

affected laboratory of any challenge, analyte, or test method for which it cannot produce a grade and the reasons why grading is not possible. A few commenters strongly disagreed with the practice of assigning a 100 percent score to PT analytes when the laboratory has not earned the score. The commenters stated that this practice penalizes laboratories that have correctly performed testing on all PT samples and causes laboratories that receive false representation of a grade to believe their test performance is exemplary, when it has not been comparatively evaluated. Additionally, laboratory testing problems that exist are not identified; therefore, no corrective actions are taken.

Response: Individual responses to the above comments are as follows:

- We agree with the commenter and are retaining the requirement formerly at § 493.1707 (now at § 493.1236) for the laboratory to review and evaluate results obtained on proficiency testing. PT result review is part of the QA process.

- We anticipate all regulated analytes (those listed in subpart I) will be graded by approved PT programs. The commenter is correct that, in some cases, not all challenges have been graded. Occasionally, as new methodologies or new instrumentation are developed for tests listed in subpart I, PT material is not always available or compatible with the new methods or instruments. In order to ensure that laboratories using new methodologies or instruments evaluate their performance, we are (now at § 493.1236(c)(2)) requiring laboratories to verify twice annually the accuracy of tests listed in subpart I for which compatible PT material is not available from approved programs.

- We agree with the commenter's recommendation to require PT programs to notify the laboratories and HHS of any challenge, analyte, or test method that cannot produce a grade and the reasons why grading is not possible. As CDC and CMS perform the annual review of PT programs required by the CLIA statute, programs must submit an annual report and, if needed, an interim report that identifies any previously unrecognized sources of variability in kits, instruments, methods, or PT samples that adversely affect the programs' ability to evaluate laboratory performance. This requires PT programs to report problems to CMS. We are also requiring programs to notify laboratories (on the laboratory's PT results report) of exceptions and/or problems that precluded an analyte from being graded.

- We appreciate the commenters' concerns regarding false grading;

however, there are reasons why false grading occurs. Almost all areas of testing under PT must be graded on an overall basis, that is, each analyte score under a subspecialty or specialty is averaged on each testing event to provide the laboratory with an overall subspecialty or overall specialty score. In order to determine an overall score, each analyte must receive a numerical score to allow the overall specialty or subspecialty to be graded. The circumstances that a PT program may assign an analyte score that does not reflect the laboratory's true test performance include: (1) Analyte evaluation does not produce at least 90 percent agreement among participant or referee laboratories that is required by regulation (the laboratory receives 100 percent score); (2) laboratory did not participate in the testing event (the laboratory receives zero percent score); or (3) laboratory's PT results were received after the cut-off date for receipt (the laboratory receives a score of zero percent for the late return of results). In response to the commenters' concerns, we are now requiring at § 493.1236(a)(2) that the laboratory verify the accuracy of the analytes for which a grade was assigned that did not reflect its true testing performance.

V. Provisions of the Final Rule

In response to public comments on the final rule with comment period and to provide policy clarifications, we made a number of changes in this final rule, which are summarized as follows:

Subpart A—General Provisions (Definitions)

- We added at § 493.2 the definitions for the terms “calibration,” “calibration verification,” “FDA-cleared or approved test system,” “reportable range,” and “test system.”

- We revised § 493.3(b)(3) to remove the words “National Institutes on Drug Abuse (NIDA)” and add, in their place, the agency's new name, “Substance Abuse and Mental Health Services Administration (SAMHSA).”

- We revised § 493.20 by removing the reference to “subpart P” and adding the cross reference to “§ 493.1773.”

- We revised § 493.25 by removing the reference to “subpart P” and adding the cross reference to “§ 493.1773.”

Subpart C—Registration Certificate, Certificate for Provider-performed Microscopy Procedures, and Certificate of Compliance

- We revised § 493.43(a) by removing the words “tests of moderate complexity (including the subcategory) or high complexity, or any combination of these

tests,” and adding, in their place, the words “nonwaived testing.”

- We revised § 493.45 by removing the reference to “subpart P.”

- We revised § 493.47 by removing the reference to “subpart P”.

- We revised § 493.47(c)(3) by removing the cross reference to “§ 493.1776” and adding, in its place, a cross reference to “§§ 493.1773” and “493.1775.”

- We revised § 493.49 by removing the reference to “subpart P.”

Subpart F—General Administration

- We added at § 493.643(c)(3)(ix) the word “Clinical before the word “Cytogenetics” to correct a technical error. The word was inadvertently omitted from the final rule with comment period.

Subpart H—Participation In Proficiency Testing for Laboratories Performing Nonwaived Testing

- We revised the heading of subpart H to read “Participation In Proficiency Testing for Laboratories Performing Nonwaived Testing.”

- We revised “§ 493.801(a)(2)(ii)” by removing the cross reference to “§ 493.1709” and adding, in its place, “§ 493.1236(c)(1).”

- We revised “§ 493.803(a)” by removing the words “tests of moderate complexity (including the subcategory), and/or high complexity” and adding, in their place, the words “nonwaived testing.”

- We revised the heading of § 493.807 to read “Condition: Reinstatement of laboratories performing nonwaived testing.”

Subpart I—Proficiency Testing Programs for Nonwaived Testing

- We revised the heading of subpart I to read “Proficiency Testing Programs for Nonwaived Testing.”

- We revised this subpart by changing the 90 percent consensus requirement to 80 percent consensus.

- We revised § 493.945 by removing the cross reference to “§ 493.1257” and adding in its place §§ 493.1105(a)(7)(i)(A) and 493.1274(f)(2).”

Revisions to Subpart J and K

As stated in section II of this preamble (Highlights and Organization of Final Rule), we have consolidated and reorganized the requirements formerly in Subpart J—Patient Test Management for Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests, Subpart K—Quality Control for Tests of Moderate Complexity (Including the