
**Commissioner's Corner**
**December 2023**

**QUESTION: Is calibration verification required after an equipment maintenance event?**

**ANSWER:** The short answer is yes as indicated by standards **D.4.1.7.1** and **D.4.1.7.2**. The longer answer is that the intensity of the process can differ depending on the level of the maintenance event. Verification after low intensity preventative maintenance (PM) which does not include replacement of critical parts or major adjustments can take the form of function check testing only.

If the equipment is moved, the maintenance event (including PM) involves replacement of critical parts, and/or the maintenance event (including PM) involve major adjustments then the verification process needs to be more intense. This verification would require testing as established by the laboratory during the initial validation. This is not to say that a repeat of the full validation is required to bring the equipment back into clinical use. Rather a subset of testing that aligns with the initial validation is required.

The specifics of the required testing and acceptance criteria for both scenarios should be documented in either an overarching policy/procedure or in the specific procedure for the equipment or assay.

**Referenced Standards:**

**D.4.1.7.1** For each applicable testing procedure which requires equipment to provide a quantitative measurement, the laboratory must perform and document instrument calibration procedures. These calibration procedures must:
**D.4.1.7.1.4** Use the criteria verified or established by the laboratory during validation.
**D.4.1.7.1.5** Include the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration as established by the laboratory.

**D.4.1.7.2** Calibration verification procedures must:
**D.4.1.7.2.4** Be performed at least once every 6 months and whenever any of the following occur:
**D.4.1.7.2.4.2** There is major preventive maintenance or replacement of critical parts that may influence test performance.