and participant summary report. Laboratories must review their performance against the +/- 6% criteria and perform corrective action for each unacceptable result.

Evidence of Compliance:

✓ Records of accuracy-based PT evaluation using the +/- 6% performance criteria

REFERENCES

1) Sacks DB, Arnold M, Bakris GL, et al. Guidelines and Recommendations for Laboratory Analysis in the Diagnosis and Management of Diabetes Mellitus. *Clin Chem*. 2023; 69(8):808-68.

QUALITY MANAGEMENT

CALIBRATION AND STANDARDS

Inspector Instructions:

	• Sampling of calibration and AMR policies and procedures • Sampling of calibration/calibration verification records • Sampling of AMR verification records • Sampling of patient reports and worksheets for verification of results outside of AMR • Current DEA license (for US laboratories that handle pure controlled substance(s))
	• Sampling of calibration materials (quality)
	• What is your course of action if calibration is unacceptable? • When was the last time you performed a calibration procedure and how did you verify the calibration? • What is your course of action when results fall outside the AMR? • What is your course of action when you receive calibration materials for non-FDA cleared/ approved assays? • How does your laboratory verify concentration techniques?
	• Further evaluate the responses, corrective actions, and resolutions for unacceptable calibration, and unacceptable calibration verification

CALIBRATION AND VERIFICATION PROCESSES – WAIVED TESTS

CHM.12950 Calibration, Calibration/Verification - Waived Tests **Phase II**

For waived tests, testing personnel follow manufacturer's instructions for calibration, calibration verification, and related functions.

Evidence of Compliance:

✓ Records for calibration/calibration verification/related functions as required by the manufacturer **AND**

- ✓ Records of recalibration or other appropriate corrective action when calibration verification is unacceptable

CALIBRATION AND VERIFICATION PROCESSES – NONWAIVED TESTS

The remaining requirements in this checklist on CALIBRATION, CALIBRATION VERIFICATION, and ANALYTIC MEASUREMENT RANGE (AMR) VERIFICATION do not apply to waived tests.

This introduction discusses the processes of calibration, calibration verification, and AMR verification.

CALIBRATION: The process of adjusting an instrument or test system to establish a relationship between the measurement response and the concentration or amount of the analyte that is being measured by the test procedure.

CALIBRATION VERIFICATION: The process of confirming that the current calibration settings for each analyte remain valid for a test system.

Each laboratory must define limits for accepting or rejecting results of the calibration verification process. Calibration verification can be accomplished in several ways. If the manufacturer provides a calibration validation or verification process, it must be followed. Other techniques include (1) assay of the current calibration materials as unknown specimens, and (2) assay of matrix-appropriate materials with target values that are specific for the method.

ANALYTICAL MEASUREMENT RANGE (AMR): The range of analyte values that a method can directly measure on the specimen without any dilution, concentration, or other pretreatment that is not part of the usual assay process.

LINEARITY AND THE AMR
Linearity is a fundamental characteristic of many analytic measurement methods, whereby there is a straight-line relationship between ‘‘true’’ analyte concentrations and measured concentrations. In this context, linearity refers to the relationship between the predicted and observed measurement results and not to the relationship between instrument signal output and analyte concentration. For most assays, this relationship is linear within the AMR.

AMR VERIFICATION
Laboratories are required to verify that the appropriate relationship is maintained over the AMR. Laboratories may verify and use an AMR that is narrower than the range defined by the manufacturer. This may be appropriate when materials available for method validation and/or AMR verification are not available to verify the full range claimed by the manufacturer, or reporting values across the full range defined by the manufacturer is not clinically relevant. For many assays, results beyond the AMR can be reported through dilution or concentration studies (see CHM.13710 & CHM.13720). AMR verification is not required for calculated test results (refer to the Definition of Terms in the All Common Checklist) as long as the individual results contributing to the calculation have AMR verification.

Minimum requirements for AMR verification can be met by using matrix appropriate materials, which include low, mid and high concentration or activity range of the AMR with recovery of results that fall within a defined range of the target value. Records of AMR verification must be available.

CLOSENESS OF SAMPLE CONCENTRATIONS OR ACTIVITIES TO THE UPPER AND LOWER LIMITS OF THE AMR
When verifying the AMR, it is required that materials used are near the upper and lower limits of the AMR. Factors to consider in verifying the AMR are the expected analytic imprecision near the limits, the clinical impact of errors near the limits, and the availability of test specimens near the limits. It may be difficult to obtain specimens with values near the limits for some analytes. In such cases, reasonable procedures should be