Evidence of Compliance:

- ✓ Personnel roster accurately indicates qualified individuals performing roles of testing personnel, clinical consultant, technical consultant, technical supervisor, and general supervisor, as applicable **AND**
- ✓ Policy or statement signed by the laboratory director authorizing individuals by name or job title to perform tasks on behalf of the laboratory director **AND**
- ✓ Records showing that delegated tasks are performed by designee, as required **AND**
- ✓ Records of on-site assessment of physical and environmental conditions and the adequacy of staffing by the laboratory director **AND**
- ✓ Records showing that designees are qualified to perform delegated tasks

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)(15)].

DRA.11450 Director Responsibility - Interaction with Government or Regulatory Interaction — Phase II

The laboratory director or designee interacts with government and other agencies as appropriate.

NOTE: The laboratory director or designee must interact with agencies such as national, federal, state (or provincial), and local health departments, as appropriate, for laboratory-related matters.

Evidence of Compliance:

- ✓ Records of any required reports of infectious diseases to the health department **AND**
- ✓ Response to any inquiry by government and other agencies, as appropriate **AND**
- ✓ Reports to OSHA, FDA or other agency, as required

DRA.11475 Director Responsibility - Equipment/Services — Phase I

The laboratory director or designee is directly involved in the selection of all laboratory equipment, supplies, and services with respect to quality.

NOTE: The intent is to ensure that the laboratory director has appropriate control over the process. The fact that economic issues are a major factor in these selections does not relieve the laboratory director of responsibility for ensuring the quality of the technical, clinical and operational aspects of the laboratory. The director must ensure that reagents, fluids, parts, materials, and other items supplied to the laboratory meet the requirements for use with instruments and equipment.

Evidence of Compliance:

- ✓ Meeting minutes indicating the laboratory director or designee's presence when purchases are discussed **OR**
- ✓ Written approval from the laboratory director or designee to purchase equipment

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24): [42CFR493.1252(a)]

DRA.11485 New Director Policy and Procedure Approval — Phase II

Following a change in laboratory directorship, the new laboratory director approves the technical policies and procedures within three months of the change of directorship (see NOTE).

NOTE:

1. The approval of the policies and procedures must be recorded.

2. *The format of such documentation is at the discretion of the laboratory director. It must include an itemization of the documents reviewed and approved, signatures and dates, and demonstrate that all technical policies and procedures have been approved.*
3. *The approval must be completed within three months of the change of directorship for most laboratories. For larger, more complex laboratories where additional time is needed, the laboratory can record an explanation and a schedule for completion of the approvals by the laboratory director. The inspector will verify completion of the approval process for compliance with the schedule.*
4. *Different requirements for approval of new and substantially changed technical policies and procedures and for routine reviews (at least every two years) appear in the All Common Checklist.*

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): [42CFR493.1251(d)], [42CFR493.1445(e)].