

42 C.F.R. § 493.35

Application for a certificate of waiver.

(a) *Filing of application.* Except as specified in paragraph (b) of this section, a laboratory performing only one or more waived tests listed in § 493.15 must file a separate application for each laboratory location.

(b) *Exceptions.* (1) Laboratories that are not at a fixed location, that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base, using its address.

(2) Not-for-profit or Federal, State, or local government laboratories that engage in limited (not more than a combination of 15 moderately complex or waived tests per certificate) public health testing may file a single application.

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