

W394

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§483.460(n)(2) If the laboratory chooses to refer specimens for testing to another laboratory,

the referral laboratory must be certified in the appropriate specialties and subspecialties of service in accordance with the requirements of part 493 of this chapter.

Guidance §483.460(n)(2)

A facility performing any laboratory service or test must have applied to CMS, and received a Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. An application for a Certificate of Waiver may be made if the facility performs only those tests on the waived list. A complete list of waived tests can be accessed at the Food and Drug Administration (FDA).

If the facility performs any test, not appearing on the waived list, a Certificate of Compliance or Certificate of Accreditation is required. An appropriate CLIA certificate is required regardless of the frequency with which the laboratory services or tests are conducted. When no tests are performed, a CLIA certificate is not needed. Facilities only collecting specimens and not performing testing do not need a certificate.

A not-for-profit, a state, or local government organization may have one certificate covering all the facilities it operates (e.g., all the separately certified residences which fall under its governing body), if no more than a total of 15 types of waived or moderately complex laboratory tests are used. This exception applies only to laboratories performing limited public health testing. See State Operations Manual (SOM) 6008. Each location where a laboratory tests are performed must file a separate application to be separately certified unless the laboratory meets one if the exceptions outlined at 42CFR493.35(b), 493.443(b), or 493.55(b).

Any laboratory located in a state that has a CMS-approved laboratory program is exempt from CLIA certification. Currently there are two states with approved programs: Washington and New York. New York has a partial exemption; therefore, if the laboratory is located in New York, contact the New York State Agency to determine if the exemption applies.