- ✓ 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