IMM.34362 Monthly QC Review **Phase II**

The laboratory director or designee reviews and assesses quality control data at least monthly.

NOTE: The reviewer must record follow-up for outliers, trends, or omissions that were not previously addressed.

The QC data for tests performed less frequently than once per month may be reviewed when the tests are performed.

The review of quality control data for tests that have an IQCP approved by the laboratory director must include an assessment of whether further evaluation of the risk assessment and quality control plan is needed based on problems identified (eg, trending for repeat failures, etc.).

Evidence of Compliance:
- ✓ Records of QC review **AND**
- ✓ Records of corrective action taken when acceptability criteria are not met

IMM.34380 Numeric QC Data **Phase II**

For numeric QC data, quality control statistics (eg, SD and CV) are calculated monthly to define and monitor analytic imprecision.

NOTE: The laboratory must evaluate the imprecision statistics (eg, SD and CV, or other appropriate statistics) monthly to confirm that the test system is performing within acceptable limits. For whole blood methods, where stabilized whole blood or other suitable material is not available for QC, such statistics may be generated from previous patient/client samples using the SD of duplicate pairs or other patient data based statistical procedures.

This checklist requirement does not apply to external controls run only to verify new lots/ shipments of test materials. However, the laboratory should have defined acceptable limits for such controls (either from the manufacturer or developed by the laboratory).

Evidence of Compliance:
- ✓ QC records showing monthly monitoring for imprecision

REFERENCES

1) Rifai N, Horvath AR, Wittwer CT, eds. *Tietz Textbook of Clinical Chemistry and Molecular Diagnostics.* 6th ed. St. Louis, MO: Elsevier; 2018.
2) Clinical and Laboratory Standards Institute (CLSI). *Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions.* 4th ed. CLSI guideline C24. Clinical and Laboratory Standards Institute, Wayne, PA, 2016.
3) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24):7146 [42CFR493.1256(d)(10)(i)]

IMM.34450 Fluorescent/Enzyme Antibody Stain QC **Phase II**

Positive and negative controls are included with each patient run for all fluorescent or enzyme antibody stains.

NOTE: When examining tissue specimens, internal antigens, when present, may serve as positive controls (eg, IgA in tubular casts, IgG in protein droplets, and C3 in blood vessels). Non-reactive elements in the tissue specimen may serve as a negative tissue control. A negative reagent control in which the patient tissue is processed in an identical manner to the test specimen but with the primary antibody omitted must be performed for each patient tissue specimen. If internal controls are not present (eg, ANA IFA), external positive and negative controls must be included with each patient run.

Evidence of Compliance:
- ✓ Records of fluorescent/enzyme antibody stain QC at defined frequency

REFERENCES

1) Clinical and Laboratory Standards Institute. *Assessing the Quality of Immunoassay Systems: Radioimmunoassays and Enzyme, Fluorescence, and Luminescence Immunoassays; Approved Guideline.* CLSI Document I/LA23-A. Clinical and Laboratory Standards Institute, Wayne, PA; 2004.
2) Walker PD, *et al.* Practice guidelines for the renal biopsy. *Mod. Pathol.* 2004;17:1555-1563

IMM.34475 Alternative Control Procedures **Phase II**

If the laboratory performs test procedures for which control materials are not commercially available, the laboratory performs and records alternative control procedures to detect immediate errors and monitor test system performance over time.

NOTE: "Performance" includes elements of accuracy, precision, and clinical discriminating power. The following are examples of alternative procedures: split sample testing with another method or with another laboratory, the testing of previously tested patient specimens in duplicate, testing of patient specimens in duplicate, or other defined processes approved by the laboratory director.

Evidence of Compliance:
✓ Records of alternative control procedures

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24): [42CFR493.1256(h)].

INSTRUMENTS AND EQUIPMENT

The checklist requirements in this section should be used in conjunction with the requirements in the All Common Checklist relating to instruments and equipment.

Inspector Instructions:

READ	• Sampling of incubator monitoring records • Sampling of radioimmunoassay policies and procedures • Sampling of calibration records • Sampling of background radioactivity records
ASK	• How does your laboratory verify concentration techniques? • What is your laboratory's course of action prior to using non-certified thermometers?

IMM.35070 Incubator QC **Phase II**

On days of use, the incubator is monitored for acceptable CO_2 concentration and humidity.

Evidence of Compliance:
✓ Incubator QC records

IMM.35275 Concentration Techniques **Phase I**

Concentration techniques for quantitative tests are verified.

NOTE: Techniques used to concentrate specimens for analysis must be verified at specified, periodic intervals (not to exceed one year or manufacturer's recommendations).

Evidence of Compliance:
- ✓ Records of concentration technique verification at defined frequency

RADIOIMMUNOASSAYS

Refer to the Laboratory General Checklist for requirements for use and storage of radioactive materials.

IMM.35965 Gamma Counter Calibration **Phase II**

Gamma counters and/or scintillation counters are calibrated, with the results recorded and compared to previous values each day of use.

Evidence of Compliance:
- ✓ Records of calibration

IMM.35975 Background Radioactivity **Phase II**

The background radioactivity is determined each day of use, including the background in each well of a multi-well counter, with defined upper limits of acceptability.

Evidence of Compliance:
- ✓ Records of background radioactivity determinations at defined frequency

IMM.35995 Counting Times **Phase II**

The laboratory defines counting times for quantitative procedures that are sufficiently long for statistical accuracy and precision.

ANALYTICAL BALANCES

COLORIMETERS, SPECTROPHOTOMETERS, AND FLUORIMETERS

The following requirements apply to stand-alone instruments; they are not applicable to instruments embedded in automated equipment for which the manufacturer's instructions must be followed.

Inspector Instructions:

READ	• Sampling of colorimeter/spectrophotometer policies and procedures • Sampling of manufacturer required system checks
ASK	• How does your laboratory verify calibration curves?

IMM.39500 Absorbance/Linearity **Phase II**