LABORATORY DIRECTOR ASSESSMENT

Inspector Instructions:

- Laboratory director’s qualifications
- Laboratory director's licensure as applicable
- Laboratory director’s job description, policy or agreement for director activities
- Laboratory director’s record of delegation of responsibilities
- Organizational chart
- Records of laboratory director activities and frequency of on-site visits. Ensure actual practice matches policy or agreement.
- Records of on-site assessment of physical and environmental conditions and the adequacy of staffing by the laboratory director

- Interaction of laboratory director with laboratory supervisory personnel and laboratory staff
- Technical staff recognition of the role and involvement of the laboratory director in setting expectations and service needs

Laboratory Director:

- What quality improvement initiatives have been most successful during the past two years? Which are works in progress?
- What educational programs have been made available to staff during the past two years?
- Have you had any complaints that would indicate that the laboratory is perceived as an unsafe working place for personnel and the patients it serves?
- How did your laboratory conduct the mid-cycle self-inspection?
- How do you ensure that the laboratory meets the expectations of hospital administration and medical staff?
- When was the last time your laboratory provided an inspection team? How did you ensure that all team members were trained?
- How do you ensure that the laboratory has adequate numbers of properly trained staff?
- How is your laboratory's QMS designed?
- How is the laboratory's QMS implemented in each section of the laboratory?

Organization Administrator:

- What level of involvement do pathologists have in organization-wide committees?
- How does the laboratory communicate important laboratory information to administration?
- How well does the laboratory meet the operational and clinical needs of the organization?

Medical Staff Representative:

- How is the laboratory involved in hospital-wide QMS activities, including patient care improvements, patient safely activities, and teaching conferences?
- What level of involvement do pathologists have in medical staff committees?
- How does the laboratory communicate important laboratory information to medical staff?
- How well does the laboratory meet the patient care needs (TAT, accuracy, responsiveness) of the organization?

DISCOVER	• If the administrator and/or the medical staff representative gave examples indicating that the laboratory did not meet their expectations, further evaluate laboratory leadership's responses, corrective actions and resolutions. • If QC failures are identified, determine whether they reflect systemic problems or involve patient safety. If so, was the laboratory director involved in the resolution? • Evaluate the laboratory director's involvement in key quality processes (proficiency testing, root cause analysis, procedure manual review, etc.) • Discuss the review of the interim self-inspection records with the Laboratory General inspector to identify issues with lack of thoroughness of the interim self-inspection or systemic problems identified during the self-inspection that have not been corrected. • Determine if there was a change of laboratory director within the last two years. If yes, confirm that the new laboratory director approved technical policies and procedures within three months of the change or that an explanation was recorded with a reasonable schedule for completion of the approval process.

QUALIFICATIONS AND GENERAL REQUIREMENTS

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

DRA.10100 Laboratory Director Qualifications **Phase II**

The laboratory director satisfies the personnel requirements of the College of American Pathologists.

NOTE: The qualifications required by the CAP for the position of laboratory director depend on the testing performed in the laboratory. The qualifications are also dependent upon whether the laboratory is subject to US regulations.

The following table contains the laboratory director qualifications based on complexity of testing and US regulatory status:

Laboratories Subject to US Regulation	
Complexity of Testing	Qualifications
1. High complexity testing	a. MD, DO, or DPM licensed to practice in the jurisdiction where the laboratory is located (if required), **and**: i. Certification in anatomic or clinical pathology, or both, by the American Board of Pathology or American Osteopathic Board of Pathology, **or** ii. Have at least two years of experience supervising high complexity testing; **and** have at least 20 CE credit hours in laboratory practice that cover director responsibilities as defined in the DRA checklist* **OR** b. Doctoral degree (PhD or DPH) in a chemical, biological, or clinical laboratory science from an accredited institution, **and:** i. Have **current** certification by a board approved by HHS**, **and** ii. Have at least two years of laboratory training or experience or both, and