Tips From the Trenches: ISO Auditing 101

The most important thing in conducting an audit is to establish a framework for how we think about the audit. The idea for this article came about recently, as I was preparing to audit one of our calibration suppliers to ISO 17025:2005 for the first time. I had conducted many ISO 13485:2009 audits, but never audited a system meant to be compliant to ISO 17025.

Just as adoption of the windows platform has made learning new software much easier, so too does adoption of ISO standards make auditing to a new standard much easier and consistent. Even as ISO gives companies a framework, upon which to construct their QMS, it also provides a roadmap for how to conduct an audit. As the ISO standards are meant to be used by a range of companies varying in product, size and organizational complexity, much latitude is given in how so meet the standards requirements. One of those latitudes is when to develop written procedures and what records are to be maintained in order to document compliance to product requirements and the standard.

Having said that, the international standards organization has identified 20 documents and 37 records that are considered critical for any effective QMS to include, and that it is mandatory for a company to have to be considered compliant to ISO 13485:2009. The lack of one of these documents or records would have to be considered a major finding. ISO 13485:2009 also requires that the entire QMS be periodically audited at an interval to be determined appropriate by the company. As I began preparing for my ISO 17025 audit, I asked myself the following questions – 1) what documents are required, 2) what records are required, 3) what information needs to be included in documented procedures and records and 4) what actions are required to be taken by upper management?

When conducting any audit, the auditor first assesses compliance of the auditee QMS to the standard, in other words, are minimum requirements dictated by the standard met? Secondly compliance of employee actions to their QMS Is considered - does the company and its employees do what they say they do? When employee actions don't match the relevant procedure, the first question that I ask, is which is correct? For myself, if the employees actions are correct and the document should be revised, it is a minor finding. If the procedure is correct and the employees actions are incorrect, then the finding is major.

How work flows, is documented and recorded is an essential part of any audit. Compliance of course is determined by a combination of document and record review, observations and interviews. It should be noted that throughout the ISO standards, there is a requirement for not just compliance but demonstrated effectiveness as well.

For me one minor finding is isolated, two *might* be a coincidence, and three starts to look like a trend. Thus typically, 3 or more minor findings related to the same issue are upgraded and considered as one major systemic finding, in my audit reports. It is imperative that each auditor establish their own CONSISTENTLY APPLIED point of view, in conducting audits and assessing audit results. In the audit report, findings should be related to the document:paragraph that was violated.

A robust internal audit program can be used as an important and potent tool for compliance, correction and continuous improvement. Obviously the International Standards Organization is in agreement, as an internal audit procedure is one of the 20 documents, and audit records are one of the 37 records that are mandated by ISO 13485:2009 and its precursor ISO 9001:2008.

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