

Assessor evaluation - Case Study 14

Name: - *Documented Procedures*

Category: - *Lead and/or Technical Assessor – Documentation*

During the document review, the assessor notes that the laboratory has comprehensive documented procedures that are controlled according to the requirements in ISO/IEC 17025:2017. The one exception to this is the section concerning making media in a microbiology method that references the instructions on the media bottle. The laboratory maintains that they are following the instructions exactly as written on the media label from the manufacturer.

During the interviews with analysts on-site, the assessor observes that not all laboratory-specific instructions are documented. Upon further investigation, it appears that the documented procedures are basically the reference method, re-written word-for-word in the laboratory's format. The laboratory maintains that they are following the reference method, and does not see the need to add instructions that they feel do not adversely affect the validity of the test results.

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?
