

**Frequently Asked Questions on Interpretive Guidance
for Laboratory Director's On-Site Visits Responsibility and Email Notifications.**

Q1 - What is the difference between the written statement regarding monthly visits and the attestation form?

A1 - The written statement has been discontinued and replaced with the attestation form.

Q2. I submitted a written statement for monthly on-site visits, do I need to submit an attestation form for the same laboratory?

A2. No, you do not need to submit an attestation form at this time in response to the updated interpretive guidance, if you previously submitted a written statement for monthly on-site visits. The director will be held to the updated interpretation.

Q3. I submitted an attestation form for quarterly on-site visits, do I need to submit a new attestation form for the same laboratory?

A3. No, you do not need to submit an attestation form at this time, in response to the updated interpretive guidance, if you previously submitted the attestation form for quarterly visits. The director will be held to the updated interpretation.

Q4. Under the updated interpretation, is the director of a laboratory that conducts only waived testing required to conduct on-site visits?

A4. The director may visit the laboratory if the laboratory conducts only waived testing but is not required to do so. The director must, however, maintain a remote/virtual presence.

Q5. I oversee multiple laboratories, and submitted a written statement for monthly on-site visits for one of the laboratories, do I need to submit the attestation form for the other facilities?

A5. Yes, the attestation form is specific to each laboratory. You must submit the attestation form for the other laboratories that you oversee, for which you did not previously submit a written statement. You do not need to submit the attestation form for the laboratory for which you already submitted a written statement.

Q6. When am I required to submit an attestation form?

A6. An attestation form is required under the following instances:

- If the laboratory has not submitted the attestation form previously or the laboratory has not submitted a written statement in the last one year.
- If there is a Change of Director – the attestation form must be submitted with the change of status form.

- Compliance recertification/Initial survey – must be submitted with the required forms at the survey.
- At the time of an Initial Survey for an Accredited laboratory – the attestation form must be submitted with the required forms.

Q7 How often do I have to submit the attestation form?

A7. Just once, unless there is a laboratory director change, or in any of the instances listed in A6.

Q8 My facility only performs waived testing, it is not a laboratory. Do I need to submit a director's attestation form?

A8. If your facility has a Pennsylvania clinical laboratory permit, you are required to submit the attestation form.

Q9. I just became the director of a new laboratory. An attestation form was submitted at the previous laboratory where I served as a director, do I need to submit one for the new laboratory?

A9. Yes, you need to submit the attestation form. A new attestation form must be submitted whenever there is a change of the laboratory director.

Q10. Does my director have to submit the attestation form since the laboratory only performs waived testing?

A10. Yes, your director needs to submit an attestation form.

Q11. What do I need to do to choose email notifications to start receiving electronic Pennsylvania Clinical Laboratory permits and invoices, and Clinical Laboratory Improvement Amendments (CLIA) certificates and fee coupons?

A11. You may send an email to RA-DHPAPERMITCOMM@pa.gov. The email must include the CLIA number, State identification number, and email address you would like to enroll.

Q12. The email address for my laboratory has changed. How do I update my laboratory's email address?

A12. You may submit an email with the new address to RA-DHPAPERMITCOMM@pa.gov. Please include the CLIA number, Pennsylvania Clinical laboratory permit Identification number and the new email address.

Q13. How do I update my laboratory permit information such as, director, laboratory name, location, ownership, and test menu?

A13. You should submit a change of status form and other required forms to update the information on your Pennsylvania clinical laboratory permit to RA-DHPACLIA@pa.gov. Please include the Pennsylvania clinical laboratory permit ID and (CLIA) number on all correspondence sent to our office. A current Change of Status Form can be obtained by clicking on the link [Change of Status Form](#).