

Assessor evaluation - Case Study 03

Name: - *Reissuing Documents*

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

A laboratory had numerous procedures with handwritten amendments, which are allowed in their quality system. The handwritten amendments were as recent as a few months prior to the assessment, although many of the handwritten amendments were several years old. Some documents also included handwritten amendments to handwritten amendments. Some of the changes the handwritten amendments were made within 6 months of the previous handwritten amendment, or documents had so many handwritten amendments that it was very difficult to read the documents. The laboratory did not have a procedure detailing when to formally revise and reissue documents.

A new document control procedure stated that documents were to be reissued because of handwritten amendments “as soon as practicable” without stating a time frame. A subsequent version of this procedure stated that documents with handwritten amendments were to be reissued within 2 years of the handwritten amendments, potentially allowing documents to not be reissued for several years, depending on the frequency of the handwritten amendments.

The lab stated that they did not have time to reissue documents on a frequent basis. The laboratory stated that if a document was legible with the handwritten amendments, it did not need to be rewritten.

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?
