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**

- ✓ Meeting minutes showing director participation **AND**
- ✓ Laboratory director review of quality management records **AND**
- ✓ Evidence of availability for consultations with medical staff as appropriate (based on interview with medical and laboratory staff or records of consultations)

DRA.10437 Director's Responsibilities - Biorepositories Only **Phase II**

The biorepository director has implemented policies to ensure that:

1. **IRB protocols and policies are followed**
2. **HIPAA is not violated**
3. **Clinical care is not compromised in the process of procuring biospecimens**
4. **Basic ethical standards related to biospecimen collection and distribution are followed (eg, all tissues are handled following protocols)**

DRA.10440 Effective Quality Management System (QMS) **Phase II**

The laboratory director ensures an effective QMS for the laboratory.

NOTE: The laboratory director must be involved in the design, implementation and oversight of the laboratory's QMS as set forth in GEN.13806.

Evidence of Compliance:

- ✓ Written QMS covering all areas of the laboratory **AND**
- ✓ Records of laboratory director approval of the QMS and the selection of quality indicators **AND**
- ✓ Records (eg, reports, QMS meeting minutes) of laboratory director review of quality indicators, annual assessment of QMS, complaints, and incidents with development and implementation of plans of corrective and preventive action (when taken)

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)(5-6), [42CFR493.1445(e)(5,13)].
2) Clinical and Laboratory Standards Institute (CLSI). A *Quality Management System Model for Laboratory Services*. 5th ed. CLSI guideline QMS01. Clinical and Laboratory Standards Institute, Wayne, PA; 2019.
3) College of American Pathologists. CAP Quality Management Education: QMS Implementation Roadmap (online course). 2021.

DRA.10445 Director Responsibility - Interim Self-inspection **Phase II**

The laboratory director ensures that a thorough interim self-inspection is performed, and all deficiencies are corrected in a timely manner.

NOTE: CAP-accredited laboratories are required to complete an interim self-inspection, using the CAP checklists, at the start of the second year of the laboratory's two-year accreditation cycle, unless an exception is granted by the CAP. It is an important aspect of continuing education, laboratory improvement, and continuous compliance. The use of a variety of mechanisms for self-inspection (residents, technologists or others trained to perform inspections) is strongly endorsed. Self-inspection by personnel familiar with, but not directly involved in, the routine operation of the laboratory section to be inspected is recommended.

Refer to the "Self & Post Inspection Toolbox" on cap.org behind e-LAB Solutions Suite for tips and forms that are available for conducting thorough self-inspections.

Examples of noncompliance include situations in which systemic deficiencies were not identified, self-inspection of more than one laboratory section was incomplete, repetitive patient or employee safety issues were not addressed, and correction of deficiencies was lacking.

Evidence of Compliance:

- ✓ Written evidence of self-inspection findings with records of corrective action