

normal diagnosis. The commenters suggested establishing a specific band level of resolution that would be dependent upon the type of study requested.

*Response:* We are revising the requirement formerly at § 493.1267(b) (now § 493.1276(b)(2)) for clarity. The requirement now states that the resolution used must be appropriate for the type of tissue or specimen, and that the type of study required is based on the clinical information provided to the laboratory.

*Comment:* One commenter suggested that substituting the words “photographic karyotypes” for “photographs” would correctly reflect what cytogeneticists read.

*Response:* We are adding new language to the CLIA regulation formerly at § 493.1267(c) (now at § 493.1276(a)) to specify karyotypes in addition to photographs.

*Comment:* A few commenters disagreed with the CLIA regulation requiring “appropriate nomenclature” and felt the CLIA regulation should require the use of the International System of Cytogenetic Nomenclature in reporting all cases because it is the only recognized system that exists and anything else would be homemade and impossible to interpret other than by that particular laboratory.

*Response:* We agree with the commenters and are replacing the words “appropriate nomenclature” formerly at § 493.1267(d) (now at § 493.1276(d)) with the words “the International System of Cytogenetic Nomenclature.”

*Comment:* One commenter stated that failure rate is an aspect of cytogenetic testing and that it is not addressed by CLIA regulations. The commenter also stated that failure rate can provide valuable information about a laboratory’s capabilities and be easily evaluated by an individual lacking specific expertise in cytogenetics. The commenter stated that accepted standards for study failure rates exist for the various types of tests done in cytogenetic laboratories.

*Response:* We agree that study and culture failure rates can be a useful tool in evaluating a cytogenetic laboratory’s performance. However, the study must be evaluated carefully because many factors outside of the laboratory’s control may influence the rates, for example, specimen transit time and conditions. In addition, what constitutes failure must be clearly defined. For this reason, we are not mandating failure rates but encourage laboratories to monitor these rates as part of a QA program.

*Comment:* One commenter recommended gestational alpha-fetoprotein (AFP) be recognized as an analyte. Gestational AFP testing should not be included under Immunology, where AFP is used as a tumor marker.

*Response:* Although the analyte alpha-fetoprotein may be used for genetic screening, the test does not entail chromosomal examination (that is, cytogenetics). Measurement of this analyte may be used for non-cytogenetic purposes. CLIA certifies laboratories in both the subspecialty of routine chemistry and general immunology for gestational and maternal AFP.

Section 493.1273 Standard: Immunohematological Collection, Processing, Dating Periods, Labeling and Distribution of Blood and Blood Products

Specific comments received and response to comments regarding § 493.1273 are set forth below.

*Comment:* One commenter requested the addition of requirements to § 493.1273 regarding the use of bar code systems for the identification of blood and blood products, stating that laboratories should document the accuracy of bar codes before putting the systems into use, and as a continuing part of quality assurance while the systems are in use.

*Response:* We agree with the commenter that the accuracy and ongoing reliability of bar code systems used for the identification of blood and blood products is an important quality issue for laboratories that use them. Laboratories involved in collecting, processing, dating, labeling, testing, and distributing blood and blood products are required to conform to the FDA requirements for blood and blood products at 21 CFR parts 606, 640, 21 CFR 610.40, and 610.53. Specifically, 21 CFR 606.121: Container label, permits the use of container labels that bear encoded information in the form of machine-readable symbols approved for use by the Director, Center for Biologics Evaluation and Research, FDA, and refers to FDA’s “Guideline for Uniform Labeling of Blood and Blood Components,” that addresses blood product labeling requirements, including standards for bar codes. Also, 21 CFR 606.140 requires the laboratory to have control procedures that provide for monitoring the reliability, accuracy, precision, and performance of laboratory test procedures and instruments.

*Comment:* A laboratory surveyor asked why CLIA personnel are responsible for surveying large sections of the FDA’s regulations. Since CLIA is

a self-funded program, the commenter wondered if the FDA reimbursed the CLIA program for these services.

*Response:* The commenter is correct in questioning the role of the CLIA surveyors’ inspection responsibilities. We have corrected the citations from 21 CFR to specify in 42 CFR part 493 the exact requirements that must be met under the CLIA regulations. The revised citations are now at §§ 493.1105(a)(1)(i), 493.1271(a)(1) and (b). When reviewed, the actual time expended surveying sections of the FDA’s regulation was minimal. Sister agencies such as the FDA and CMS frequently assist one another without charge when expenditures to provide such assistance are *de minimis*.

*Subpart M—Personnel for Moderate Complexity (Including the Subcategory) and High Complexity*

In the February 28, 1992 final rule with comment period, the personnel requirements are located in subpart M and include qualification requirements for individuals to direct a laboratory performing high complexity testing. A phase-in period was provided for individuals with a doctoral degree to obtain board certification. In response to the publication of the date extension rules, we received comments suggesting that we develop alternative provisions to qualify individuals with a doctoral degree on the basis of laboratory training or experience, instead of requiring board certification. On December 28, 2001, we published a proposed rule in the **Federal Register** (66 FR 67163) that included provisions to end the phase-in period and revise and expand the qualifications required for an individual with a doctoral degree to direct a laboratory performing high complexity testing.

Following publication of the proposed rule, we received 113 comment letters, which contained approximately 300 comments. Of these, 168 comments agreed with one or more provisions in the proposed rule, 120 comments disagreed with at least one of the provisions, 6 comments addressed the education requirements, and 1 comment reflected misinterpretation of the proposed requirements. Fifty-three of the 113 comment letters specifically addressed qualification requirements for directors of laboratories performing histocompatibility testing.

Specific comments received and responses to comments regarding the proposed rule are set forth below.

*Comment:* The majority of the comments on the first provision (at the proposed and former § 493.1443(b)(3)(i)) agreed with requiring board certification