

Laboratory Director Changes

COLA PRIMER 18



Laboratory Director Changes

Each laboratory within COLA's Accreditation program must operate under the guidance of an active and qualified laboratory director. Please see COLA Primer 4 (available under the Education Center tab on COLAcentral) for further details on laboratory director eligibility requirements.

Please understand that at any given time, COLA is facilitating a large number of laboratory director change requests. We commit to completing our review and processing of these materials within approximately 10 business days.

To ensure that your changes are processed in the most expeditious manner, please adhere to the following guidelines:

If Your Facility Needs to Make a Change in Laboratory Directorship

- 1. Upload **all** necessary supporting materials (e.g., degree, license, board certification, CV/resume) to the laboratory's Document Repository on COLAcentral.
- 2. Upload the completed Laboratory Director Qualifications and Signature Form, **signed by the new incoming laboratory director**, to the laboratory's Document Repository on COLAcentral.
- 3. Submit all of the new director's credentials <u>each time</u> a laboratory director change is made, even if these documents were previously provided. COLA does not maintain a database of these documents for future reference.
- 4. Credentials are reviewed as soon as possible after they are uploaded to COLAcentral.
- 5. A director change is official when the director's name appears on the Director tab under My Lab Information on COLAcentral.
- 6. COLA will inform CMS about the change in laboratory director. It can take several weeks for the CMS database to be updated to reflect the change.

Note: The most efficient means of submitting documents to COLA for review is via upload to the COLAcentral Document Repository. Documents submitted by any other means (e.g., fax, email, postal mail) must be uploaded to the Document Repository by COLA staff prior to review, which may lengthen the turnaround time for completion of laboratory director change requests.

If COLA Requires More Information

If documentation submitted for a laboratory director change request is found to be incomplete, COLA staff will contact the laboratory for more information. Please ensure that COLAcentral always lists the current telephone number(s) and valid email address(es) for responsible personnel within the laboratory so that COLA staff can reach the laboratory without delay.

When contacted by COLA staff, an immediate response from the laboratory is expected. If an adequate response is not received after COLA requests additional information about the laboratory director, the laboratory will receive a formal letter, posted to COLAcentral, indicating that the laboratory has been non-responsive to COLA communications and may be at risk of withdrawal from COLA's accreditation program as a result.

COLA staff will make an additional attempt to follow up with the laboratory to obtain the necessary information to complete the change in laboratory director.

If the laboratory cannot provide appropriate evidence of the qualifications of the laboratory director, the laboratory must immediately agree, in writing, to cease (or not begin) testing until COLA obtains the documentation required to approve a qualified laboratory director.

Failure to provide COLA with the name of the laboratory's director, along with their supporting credentials and signed Laboratory Director Qualifications and Signature form, may result in the facility being withdrawn from COLA.

Reminders

It is a CLIA regulatory requirement (<u>42 CFR 493.63</u>) that the laboratory notify both CMS and COLA about any change(s) to the laboratory's name, location, ownership, or laboratory director. This notification must be made within 30 days of the change(s).

At no time may a laboratory perform any patient testing without a qualified laboratory director. Continuing patient testing without a qualified laboratory director may result in sanctions, including denial of accreditation or the loss of the laboratory's CLIA certificate.