

## Assessor evaluation - Case Study 05

**Name:** - *Verification of Incubators*

**Category:** - *Lead Assessor – Testing etc.*

A laboratory was found to be conducting verification of its incubators used in microbiology testing, although the procedure used was entitled: “Incubator Calibration.” The procedure did not include any consideration regarding uncertainties of measurement.

A check of equipment documents related to the incubator revealed that it had been calibrated three years earlier by an accredited calibration laboratory, at the time it was purchased by the testing laboratory. No other certificates of calibration could be found and interview of laboratory staff indicated that there had not been any formal calibration conducted on the incubator in the intervening period.

The verification procedure included taking 10 measurements at both ends of all three levels of the multi-level incubator using a calibrated liquid-in-glass reference thermometer with an expanded uncertainty of  $\pm 0.05$  degrees Celsius. The reference thermometer is calibrated annually by a calibration laboratory that is accredited to ISO/IEC 17025 by an ILAC-recognized accreditation body with “calibration” on its scope of recognition. The accredited calibration laboratory’s scope of accreditation was found with the reference thermometer’s calibration certificate, and it contained reference to a CMC of  $\pm 0.02$  degrees Celsius for liquid-in-glass thermometers.

When interviewed, the laboratory staff felt that their procedure was sufficient to demonstrate traceability of measurement of their incubator.

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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