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.

3) Boyd JC, Savory J. Genetic algorithm for scheduling of laboratory personnel. *Clin Chem.* 2001;47:118-123

DRA.11400 Director Responsibility - Safe Environment Phase II

The laboratory director ensures implementation of a safe laboratory environment in compliance with applicable regulations.

NOTE: The laboratory director must ensure compliance with OSHA and national, federal, state (or provincial), and local laws and regulations, as well as other applicable safety regulations. Details may be found in the Laboratory Safety and Specimen Transport and Tracking sections of the Laboratory General Checklist. Additional safety requirements may also be found in the discipline-specific checklists (eg, Microbiology Checklist, Anatomic Pathology Checklist).

Evidence of Compliance:

- ✓ Safety policies and procedures **AND**
- ✓ Records of safe work practice reviews with corrective action taken to correct violations **AND**
- ✓ Safety meeting minutes **AND**
- ✓ Chemical hygiene plan **AND**
- ✓ Records of periodic on-site assessment of physical and environmental conditions 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)(2)], [42CFR493.1445(e)(2)].

DRA.11425 Director Responsibility - Delegation of Functions Phase II

If specific laboratory director functions or responsibilities are delegated, the delegation is in writing (by name or job title) and the director ensures that the functions or responsibilities are properly performed by a qualified individual.

NOTE:

1. *Examples of functions that may be delegated include the following:*
   - *Review of QC data*
   - *Proficiency testing performance*
   - *Competency assessment*
   - *Test methodology performance studies.*
2. *Functions that may <u>not</u> be delegated include the following:*
   - *Provision of appropriately trained supervisory and technical staff and the identification of their responsibilities*
   - *Personal on-site visits, including assessment of physical and environmental conditions and the adequacy of staffing on a periodic basis, as defined in written policy*
   - *Approval of new technical policies and procedures, as well as substantial changes to existing documents (except as defined in COM.10250 for laboratories not subject to US regulations)*
   - *Approval of individualized quality control plans (IQCP).*
3. *For CLIA-required roles not performed by the director, the director delegates those responsibilities to qualified individuals. The responsibilities and duties of supervisors, consultants, and testing personnel involved in preanalytic, analytic, and postanalytic phases of testing must be defined in writing, with records of authorization to perform testing, and the level of supervision required, as applicable.*
4. *If a delegated duty is not being properly performed by the designee and there is no evidence of corrective action, the team leader should cite this requirement as a deficiency, in addition to the specific checklist requirement(s) that relates to the duty not performed (eg, monthly QC review, approval of method validation/verification studies).*
5. *Delegated functions may not be sub-delegated to others by a designee except as specifically outlined in other requirements (eg, GEN.53400, GEN.53600).*