

Assessor evaluation - Case Study 02

Name: - Trend Analysis

Category: - Lead and/or Technical Assessor – Quality Control etc.

The Laboratory used a LIMS for its test data handling. The Laboratory recorded quality control data from tests in its LIMS as tests were conducted. The laboratory staff did not compare the results of the quality control data; however, the LIMS system compared the quality control data to pre-determined limit criteria to determine in the specific quality control measure passed or failed its appropriate limit. This comparison was made on an on-going basis. The LIMS would notify the person reviewing the data if there was a failure in any of the quality control data.

The Laboratory did employ control charts for its quality control data. As the quality control data was entered into LIMS and the LIMS made the acceptance judgement, the analysts did not have quality control charts that were filled out on an on-going basis. The quality control charts were printed from the LIMS once per year for the annual trend analysis review. The laboratory stated that this procedure met the requirement that the quality control data be recorded in a way to detect trends.

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?
