

Assessor evaluation - Case Study 11

Name: - *Record keeping*

Category: *Technical Assessor – Record keeping*

While assessing an analytical method the assessor asked the analyst to see records associated with the chemicals and reagents used for the test. When a chemical is received in the laboratory, a unique ID is assigned to the chemical bottle and information about chemical, purity, supplier, lot number and date received is recorded in this log. The assessor observed that all chemicals that he observed were recorded in this log.

The assessor also noted that there were usually two bottles for each chemical on the shelf, one opened and one unopened. When asked about this the analyst stated that this practice ensures that they do not run out of any critical chemical. Whenever a bottle is emptied, a replacement is ordered, and the unopened bottle is opened. When asked how they knew when the lab started using a new bottle he was told that whenever a bottle is opened for the first time, the analyst writes the date on the bottle. An observation of the bottles on the shelf confirmed the statement.

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?
