

§ 493.19(e)(1) by removing the reference to the former Subpart P.”

■ On page 3675, in column one, in the first paragraph carried over from the preceding page, “Systems” is corrected to read “System”.

■ On page 3675, in column two, in the section heading and in bullets number one and three, remove the “s” from the word “systems”.

■ On page 3694, in column two, in the last paragraph, and on page 3696, in column one, in the last paragraph of the page, “(Eisenberg, 1998)” is corrected to read “(Isenberg, 1998)”.

■ On page 3701, in column three, in the “References” section, “Eisenberg, Henry D., Ed.” is corrected to read “Isenberg, Henry D., Ed.” and is placed in alphabetical order.

B. Omitted Regulatory Text

The January 24, 2003 final rule (68 FR 3640) utilized a couple of terms that have never been formally defined in the CLIA regulations. We believe that any ambiguities about “nonwaived test” and “waived test” would be resolved by defining them at § 493.2.

The definition of “waived test” need not be subject to notice and comment rulemaking as the definition merely cites to the statutory criteria for waiver as specified in section 353(d)(3) of the Public Health Service Act (PHS). “Non-waived tests” is likewise defined in terms of the statutory criteria for waiver. As notice and comment rulemaking is unnecessary, we are adding these definitions to § 493.2.

In addition, we explained in the January 24, 2003 final rule that we were renaming, reorganizing, and consolidating similar requirements into one section, deleting duplicate requirements, and rewording numerous requirements to maintain and/or clarify their original intent, making the revised regulations easier to read and understand. As part of this effort, we removed “subpart P”, but neglected to remove references to subpart P in §§ 493.19(e)(1), 493.20(c), 493.25(d), 493.47(c)(2), and 493.1359(b)(2). As section “P” no longer exists, it is unnecessary to seek comments on these deletions as no purpose or interests would be served if they were maintained. As such, these references to subpart “P” are deleted by this final rule.

C. Regulatory Text Corrections

■ In FR Doc. 03–1230 of January 24, 2003 (65 FR 3640):

PART 493—LABORATORY REQUIREMENTS

■ The authority citation for part 493 continues to read as follows:

Authority: Sec. 353 of the Public Health Service Act, secs. 1102, 1861(e), the sentence following sections 1861(s)(11) through 1861(s)(16) of the Social Security Act (42 U.S.C. 263a, 1302, 1395x(e), and the sentence following 1395x(s)(11) through 1395x(s)(16)).

■ In § 493.2, the following definitions are added in alphabetical order to read as follows:

§ 493.2 Definitions.

* * * * *

Nonwaived test means any test system, assay, or examination that has not been found to meet the statutory criteria specified at section 353(d)(3) of the Public Health Service Act.

* * * * *

Waived test means a test system, assay, or examination that HHS has determined meets the CLIA statutory criteria as specified for waiver under section 353(d)(3) of the Public Health Service Act.

■ In § 493.19, paragraph (e)(1) is revised to read as follows:

§ 493.19 Provider-performed microscopy procedures.

* * * * *

(e) * * *

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

* * * * *

■ In § 493.20, paragraph (c) is revised to read as follows:

§ 493.20 Laboratories performing tests of moderate complexity.

* * * * *

(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.

■ In § 493.25, paragraph (d) is revised to read as follows:

§ 493.25 Laboratories performing tests of high complexity.

* * * * *

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

■ In § 493.47, paragraph (c)(2) is revised to read as follows:

§ 493.47 Requirements for a certificate for provider-performed microscopy (PPM) procedures.

* * * * *

(c) * * *

(2) The applicable requirements of this subpart and subparts H, J, K, and M of this part; and

* * * * *

Table of Contents for Subparts J and K of Part 493 [Corrected]

■ On page 3703 in column one, in the heading of the Table of Contents for Subpart K, the word “Systems” is corrected to read “System”.

■ On page 3703, in column one, in the Table of Contents for Subpart K—Quality System for Nonwaived Testing, line 18, “§ 493.1125” is corrected to read “§ 493.1225”.

■ On page 3703, in column one, in the Table of Contents for Subpart K—Quality System for Nonwaived Testing, General Laboratory Systems, in line 15, add the word “quality” before “assessment.”

■ On page 3703, in column one, in the Table of Contents for Subpart K—Quality System for Nonwaived Testing, Preanalytic Systems, in line 5, add the word “quality” before “assessment.”

■ On page 3703, in column two, in the Table of Contents for Subpart K—Quality System for Nonwaived Testing, Analytic Systems, in line 22, “§ 493.1189” is corrected to read “§ 493.1289” and the word “quality” is added before “assessment.”

■ On page 3703, in column two, in the Table of Contents for Subpart K—Quality System for Nonwaived Testing, Postanalytic Systems, in line three, add the word “quality” before “assessment.”

§ 493.1105 [Corrected]

■ On page 3704, in column one, in paragraph (a)(3), in line four, “all analytic systems” is corrected to read “records documenting all analytic systems”.

■ On page 3704, in column one, in paragraph (a)(3)(ii), in line four, “CFR 606.160(b)(3)(ii), (b)(3)(v), and (d)” is corrected to read “CFR 606.160(b)(3)(ii), (b)(3)(iv), (b)(3)(v), and (d)”.

■ On page 3704, in column one, in paragraph (a)(5), in line one, the heading is corrected to read “*Quality system assessment records.*”

■ On page 3704, in column one, in paragraph (a)(6)(i), in lines two and three, “21 CFR 606.160(b)(3)(ii), (b)(3)(iv), and (d)” is corrected to read “21 CFR 606.160(d).”

■ On page 3704, in column one, in paragraph (b), in line five, “maintained” is corrected to read “retained”.