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).

Evidence of Compliance:

- ✓ Records of laboratory director activities for on-site visits **AND**
- ✓ Records for frequency of on-site visits **AND**
- ✓ Document defining frequency for on-site visits

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):[42CFR493.1445(c)].
2) 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)].

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

DRA.10433 Director On-Site Visits - Laboratories Not Subject to US Regulations **Phase II**

For laboratories not subject to US regulations, on-site laboratory director visits occur at least once per year.

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 based upon the complexity and volume of testing.

The requirement for on-site visits pertains to only one location site visit per CAP-accredited laboratory. 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).

Evidence of Compliance:

- ✓ Records of laboratory director activities for on-site visits **AND**
- ✓ Records for frequency for on-site visits **AND**
- ✓ Document defining frequency for on-site visits

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

DRA.10435 Director Involvement **Phase II**

The involvement of the laboratory director, including activities performed on-site and through remote consultation, is considered adequate by the laboratory administration, medical staff, and the inspection team, and follows written policy or agreement.

NOTE: The laboratory director must ensure that there is an effective communication mechanism between the laboratory director and medical staff, laboratory management, and staff, including maintenance of records of the communications.

Examples of situations where director involvement is insufficient include the following:

- *Laboratory director does not perform duties as defined in the job description, policy or written agreement;*
- *Unsatisfactory availability of consultation services concerning test results and the interpretation of those results as they relate to specific patient conditions;*
- *Serious quality, personnel, or safety issues are not addressed in a timely manner;*
- *Delegated duties are not being performed and recorded, or are not performed in an effective manner;*
- *New laboratory practices are not implemented properly;*
- *Interviews with the hospital administrator, the chief of staff, laboratory supervisors, or technical staff identify situations (eg, ineffective communication mechanisms) where greater personal involvement on the part of the laboratory director is needed.*

Evidence of Compliance:

- ✓ Records of laboratory director activities (on-site and remote) **AND**