Assessor evaluation - Case Study 09

Name: - *Documenting of quality control records.*

Category: *Lead Assessor –Non-conformance system*

During a review of the laboratory's non-conformance system, it was noted that the lab has a well-documented procedure that states that a non-conformance form is completed for every non-conformance to pre-established criteria. Each non-conformance is assessed for risk, and, where risk is deemed unacceptable, root cause analysis performed. A corrective action is selected from a list of possible actions, the corrective action is implemented, and then monitored for effectiveness. When reviewing the file of non-conformance forms the assessor observed that all records were complete and thorough.

During this review the assessor also noted that there did not appear to be any analytical QC non-conformances. When asked about this, the Quality Manager stated that their procedure clearly states that QC failures are not considered non-conformances to be handled under their corrective action procedure. When asked why this was so, the Quality Manager stated that the QC protocol is in place to identify possible analytical problems. A QC failure is simply the system working the way it is intended. The only time a QC failure would end up going through the complete corrective action system would be if a result were reported to a client in spite of the QC failure. When asked if the QC failures are recorded the Quality Manager stated that there was a log for each method that records QC failures and actions taken.

Would you have rated this discovery a non-conformance? Yes? No?
If No – Why?

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If yes - What ISO/IEC 17025 clause/s is/are applicable and why?

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If yes – What AB Policy/ies is/are applicable and why?

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If yes - What corrective action would you expect?

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