DRA.10460 Director Responsibility - PT/QC **Phase II**

The laboratory director ensures that proficiency testing, alternative performance assessment, and QC procedures are sufficient for the extent of testing performed in the laboratory.

Evidence of Compliance:
- ✓ Records of PT and alternative performance assessment data, investigation, and corrective action, as applicable **AND**
- ✓ Written QC procedures for all areas of the laboratory **AND**
- ✓ Records of laboratory director or designee review of QC and corrective actions **AND**
- ✓ Records of laboratory director or designee involvement when PT/QC problems directly affect patient care

DRA.10475 Director Responsibility - New Method Validation/Verification **Phase II**

The laboratory director ensures that the performance specifications for new tests, instruments, and methods introduced to the laboratory have been properly validated or verified prior to being used for patient testing.

NOTE: Specific requirements are in the All Common Checklist (Instruments & Equipment, Test Method Validation/Verification, and Method Performance Specifications sections) and in other checklists.

Artificial intelligence and machine learning algorithms implemented by the laboratory for patient testing are subject to this requirement.

Evidence of Compliance:
- ✓ Written procedures for validation/verification studies **AND**
- ✓ Records of new method validation/verification approval and supporting data

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2023(Dec 28):[42CFR493.1407(e)(3), [42CFR493.1445(e)(3)].
2) College of American Pathologists. *CAP Laboratory Accreditation Program Standards for Accreditation.* Northfield, IL: CAP; 2023.

DRA.10500 Director Responsibility - Communication **Phase II**

The laboratory director ensures communication of laboratory data and appropriate result reporting.

Evidence of Compliance:
- ✓ Records of oversight of computer services and changes **AND**
- ✓ Evidence that test reports have been reviewed within the medical record **OR**
- ✓ Lab communications, newsletters, etc.

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2023(Dec 28): [42CFR493.1407(c), (e)(8,9)], [42CFR493.1445].
2) College of American Pathologists. *CAP Laboratory Accreditation Program Standards for Accreditation.* Northfield, IL: CAP; 2023.

DRA.10700 Director Responsibility - Consultations **Phase II**

The laboratory director provides for intralaboratory consultations and clinical consultations regarding the ordering of appropriate tests and the medical significance of laboratory data.

NOTE: Only physicians or doctoral scientists may provide clinical consultations.

The laboratory director must be accessible to the laboratory for on-site, telephone, or electronic consultations, as needed, or ensure that a qualified designee is available in the director's absence.

Evidence of Compliance:

- ✓ Policy or call schedule for the availability of the laboratory director and designee(s) to provide consultations **AND**
- ✓ Policy or statement signed by the laboratory director authorizing individuals responsible for clinical consultations **AND**
- ✓ Records of laboratory director or designee involvement for the ordering of tests and/or interpretation of results **AND**
- ✓ Evidence of the availability of the laboratory director or designee for consultative services (based on interview with medical staff or records)

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2023(Dec 28): [42CFR493.1407(e)(8,9)], [42CFR493.1445].
2) College of American Pathologists. *CAP Laboratory Accreditation Program Standards for Accreditation.* Northfield, IL: CAP; 2023.
3) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2004(Oct 1):1067 [42CFR493.1457]

DRA.11200 Director Responsibility - Education/R&D — Phase II

The laboratory director ensures provision of educational programs, strategic planning, and research and development appropriate to the needs of the laboratory and institution.

Evidence of Compliance:

- ✓ Schedule or description of available educational activities **AND**
- ✓ Records or minutes from strategic planning sessions demonstrating participation and role of laboratory director

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2023(Dec 28): [42CFR493.1407(e)(12)], [42CFR493.1445(e)(12)].
2) Clinical and Laboratory Standards Institute (CLSI). *Training and Competence Assessment.* 4th ed. CLSI guideline QMS03. Clinical and Laboratory Standards Institute, Wayne, PA, 2016.

DRA.11300 Director Responsibility - Personnel — Phase II

The laboratory director ensures sufficient numbers of personnel with appropriate educational qualifications, documented training and experience, and adequate competency to meet the needs of the laboratory.

NOTE: For laboratories subject to US regulations, all personnel must meet the personnel requirements of CLIA or other US equivalent regulations (eg, Clinical Laboratory Improvement Program Procedures for Department of Defense laboratories, Veterans Health Administration Handbook 1106.01). For laboratories not subject to US regulations, all personnel requirements must be defined and met.

While the laboratory director must ensure provisions of appropriately trained supervisory and testing personnel, the laboratory director may delegate (in writing) many of the duties relating to hiring, training, and supervising personnel to other qualified designees.

Staffing should be considered insufficient if there is clear evidence from quality monitoring records, data derived from complaints or concerns, turnaround time, error statistics, etc.

Evidence of Compliance:

- ✓ Records indicating that personnel meet requirements for the level of testing (complexity) performed and delegated tasks are performed **AND**
- ✓ Records of training, competency assessment, and continuing education in personnel files **AND**
- ✓ Records of periodic on-site assessment of the adequacy of staffing by the laboratory director

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2023(Dec 28): [42CFR493.1407(e)(10-11)], [42CFR493.1445(e)(12)].
2) Clinical and Laboratory Standards Institute (CLSI). *Training and Competence Assessment.* 4th ed. CLSI guideline QMS03. Clinical and Laboratory Standards Institute, Wayne, PA, 2016.