

#### IV. Analysis and Responses to Public Comments

We received numerous comments on the final rule with comment period published on February 28, 1992 in the **Federal Register**. These comments were from State agencies, proficiency testing programs, professional organizations, the Clinical Laboratory Improvement Advisory Committee (CLIAC), laboratories, physicians, and the general public. Summaries of the public comments received and our responses to those comments are set forth below.

##### *Subpart I—Proficiency Testing Programs for Tests of Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests*

We received a number of comments on the topic of proficiency testing. We intend to publish a notice of proposed rulemaking addressing proficiency testing issues in more detail in the future. We have, however, determined that it would be appropriate to include in this final rule a change that we believe is necessary to improve the operation of the CLIA proficiency testing program, related to the percentage of required agreement among participant or reference laboratories. Thus, we are addressing only one of the changes requested by the commenters and recommended by the CLIAC.

Specific comments received and response to comments regarding subpart I are set forth below.

*Comment:* A few commenters, professional organizations, and proficiency testing programs expressed their concerns over the change to a 90 percent consensus requirement to be reached before a proficiency testing sample could be graded. Commenters felt there should be a grade assigned to their samples. One commenter stated that their laboratory paid for samples, so grading should be required. Proficiency testing programs had similar opinions. The CLIAC recommended reducing the consensus required for grading proficiency testing challenges to decrease the number of ungradeable samples as ungraded proficiency testing is not effective in assisting laboratories in their quality assessment of test performance.

*Response:* We agree with the commenters and are changing the percentage of required agreement among participant or referee laboratories to 80 percent in the specialties and subspecialties where 90 percent agreement was previously required.

##### *Subpart J—Patient Test Management for Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests*

Following publication of the final rule with comment period, we received approximately 150 comments regarding subpart J. The comments were in response to the requirements for specimen submission and handling; test requisition including oral requests and authorized persons; and test records and test reports, including confidentiality and referral of specimens. The majority of the commenters disagreed with some portion of the requirements and some commenters requested clarification of certain requirements while others offered specific revised language.

Specific comments received and responses to comments regarding subpart J are set forth below.

*Comment:* A number of State agencies disagreed with our removal of the requirement that laboratories comply with applicable Federal, State, and local laws.

*Response:* We agree with the commenters and are reinstating the requirement now at § 493.1101(c). As part of the partnering relationship with State agencies and local governments, the reinstatement of this requirement will allow us to support a State or local government that seeks to protect the public from actions it finds would be detrimental to public health.

*Comment:* Some commenters disagreed with requiring written authorization for oral test requests, describing the difficulties that this requirement causes.

*Response:* We acknowledge that when a laboratory asks that an oral request for patient testing be followed with a written request, there is no guarantee that one will be received. On January 19, 1993, we published a technical correction in the **Federal Register** (58 FR 5215) and (58 FR 5229) that amended the requirement formerly at § 493.1105. This requirement, now at § 493.1241(b), states that oral requests for laboratory tests are permitted only if the laboratory requests written or electronic authorization for testing within 30 days of the oral request and documents the efforts made to obtain a written or electronic authorization.

*Comment:* We received several comments recommending information the laboratory should solicit and obtain on the test requisition. Specifically, the commenters believe the age and sex of the patient, time of specimen collection, and the specimen source should be included since they are pertinent to either how the laboratory processes the

specimen and/or how the test results are interpreted.

*Response:* We agree with the commenters. The requirement, formerly at § 493.1105(f), requires the laboratory to ensure that the requisition or test authorization includes any additional information relevant and necessary for accurate and timely testing and result reporting (for clarity, we are adding “interpretation” if applicable to this requirement). The requirement, now at § 493.1241(c)(3), specifies that the laboratory must request the patient’s sex and age or date of birth as normal values and interpretation of test results are often dependent on this information. Concurrently, we are redesignating age or date of birth requirements, formerly at § 493.1105(e), for Pap smear requisitions to test requests (now at § 493.1241(c)(3)). The time of specimen collection must also be requested when it is relevant for the testing to be performed. For example, this information is important when interpreting the results of peak and trough therapeutic drug assays. In addition, we are requiring that specimen source, when appropriate, be solicited on the test requisition. Specimen handling, preservation, and preparation (for example, use of proper transfer media, inoculation of media in microbiology and clinical cytogenetics, and the application of appropriate normal values reported with patient test results) are dependent on the origin of the specimen. Therefore, we are including specimen source, when appropriate, as part of the laboratory’s submission, handling, and referral procedures (now at § 493.1242(a)(3)). We are also requiring specimen source to be included on the test report if warranted (now at § 493.1291(c)(5)). This routine laboratory practice was inadvertently omitted from the final rule with comment period.

*Comment:* One organization representing members of the laboratory community objected to the amount of information that a laboratory must have on the test requisition, specifically the information that is needed when submitting a Pap smear. The organization stated that laboratories do not have access to patient records and are dependent on the authorized person ordering the test to provide this information. The organization agreed the information was important but assumed we would prohibit testing if all information was not obtained by the laboratory.

*Response:* We agree with the commenter that the information being requested is important. Therefore, we are retaining the test request