managers and employees about their day to day compliance management challenges, lack the capacity to provide business managers and owners a complete picture of potential issues and opportunities. We recommend that the audit team conduct an opening conference with site management and supervisors to discuss both the audit objective and process. Teams should lay out what procedures and records they need to review, how long the audit will take, and who they wish to interview. We highly recommend that auditors observe employees (such as fillers) as they conduct their job tasks, to verify compliance with procedures, as well as to assess if these employees have developed any bad work habits. Observing employees at their job tasks is something FDA inspectors are increasingly incorporating into their audits. At the end of each day, the audit team should meet with site managers to discuss any findings, audit progress, and plan the next steps. At the end of the audit, the team should present its findings to site management and discuss suggested action items needed to address any issues uncovered during the audit.

After the Audit is Completed

Once the audit is concluded, it is important to develop an action item list and establish who is responsible for completing each item. Too often, we have seen firms take the time to perform audits, but never establish a process that ensures that the issues uncovered get fixed. The same deficiencies keep getting identified in subsequent audits, and often, firms do not get them fixed until a regulatory agency issues a citation. In our opinion, taking the time to identify improvement areas, and then failing to invest the resources needed to fix the problem, is a waste of the time and effort that went into conducting the original audit. Increasingly, we see regulatory agencies advocating the concept of corrective and preventive actions (CAPA). Today, enforcement bodies expect companies to find and fix their own problems, and not wait until the agency shows up to conduct a site inspection. FDA, for one, has announced that the effectiveness of a firm's CAPA process will be one of the determining factors in establishing an inspection frequency for that company. The better your company is at finding and fixing your own problems, the less often you can expect to see FDA in your business. I can't think of a better reason for having an audit program and CAPA process in your business.

How often you conduct audits is up to you. Many firms use an annual audit frequency. Others vary the frequency from every six months to once every two years, based on a number of factors, such as the number of deficiencies found in the previous audit. A mistake we see firms make is to not make any attempt to audit at all. Some business managers are hesitant to face making changes in their business to improve compliance, and are willing to "roll the dice," hoping that nothing will come up at the next regulatory inspection. We often hear . . . "XYZ agency was here recently and they did not find a problem with our program" . . . as the rationale given for not looking for opportunities to self improve. With a number of new inspectors out there today who are still learning about our industry, it should not surprise anyone that a regulatory inspector might overlook a potential issue. This is also not to say that the next inspector through the door won't find it either. Ultimately, it is much more cost effective to find and fix any compliance problems through your own initiative, rather than to wait for a regulatory citation and then try to develop and implement fixes with the agency looking over your shoulder. Since regulatory citations are in the public record, it also keeps you from having to potentially explain the problem and what you are doing about it to your customers. SGR

For more information of audits conducted in gas producer companies contact Ron Ball at B&R Compliance Associates LLC (317) 297-8518; e-mail: bob.jyeoman@brcompliance.com, or visit B&R on the web at www.brcompliance.com