Assessor evaluation - Case Study 13

Name: - *Fitness for Purpose*

Category: - *Lead and/or Technical Assessor – Method Validation.*

Review of a laboratory's request for exemption from participation in a required Proficiency Testing (PT) program has led to an investigation as to whether the particular method is fit for use.

The laboratory states their test method is based on two internationally recognized methods. The first is an older method that specifies the use of an uncommon chromatographic detection system with three detectors used in series and several possible columns. The serial detectors and various columns are included to analyse several fractions from the same sample extract. The second reference method is a more modern method that specifies the use of a common detector and several possible columns.

The laboratory uses the uncommon chromatographic detection system and one of the three columns specified in the older reference method and has substituted two other columns for their method. The laboratory does not use the detection system and only one of the four columns specified in the newer, common reference method.

The laboratory has determined method detection limits, uncertainty, precision and bias for the majority of the target analytes.

When the laboratory analyses a mixed PT sample from the required PT program with numerous target analytes, the laboratory cannot resolve all of the chromatographic peaks for the target analytes because some of the peaks overlap with other target analytes and/or with non-target PT analytes.

The lab states that all of the target analytes can be resolved in PT from another supplier where the target analytes are put in smaller groupings, which the laboratory can analyses without overlapping interferences. As some of the analytes from the separate PT groupings could occur together, this separated PT with smaller groupings may not represent the type of samples that may be found in the environment.

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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