

Assessor evaluation - Case Study 01

Name: - Remote Quality Assurance

Category: - Lead – Quality Assurance

At a laboratory, the daily quality control checks are reviewed by the Laboratory Supervisor. The Laboratory Supervisor reports to the Laboratory Manager, and this Laboratory Manager is the back-up for the Laboratory Supervisor. The Laboratory Manager, in turn, reports to the Director who is located at another facility.

Also reporting to the Director is a Quality Manager. The Quality Manager is located at another facility several hours away and infrequently (2 to 3 times per year) visits the laboratory to check on the laboratory's implementation of the quality system. The Quality Manual and the test procedures are produced and administered from the other facility.

Currently, because of the departure of the Laboratory Manager, the Director is also the Acting Laboratory Manager. If the Laboratory Supervisor has questions, she asks the Quality Manager at the other facility.

If the Laboratory Supervisor was to leave the company, then the Acting Laboratory Manager (who is also the Director) takes over the on-site review of the quality control checks and if he has questions, he asks the Quality Manager. The Quality Manager reports to this same Director.

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

If No – Why?

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

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

If yes - What corrective action would you expect?
