

Subpart K—[Corrected]

■ On page 3704, in column one, in the section heading for Subpart K, the word “Systems” is corrected to read “System”.

§ 493.1200 [Corrected]

■ On page 3704, in column one, in paragraph (a), in line five, “quality systems” is corrected to read “a quality system”.

■ On page 3704, in column two, in paragraph (b), in line one, remove the words “Each of”, and capitalize the letter “T” in the word “The”.

■ On page 3704, in column two, in paragraph (b), in line two, “an assessment” is corrected to read “a quality assessment”.

■ On page 3704, in column two, in paragraph (c), in line two, the word “systems” is corrected to read “system”.

§ 493.1208 [Corrected]

■ On page 3704, in column three, in line two, “§§ 93.1281” is corrected to read “§§ 493.1281”.

§ 493.1234 [Corrected]

■ On page 3705, in column two, in line six, “individual” is corrected to read “person”.

§ 493.1239 [Corrected]

■ On page 3705, in column two, in the section heading, add the word “quality” before “assessment.”

■ On page 3705, in column three, in paragraph (a), in line three, “system requirements” is corrected to read “systems requirements”.

■ On page 3705, in column three, in paragraph (b), lines one and seven, add the word “quality” before “assessment”.

■ On page 3705, in column three, in paragraph (c), in line two, add the word “quality” before “assessment”.

§ 493.1249 [Corrected]

■ On page 3706, in column one, in the heading of § 493.1249 add the word “quality” before “assessment.”

■ On page 3706, in columns one and two, in paragraph (b), in lines one and seven, add the word “quality” before “assessment”.

■ On page 3706, in column two, in paragraph (c), in line two, add the word “quality” before “assessment”.

§ 493.1251 [Corrected]

■ On page 3706, in column two, in paragraph (b)(11), in line two, “results or panic or alert values” is corrected to read “results, or panic or alert values”.

■ On page 3706, in column three, in paragraph (b)(13), in lines five and six, “reporting imminent life threatening results, or panic, or alert values” is

corrected to read “reporting imminently life-threatening results, or panic or alert values”.

§ 493.1253 [Corrected]

■ On page 3707, in column one, in paragraph (b)(2), in lines eight through ten, remove the words “Gram stain, or potassium hydroxide preparations”.

§ 493.1256 [Corrected]

■ On page 3707, in column three, in paragraph (a), in line four, the word “analytical” is corrected to read “analytic”.

■ On page 3708, in column two, in paragraph (e)(1), in line four, add the phrase “(except those specifically referenced in § 493.1261(a)(3))” before the word “and”.

§ 493.1271 [Corrected]

■ On page 3709, in column three, in paragraph (f), in line one, the heading “Documentation.” is added.

§ 493.1273 [Corrected]

On page 3709, in column three, in paragraph (a), in line one, the phrase “As specified in § 493.1256(e)(3),” is added at the beginning of the first sentence, and the word “Fluorescent” is corrected to be lower-case.

§ 493.1274 [Corrected]

■ On page 3710, in column three, in paragraph (d)(2)(iii), in line one, “Nongynecologic slide preparation” is corrected to read “Nongynecologic slide preparations”.

■ On page 3711, in column two, in paragraph (h), in line one, the heading “Documentation.” is added.

§ 493.1276 [Corrected]

■ On page 3711, in column two, in paragraph (d), in line five, “System of Cytogenetic Nomenclature” is corrected to read “System for Human Cytogenetic Nomenclature”.

§ 493.1278 [Corrected]

■ On page 3712, in column two, in paragraph (g), in line one, the heading “Documentation.” is added.

§ 493.1289 [Corrected]

■ On page 3713, in the heading of § 493.1289, add the word “quality” before “assessment”.

■ On page 3713, in column one, in paragraph (b), in lines one and seven, add the word “quality” before “assessment”.

■ On page 3713, in column one, in paragraph (c), in line two, add the word “quality” before “assessment.”

§ 493.1291 [Corrected]

■ On page 3713, in column one, in paragraph (a), in line one, add the word “an” before the word “adequate”.

■ On page 3713, in column one, in paragraph (a), in line two, “systems” is corrected to read “system(s)”.

■ On page 3713, in column two, in paragraph (c)(1), in line three, “or an unique” is corrected to read “or a unique”.

■ On page 3713, in column two, in paragraph (g), in line six, “imminent” is corrected to read “imminently”.

§ 493.1299 [Corrected]

■ On page 3713, add the word “quality” before “assessment”: in the section heading; in column three, in paragraph (b), in lines one and seven; and in column three, in paragraph (c), in line two.

§ 493.1359 [Amended]

■ In § 493.1359, paragraph (b)(2) is revised to read as follows:

* * * * *

(b) * * *

(2) Is performed in accordance with applicable requirements in subparts H, J, K, and M of this part.

III. Waiver of Proposed Rulemaking

We ordinarily publish these changes in a notice of proposed rulemaking in the **Federal Register** and invite public comment before final changes are adopted. However, we can waive this notice and comment rulemaking if we find good cause to do so (that is, notice and comment procedure is impracticable, unnecessary, or contrary to the public interest) and the agency incorporates a statement of the finding and the reasons therefore in the final rule that is published.

In this case, we believe that it is unnecessary to undertake notice and comment rulemaking procedures because the changes this notice adopts have no substantive effect. Specifically, in this notice, the two definitions that have been adopted merely refer the reader back to the statutory criteria for waiver. The correction and/or update of names of entities and persons does not alter to whom the regulations are referring. The citations that have been removed were to non-existent regulatory cites. The addition of the word “quality” throughout the regulations merely provides clarification as to what the regulated entity is ultimately assessing without altering the means to be used for such assessments or the parties that must conduct those assessments. The relocation of one requirement from under one heading to