The Human Side of Auditing

Laura A. Halper

Given the wealth of written material about internal audits, which are essential to the success of any quality assurance (QA) system, surprisingly little has been written about how auditors can best relate to those whose operations they audit Although the purpose of the audit is to ensure the quality of the product, companies are nun by people and. as such. audits can be perceived as evaluations of individuals. There are a number of personal attributes that auditors can try to refine, and ways to approach their auditees - or specific area managers - that can make the audit more comfortable for all parties involved

FDA emphasizes the significance of internal auditing in its *Medical Device Good Manufacturering Practices Manual*, where it states that "the quality audit of a QA system is one the most important requirements of the GMP regulation....Firms that have a total QA system . . should audit the entire system, otherwise, it is no longer a total QA system!' Internal audits are also a requirement of the ISO 9001 and 9002 quality system standards. The GMPs and ISO standards both state that area managers must review the results of the audit and take remedial action where indicated if all participants understand that the purpose of these requirements is to uncover and correct any flaws in the system, the auditors and the area managers need not approach the audit in terms of personalities or human imperfection.

The auditing process can be divided into four stages: planning, conducting, reporting. and follow-up. Detailed information about each of these stages can already be found in auditing textbooks 2 1 To complement that material, the following strategies are presented with regard to the human factors inherent in each of these stages.

PLANNING THE AUDIT

Scheduling. An audit schedule should be distributed to each area manager so that time conflicts can me avoided or adjusted in advance. For example, the person who draws up the schedule may not know that certain lines are to be shut down for planned maintenance Distribution of the audit schedule is a basic courtesy to the area manager; the implicit message is that the audit's objective is to ensure quality. rather than to embarrass or “entrap” the manager Scheduled audits also motivate the manager to conduct informal self-audits and to initiate necessary corrective action before the formal audit. The area manager thus assumes more responsibility for the quality system, makes improvements more quickly, and facilitates the auditors' job. Occasionally, an area manager will simply try to conceal a problem before a scheduled audit, but this ploy is seldom successful because qualified auditors will usually discover a systemic problem.

All areas of an operation that affect overall quality should be audited at least once a year. The frequency and duration of the audit must be based on logical criteria (such as the history of quality problems in that specific area. or the impact of the particular operation on product quality) rather than on personal opinions of particular staff members. New areas - perhaps design control or a new manufacturing process - ought to be audited more frequently to establish a quality history.

Team audits take less time and enable auditors to focus on areas in which they have demonstrated expertise.

Staffing Considerations. The company must assess whether the internal audit would best he conducted by an individual auditor or an audit team. insofar as people, in general, are most comfortable dealing with familiar situations in which they do not risk failing or appearing ignorant, auditors' particular strengths and weaknesses may inadvertently affect each stage of the audit. Auditors are not equally familiar with all of the processes, equipment. and procedures that they might be authorized to assess. But they should avoid spending a disproportionate amount of time examining familiar areas at the expense of other, less-familiar areas. Auditors should think of the auditee or area manager, as a client whose needs must be satisfied.

Individual auditors may be able to examine a single function, such as calibration, receiving. or welding. But larger audits are best handled by an audit team, headed by a lead auditor who has overall responsibility for planning, conducting, and reporting the entire procedure. A team approach takes less time, and enables auditors to be assigned to areas in which they have demonstrated expertise. Teamwork also provides an opportune context in which to pair new or less-expenenced auditors with seasoned veterans. thereby providing ongoing training to the auditors. But perhaps the most important advantage of a team approach is that it prevents one person's interpretation of standards and practices from governing the direction of the quality system.

In smaller companies where an audit team may not be practical, at least two individuals should be trained so they can conduct audits on an alternating basis.

CONDUCTING THE AUDIT

The Entry Meeting. The audit

begins with the entry meeting, which is usually less formal for an internal audit than for an external (supplier) audit. In either case, auditors are guests in their client's area and should inform the area manager of their arrival. Managers that have been involved in previous audits will probably help auditors get started right away. However. if the manager has not been audited before, or if the auditors are assessing a new area. auditors ought to take a few minutes m explain the purpose of the audit and describe the protocol. A first-time auditee will likely have some anxiety and may become defensive even before the audit begins. One way auditors can reduce the tension is to ask the area manager about any particular aspects of the operation that he or she would like to see included in the audit. This reinforces the idea that the manager is a client to whom the auditors are providing a useful service. As a result, the area manager will feel more like a participant. will more readily accept responsibility for the outcome, and will rest assured that all players share a common goal. namely, to improve the system

Personal Strategies. Auditors should try to begin each audit on a positive note. They should not assume that a particular person will cause trouble When interacting with a defensive area manager. auditors must remember that their demeanor is critical to the success of the audit. They must not get drawn into heated arguments or distracted by tangential issues. and must always focus on the business at hand.

Auditors should display self-confidence and professionalism. Seasoned auditors achieve confidence through experience. Less-expenenced auditors can bolster self-confidence by being thoroughly prepared for the audit. Preparation involves knowing the requirements of the applicable quality standards (for example, GMPs or ISO standards); reviewing past audit reports for insight into areas that may need more emphasis; and using checklists and flowcharts to provide structure and organization to the audit. and to help ensure that all relevant areas are investigated.

The best way for auditors to earn trust during the audit is to show interest in the area manager's work: be courteous when asking questions and demonstrate respect for the responses. Most area managers will cooperate, even if only to end the audit more quickly. A non responsive auditee can be drawn out by asking open-ended questions that start with "how, what, when, where, who, or why," and cannot be answered with a simple "yes" or "no." People enjoy talking about what they do, and they appreciate auditors who recognize that their job is important.

Good auditors acknowledge that they do not know everything. They admit mistakes. and tell their clients when they do not understand something The area managers appreciate the honesty, and can usually perceive when an auditor is feigning knowledge anyway.

A powerful interviewing technique is to convey unspoken questions. Prolonged silences make people uncomfortable. By looking expectantly at their client without saying anything, auditors can often elicit information. This approach is especially useful as a follow-up “question “ when auditors believe that the area manager is holding something back. But this technique should not be overused: unrelenting silence on the part of the auditors can backfire by annoying the area manager and engendering a divisive relationship.

Impatient auditors may jump to premature conclusions based on verbal information Although interviews are valuable sources of information, the area manager's statements must always be corroborated with other means of objective evidence. If the auditors ask, for example, how often a test instrument is calibrated, they must verify the response by examining the calibration records for that instrument. Auditors should explain that this is a procedural formality that is not intended to communicate distrust The evidence will usually support the manager's response, but if it does not, the manager must he informed of the discrepancy.

When auditors observe a practice that seems contrary to an approved procedure, they must not immediately conclude that a major problem exists. They must explain the discrepancy to the area manager, and ask why the activity is being done that way. The manager may be able to show that the practice actually does comply with the approved procedure, or that it actually provides better quality assurance than the approved procedure. The appropriate corrective action in the latter case would be to modify the approved procedure, following formal change control, to reflect the actual practice

The ISO "Guidelines for Auditing Quality Systems 4 recommend several personal attributes that auditors ideally possess, such

Deficiencies that the area manager corrected during the audit should not be included in the written report.

as sound judgment, analytical skills, tenacity, open mindedness, and the ability to perceive situations in a realistic way. They must also grasp complex operations from a broad perspective in order to evaluate whether an observed nonconformity is an isolated incident or part of a systemic problem. For example, auditors will almost always find an error in the quality records: someone at some time will have left a field blank, transposed two digits, not indicated a unit of measure, or forgotten to record a date. If this type of nonconformity exists, auditors must examine enough records to determine whether there are a significant number of such errors They need not include isolated, non critical observations in the audit report that do not suggest deficiencies in the quality system. Most employees genuinely want to produce high-quality products. Auditors must demonstrate concern with the integrity of the quality system, and not indulge in nit-picking attacks on individuals. The area manager will then commit more enthusiastically to taking corrective action for any systemic deficiencies that may be found.

Members of an audit team should meet at the end of each day to review their observations. Team discussions help to ensure consistency and prevent individual bias in the audit report. If similar deficiencies have been observed in more than one area, then a system wide problem may exist, and further investigation should be done for verification. Each nonconformity should be identified in terms of the specific requirements of the standard against which the audit has been conducted.

The Closing Meeting. Auditors shout hold a closing meeting at the conclusion of the audit. The area managers and the QA manager should attend. Negative findings will be better received if auditors mention the positive attributes first. Auditors should focus on improving the system, rather than on personalities.

Auditors may have to persuade an area manager that the conclusions are based on fact and represent the true state of things. If the findings are contrary to the prevailing management belief about the state of the quality system, the auditors ought to present concrete, convincing evidence that particular deficiencies affect the overall quality of the system.

The closing meeting is a final opportunity for the participants to clarify any issues before the auditors prepare a written report. Auditors should amend the conclusions if appropriate new evidence is presented. Management will want to know how effective the current quality system is, and how the problems cited could affect product quality.

Auditors are responsible for determining where corrective action is needed. The area manager is responsible for planning and implementing the corrective action. If a schedule for completing corrective action cannot be provided during the closing meeting, the manager should commit to a date by which the schedule will be provided.

REPORTING THE AUDIT

The written audit report summarizes the information that was presented during the closing meeting. If a team performed the audit the report should be written by the lead auditor. Information not presented during the meeting should not be included in the report. The written report, like the oral summary, should deal with verifiable evidence rather than subjective opinion. The report should begin with positive statements. Deficiencies that the area manager corrected during the audit should not be included in the report.

The written report allows no opportunity for discussion or clarification. Therefore, the report must be very specific about why nonconformities do not comply with the applicable standard. A written report may be seen by people who are not on the original distribution list, so statements that might be viewed as derogatory toward any individual should be avoided.

FOLLOW-UP

The auditors must ensure that the area manager has both rectified the immediate problems cited in the report and taken effective corrective action to eliminate the root causes of the deficiencies. Auditors should review the results with the audit team, if possible, to prevent personal preference from influencing he follow-up evaluation. Auditors should document the formal close of the audit after verifying that all corrective actions have been effectively completed.

CONCLUSION

Audits, by their nature, always involve some stress for the individual or team performing the audit as well as the company or specific area being audited. Auditors can help the process run smoothly by preparing ahead of time, sharing information with the specific area manager, listening to that manager's point of view, and remaining composed in the face of opposition.

Advanced distribution of an audit schedule assures the staff that the purpose of the audit is not to embarrass or “entrap” them.

The *Medical Device Goad Manufacturing Practices Manual* states that auditors need a working knowledge of how a device is made, the manufacturing processes, the QA principles that apply, and the human relations aspect of auditing. This last aspect of auditing is far from the least.

REFERENCES

1. *Medical Device Good Manufacturing Practices Manual*, 5th ed, Rockville, MD, FDA, pp 15-1 and 15-3,1991.

2 Arter DR, *Quality Audits for Improved Performance*, Milwaukee, ASQC Quality Press, 1989.

3. Sayle AJ, *Management Audits*, 2nd ed, London, McGraw-Hill, 1981.

4. “Guidebnes for Auditing Quality Systems - Parts 1-3,” ISO 10011-1, ISO 10011-2, and 1S0 10011-3, Geneva Switzerland, 1990,1991.