3) Boyd JC, Savory J. Genetic algorithm for scheduling of laboratory personnel. *Clin Chem.* 2001;47:118-123

DRA.11400 Director Responsibility - Safe Environment Phase II

The laboratory director ensures implementation of a safe laboratory environment in compliance with applicable regulations.

NOTE: The laboratory director must ensure compliance with OSHA and national, federal, state (or provincial), and local laws and regulations, as well as other applicable safety regulations. Details may be found in the Laboratory Safety and Specimen Transport and Tracking sections of the Laboratory General Checklist. Additional safety requirements may also be found in the discipline-specific checklists (eg, Microbiology Checklist, Anatomic Pathology Checklist).

Evidence of Compliance:

- ✓ Safety policies and procedures **AND**
- ✓ Records of safe work practice reviews with corrective action taken to correct violations **AND**
- ✓ Safety meeting minutes **AND**
- ✓ Chemical hygiene plan **AND**
- ✓ Records of periodic on-site assessment of physical and environmental conditions by the laboratory director

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)(2)].

DRA.11425 Director Responsibility - Delegation of Functions Phase II

If specific laboratory director functions or responsibilities are delegated, the delegation is in writing (by name or job title) and the director ensures that the functions or responsibilities are properly performed by a qualified individual.

NOTE:

1. *Examples of functions that may be delegated include the following:*
   - *Review of QC data*
   - *Proficiency testing performance*
   - *Competency assessment*
   - *Test methodology performance studies.*
2. *Functions that may <u>not</u> be delegated include the following:*
   - *Provision of appropriately trained supervisory and technical staff and the identification of their responsibilities*
   - *Personal on-site visits, including assessment of physical and environmental conditions and the adequacy of staffing on a periodic basis, as defined in written policy*
   - *Approval of new technical policies and procedures, as well as substantial changes to existing documents (except as defined in COM.10250 for laboratories not subject to US regulations)*
   - *Approval of individualized quality control plans (IQCP).*
3. *For CLIA-required roles not performed by the director, the director delegates those responsibilities to qualified individuals. The responsibilities and duties of supervisors, consultants, and testing personnel involved in preanalytic, analytic, and postanalytic phases of testing must be defined in writing, with records of authorization to perform testing, and the level of supervision required, as applicable.*
4. *If a delegated duty is not being properly performed by the designee and there is no evidence of corrective action, the team leader should cite this requirement as a deficiency, in addition to the specific checklist requirement(s) that relates to the duty not performed (eg, monthly QC review, approval of method validation/verification studies).*
5. *Delegated functions may not be sub-delegated to others by a designee except as specifically outlined in other requirements (eg, GEN.53400, GEN.53600).*

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.