

Laboratory Changes that Require Submitting a Completed CMS-116 Application

A new CMS-116 application MUST be obtained when any of the following laboratory changes take place:

- Initial Application – for any certification type
 - When applying for the temporary testing site exception, a list of the temporary testing sites must be included on or attached to the CMS-116 application.
[QSO-22-13-CLIA](#).
- Certificate Type Change
- Reinstatement of CLIA certificate (Reactivation)
- Adding a multiple site exception, including temporary testing sites, to an existing CLIA certificate
 - A list of temporary testing sites must be included on or attached to the CMS-116 application.
- Director Change (Provider-Performed Microscopy (PPM) Certificate or Certificate of Compliance).
 - For laboratory director changes on an existing Certificate of Accreditation, you must contact the laboratory's Accreditation Organization to process the change
- Ownership
- Change in Accreditation Organization

A Facility Status Change Form is required for the following changes:

- Name of the Laboratory
- Location (Physical location)
- Location (Mailing Address)
- Director change on a Certificate of Waiver
- Tax ID (EIN) – not associated with a change in ownership
- Telephone and Fax Numbers
- Email Address and requests to receive future notifications via email

Written Notification must be submitted to your state agency for the following changes (in the form of an attached letter, not documented in the body of an email)

- Termination of CLIA certification – A letter must include the CLIA#, facility name, address, reason for termination, and effective date of termination. The letter must be signed by the laboratory director or an authorized individual.
- Specialty or Sub-specialty changes on existing Certificate of Compliance – must include the name of the test/analyte which is added or discontinued, the effective date, and the test volume.
- Changes to existing Multiple Site locations on a CLIA certificate– must include the CLIA# and changes needed (name change, address/phone number change, or to remove the multiple site location from the CLIA certification). Please note, adding a new multiple site location requires a completed CMS-116 form, as indicated above.
- Personnel – Change or addition of Technical Supervisor only