

## **Interpretive Guidance for Laboratory Directors Responsibilities and Duties.**

**October 2025**

The Department of Health (“Department”) is providing updated interpretive guidance regarding the laboratory director’s responsibilities and duties. A laboratory director is required to be present for a reasonable period of each working day in each laboratory for which he is a director. 28 Pa. Code § 5.22 (g)

The Department has previously interpreted the term “present” as including a remote/virtual (i.e. telephonic, email, video conferencing) presence in combination with an intermittent on-site physical presence. Historically, the Department has considered quarterly visits to the laboratory to be the appropriate minimum. However, the Department has updated this interpretation to allow laboratory directors to maintain a “remote/virtual” only presence in laboratories that perform only waived testing. For laboratories that perform moderate/high complexity testing, the Department requires the director to be on-site once every 6 months, with at least 4 months between the minimum two on-site visits. The director’s on-site visits may not be delegated.

To demonstrate that the laboratory director can maintain appropriate oversight of the laboratories for which they will serve as director, the Department requires the laboratory director to complete a revised attestation indicating they understand and will complete their duties as outlined. [Pennsylvania Clinical Laboratory Permit Application for In-State Laboratories](#)

**Please do not submit a new attestation form in response to this update if you previously submitted a written statement for monthly on-site visits or the attestation form for quarterly visits.** The director will be held to this updated interpretation.

An attestation form is required under the following instances:

- Change of Director – must be submitted with the change of status form.
- Compliance recertification/Initial survey – must be submitted with the required forms at the survey.
- Initial Survey for an Accredited laboratory – must be submitted with the required forms.

If you have any questions, you may reach out to the Bureau of Laboratories at [ra-dhpaclia@pa.gov](mailto:ra-dhpaclia@pa.gov)