WAC 16-309-120 Quality control and assurance. (1) The laboratory must develop and maintain an extensive quality control (QC) program which involves the concurrent analysis of calibrators and controls with samples to demonstrate if the analytical system is operating within defined tolerance limits and that random and systematic errors can be identified in a timely manner.

(2) Laboratories must use controls that evaluate the performance of the sample prep and analytical instrument(s) in each preparation batch and must monitor the results of those samples within each batch and across batches for methods that include:

(a) A negative or blank control to demonstrate the assay(s) ability to perform without interference or contamination.

(b) A CCV above the cutoff or decision point but below the upper limit of linearity. Using a calibrator from the initial calibration is an acceptable CCV.

(c) A matrix spike (MS) and matrix spiked duplicate (MSD) at least every 20 samples per matrix for high complexity tests.

(d) If a matrix is not available, a representative matrix may be used and must be spiked at a concentration above the action limit with the target analytes. This is also known as a laboratory control sample (LCS).

(e) A laboratory control sample (LCS) may be used in place of a continuing calibration verification (CCV)(but not as a replacement for a failing CCV) for methods where the calibration goes through the same process as the LCS.

(f) A sample duplicate and a singular matrix spike is acceptable, when a matrix spike duplicate is not used, for each preparation batch.

(3) Positive control materials must be processed in the same manner and included with the test sample batches through the entire testing process. This does not include the ICV or CCV.

(4) Calibration curves must be verified from a second source including, but not limited to, an ICV. Laboratories must use a standard obtained from a second manufacturer if available for purchase. Laboratories may use a separate lot prepared independently by the same manufacturer if a standard obtained from a second manufacturer is unavailable for purchase. The ICV must include all required analytes for each analysis performed.

(5) Laboratories must use reference standards that are traceable to a primary standard through a certificate of analysis, when possible.

(6) Laboratories must use surrogate analytes or internal standards for all high complexity testing. Internal standard response must be within 50-200 percent of the response of a midpoint initial calibration standard.

(7) The use of quality control material must determine the accuracy and precision of all required analytes in each analyses performed.

(8) For any method in which quality control acceptance criteria is not defined, the criteria must not exceed 30 percent.

(9) New lots of reagents, calibrators, and control material must be validated against a currently validated calibration or method before it is put into service.

(10) All control results must be documented in a manner to allow the laboratory to detect instrument or process failure and to identify trends or bias.

(11) Quality control results must be reviewed by a qualified analyst and must meet the acceptance limits prior to reporting out sample results.

(12) Cumulative quality control records must be reviewed by the individual responsible for oversight of the laboratory's QC program on a regular basis so that they can detect assay problems, trends, shifts, and bias.

(13) The laboratory must have procedures describing corrective action to be taken and take action when cumulative control results show evidence of problems. Control records must include documentation of the specific problem noted and documented evidence of the corrective actions to resolve the problem.

(14) The laboratory must use notebooks, logbooks, or other electronic means of communicating with staff regarding issues, problems, or communications between shifts.

(15) The laboratory must have a quality assurance manual, policy, or procedure to identify operational procedures, organization objectives, functional activities, and quality control activities designed to achieve quality goals desired for operation of the lab.

(16) The laboratory must designate a quality manager who, irrespective of other duties and responsibilities, must have defined responsibility and authority for ensuring that the quality system is implemented and followed. The quality manager must have direct access to the highest level of management at which decisions are made on laboratory policy or resources.

(17) The laboratory's quality assurance plan must measure meaningful data throughout laboratory processes that establish thresholds or limits for the indicators to trigger evaluation of the services if not met. Meaningful indicators established within the laboratory can be qualitative or quantitative and may be related to structure, processes, or outcome of the service involved.

(18) The quality assurance data must be reviewed by the scientific director on an ongoing basis that allows timely identification of problems to catch trends or issues early enough to make changes.

(19) The laboratory must maintain documentation and tracking of failed samples and batches like all other data and must make them available when requested.

(20) Instruments that use a multipoint curve must be calibrated using a minimum of a four-point curve with the first calibrator at the LOQ. No blanks can be used as a point unless required by the manufacturer. The linear correlation determination (r^2) must be ≥ 0.9950 or the correlation coefficient (r) must be ≥ 0.9975, unless otherwise specified in a CLASP-approved method. Linear regression with $1/x$ or no weighting must be used. Forcing the curve through zero is not allowed.

(21) To ensure the quality of data for mass spectrometry methods, the laboratory must:

(a) Perform mass spectrometric tuning at relevant frequencies or at the frequency specified by the manufacturer.

(b) Ensure method performance by comparing transitions and retention times between duplicated controls, calibrators, and samples.

(c) Use an internal or external standard to minimize errors caused by evaporation of solvents and injection errors or discrepancies.

(d) Have a detailed procedure for the manual integration of any peaks, including the review of automated integration and adjustments.

(e) Maintain all information necessary for reconstruction of the data.

(22) To ensure the quality of data for an immunoassay method, the laboratory must:

(a) Ensure functionality of new test kits and reagent lots by utilizing positive and negative controls.

(b) Ensure absorbance intensity is within the acceptable range as defined by the manufacturer.

(c) Challenge the linearity of the calibration curve by using:

(i) Different levels of positive controls to challenge the low and high end of the corresponding curve assuring results are reliable throughout the whole range of the curve;

(ii) A negative or blank control to demonstrate the assay's ability to distinguish a positive from a negative and to perform without interference or contamination.

(d) Perform second source verification by utilizing a control separate from calibration material:

(i) For multianalyte assays, calibration curves and controls must be specific for each analyte;

(ii) Control analytes with similar chemical properties as the target analyte may be used.

(23) The laboratory may verify expired neat analytical standards if the standard is recertified by the vendor and new documentation is obtained or the standard is verified by comparison to unexpired neat standard. The response factors must be within 10 percent to be considered fit for purpose. Verified expired standards must be recorded in the verification logs.

(24) The laboratory may only report quantitative results that are above the limit of quantification and below the upper limit of linearity.

(25) The laboratory must use at minimum reagent grade acids and bases, ultra-high purity grade gases, Type II water, and analytical quality materials in the preparation of standards and sample processing.

(26) Laboratory records must be legible and in ink or computerized system. Documents must be signed and dated. Changes must be initialed and dated, and there must be evidence of periodic review.

(27) When corrective action is needed, the laboratory must identify and document the issue, determine a plan for corrective actions, evaluate the results from the plan, and ensure that sample results are not reported until after the corrective actions have provide accurate and reliable results.

[Statutory Authority: RCW 15.150.030 and 2022 c 135. WSR 24-09-079, § 16-309-120, filed 4/17/24, effective 5/18/24.]