Evidence of Compliance:

- ✓ Records of director qualifications appropriate to the type of laboratory and level of complexity

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):[42CFR493.1405], [42CFR493.1407] and [42CFR493.1443].
2) 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):1049 [42CFR493.1357]
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):979 [42CFR493.19]
4) College of American Pathologists. *CAP Laboratory Accreditation Program Standards for Accreditation.* Northfield, IL: CAP; 2023.
5) 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): [42CFR493.1445(d)].

DRA.10125 Director Qualifications - Biorepositories Only — Phase II

The qualifications of director of the biorepository are appropriate for the scope of activities.

NOTE: The director must have had four or more years of full-time general laboratory training and experience of which at least two years were spent acquiring proficiency in biorepository operations and management. The director must be qualified to assume professional, scientific, organizational, administrative, and educational responsibilities for the services provided. The director's experience and qualifications must also meet the institutional policy for the degree of responsibility acceptable to operate and manage the scope of the biorepository.

*****REVISED** 12/26/2024***

DRA.10150 Provision of Anatomic Pathology (AP) Services — Phase II

Anatomic pathology services are provided by a pathologist certified in anatomic pathology. Exceptions for other qualified individuals for specific subspecialties are described in the NOTE.

NOTE: In facilities where anatomic pathology services are provided, a pathologist certified in anatomic pathology must perform such services. Pathologists who qualified to provide these services prior to December 28, 2024, may continue to provide these services if they have done so continuously in a CLIA-certified laboratory. The services of a consulting anatomic pathologist shall be retained if necessary.

The following are exceptions for specific types of tissue diagnosis for non-pathologist individuals:

- *Neuromuscular pathology specimens may be interpreted by an MD or DO who is licensed to practice in the jurisdiction where the laboratory is located (if required) and has completed a training program in neuromuscular pathology approved by HHS (ie, the American Academy of Neurology Committee for Neuromuscular Pathology Training Program).*
- *Other exceptions for dermatopathology, ophthalmic pathology and oral pathology as defined in the CLIA regulation 42CFR493.1449(f) and (g).*

***For laboratories not subject to US regulations**, individuals must meet national, state or provincial, or local laws and regulations, and education must be equivalent to US qualifications.*

Evidence of Compliance:

- ✓ Listing of AP services provided by the institution **AND**
- ✓ Records of pathologist qualifications (eg, degree, license, board certification, training and experience)

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):[42CFR493.1449(f)(g)].

DRA.10200 Section Director/Technical Supervisor Qualifications — Phase II

If the laboratory director is not qualified to direct any of the individual sections of the laboratory, the laboratory retains the services of individuals qualified to direct those sections.

Evidence of Compliance:

- ✓ Records of section director qualifications (eg, degree, license, board certification, training and experience)

LABORATORY DIRECTOR RESPONSIBILITY AND OVERSIGHT

NOTE TO THE INSPECTOR: Appropriate checklist requirements in this subsection should be cited if the inspection reveals serious deficiencies that may impact patient care or systemic problems where inspectors cited the same or related deficiencies in multiple laboratory sections. If the Team Leader marks "NO" to any of the Part A questions in the Inspector's Summation Report, one or more related DRA requirements must also be cited.

When the term laboratory director is used, it refers to the individual who is listed on the laboratory's CAP and CLIA certificate (as applicable). Laboratory directors may delegate tasks to other qualified individuals, but the laboratory director retains full responsibility for such tasks. Delegation does not negate the need for laboratory director involvement in the laboratory.

The requirements for laboratory director responsibilities apply to all laboratories. Laboratory directors must ensure that all laboratory director responsibilities are carried out as required. Refer to DRA.11425 for information on delegation of duties and duties that may not be delegated.

DRA.10430 Director Responsibility/Authority **Phase II**

The laboratory director has sufficient responsibility and authority to implement and maintain the standards of the College of American Pathologists.

NOTE: Examples of how the team leader may obtain information on the laboratory director's responsibility and authority include: interviews with the laboratory director, institution's administration, medical staff, laboratory management and laboratory supervisory staff; review of the laboratory organizational chart; and review of minutes of quality management and other laboratory meetings.

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], [42CFR493.1443].
2) College of American Pathologists. *CAP Laboratory Accreditation Program Standards for Accreditation.* Northfield, IL: CAP; 2023.

*****NEW** 12/26/2024***

DRA.10432 Director On-Site Visits - Laboratories Subject to US Regulations **Phase II**

For laboratories subject to US regulations, on-site laboratory director visits occur at least every six months (with at least four months between the two on-site visits).

NOTE: This requirement applies when the laboratory director is not routinely on site. On-site visits must, at minimum, occur at the frequency described above. More frequent visits may be defined based on input from the medical staff and administration, and upon the complexity and volume of testing.

The requirement for on-site visits pertains to only one location site visit per CLIA certificate. The laboratory director may determine which site needs to be included during each on-site visit.

Records of on-site visits must include evidence that activities were performed that are part of the laboratory director responsibilities (eg, assessment of physical environmental conditions and adequacy of staffing).