§ 493.20 Laboratories performing tests of moderate complexity.

(a) A laboratory may qualify for a certificate to perform tests of moderate complexity provided that it restricts its test performance to waived tests or examinations and one or more tests or examinations meeting criteria for tests of moderate complexity including the subcategory of PPM procedures.

(b) A laboratory that performs tests or examinations of moderate complexity must meet the applicable requirements in subpart C or subpart D, and subparts F, H, J, K, M, and Q of this part. Under a registration certificate or certificate of compliance, laboratories also performing PPM procedures must meet the inspection requirements at §§ 493.1773 and 493.1775.

(c) If the laboratory also performs waived tests, compliance with subparts H, J, K, and M of this part is not applicable to the waived tests. However, the laboratory must comply with the requirements in §§ 493.15(e), 493.1773, and 493.1775.

§ 493.25 Laboratories performing tests of high complexity.

(a) A laboratory must obtain a certificate for tests of high complexity if tests of high complexity are performed.

(b) A laboratory must obtain a certificate for tests of high complexity if it also performs tests of moderate complexity.

(c) Laboratories that perform only tests of high complexity must submit an application to the CLIAC for a certificate of compliance with the requirements in this part. The CLIAC conducts reviews upon HHS’ request and recommends to HHS revisions to the criteria for categorization of procedures.

(d) HHS determines whether a laboratory procedure meets the criteria listed under paragraph (b) of this section for a PPM procedure. Revisions to the list of PPM procedures proposed by HHS are published in the Federal Register as a notice with an opportunity for public comment.

(e) Laboratory requirements. Laboratories eligible to perform PPM examinations must—

(1) Meet the applicable requirements in subpart C or subpart D, and subparts F, H, J, K, and M of this part.

(2) Be subject to inspection as specified under subpart Q of this part.

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