

were generated as a final report and must not change on copies reported at a later date.

The above requirements are intended to respond in part to the commenters' requests. We intend to publish, at a later date, a rule specific to laboratory information systems. For example, requirements for the establishment and verification of system programs, system security, system and device maintenance, system operator functions and responsibilities, and system backups.

Comment: One commenter was concerned about limited record storage space on-site and asked if off-site storage of records would be acceptable provided the laboratory was able to produce these records during an inspection.

Response: Records may be stored at a place of the laboratory's choosing providing the storage is appropriate and the laboratory can produce the documents within a reasonable time during the course of an inspection as required at § 493.1773(c).

Comment: Several commenters disagreed with the requirement to retain records for a minimum of 2 years or 5 years, depending upon the type of record. A professional organization questioned whether instrument printouts must be retained for 2 years if appropriate data are saved in a retrievable manner. Other commenters felt that 3 months, and, in one case, 6 months, would be sufficient time to retain instrument printouts.

Response: We believe all records related to testing, for example, records of test requests, patient test records including, if applicable, instrument printouts, and copies of test reports are essential for the ongoing QA reviews performed by the laboratory. Instrument printouts are test records and are sometimes used as test reports and for these reasons must be retained for the appropriate length of time unless all information is duplicated in another record system. Additionally, CLIA requires biennial certification that includes an inspection of the laboratory's activities for compliance with CLIA requirements by either an on-site inspection of the laboratory or a self-assessment inspection through use of the Alternate Quality Assessment Survey (AQAS). These inspections require a review of the testing performed by the laboratory since the previous biennial inspection. Two years is the minimum amount of time records must be retained to ensure that they are available for review at inspection. However, we are clarifying the record retention requirements for

immunohematology and blood and blood products formerly at § 493.1107 introductory text and § 493.1221 (now at § 493.1105(a)(3)(ii)) and formerly at § 493.1109 introductory text (now at § 493.1105(a)(6)(i)) to ensure consistency with the FDA requirements for these types of records.

Subpart K—Quality Control for Tests of Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests

In the final rule with comment period, the QC rules are located in subpart K and include the general QC requirements and specific QC requirements for each specialty and subspecialty of testing. A phase-in period provided less stringent general QC requirements for unmodified moderate complexity tests approved by the FDA through the premarket notification 510(k) or premarket approval (PMA) process.

Following publication of the final rule with comment period, we received approximately 1,030 comments. Of these comments, 280 were directed at the general QC requirements, 67 pertained to the specialty and subspecialty QC requirements, and approximately 680 pertained to cytology and histopathology requirements. The majority of the comments disagreed with some portion of the requirements, indicating that the final rule with comment period was either too restrictive or too lenient. Some commenters requested clarification of certain requirements, while others offered specific revised language. A few comments agreed with the final rule with comment period, while others indicated the requirements had either been misinterpreted or misread. We addressed some of the commenters' issues in a technical correction published on January 19, 1993 in the **Federal Register** (58 FR 5215).

In evaluating the comments and considering the types of revisions to make in this subpart, we obtained recommendations from the CLIAC and consulted with various professional organizations and laboratory personnel. In September 1996, we participated in public discussions at a 2-day meeting in Atlanta, Georgia. At the public meeting, manufacturers, laboratory organizations, and State representatives made presentations concerning QC principles, control materials and systems, manufacturers' recommendations, costs associated with control testing, and personnel implications. Their recommendation was to make changes to accommodate new technology. Our

changes in this final rule are based on the advice and comments we received.

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

Comment: We received mixed comments concerning the general QC requirements. Some commenters felt the QC requirements were burdensome and would increase the cost of testing and asked that these requirements be deleted or revised. Conversely, some commenters agreed with the requirements, indicating that QC is absolutely essential to producing accurate test results and is good laboratory practice. Others stated the requirements of subpart K were both reasonable and attainable. A few commenters requested further clarification.

Response: We agree with the comments that QC procedures are essential to good laboratory practice and production of accurate test results. Control procedures verify that the patient results are substantially unaffected by day-to-day variation caused by the test system, environment, or operator. While the requirement for implementing QC may initially increase the cost of testing in some settings, it may decrease the long term cost as improved accuracy and reliability of testing reduces the need for retesting and unnecessary procedures or treatments.

Comment: A manufacturer's organization requested that § 493.1202(c) be revised to include those products not subject to the FDA clearance process to allow laboratories performing these tests to meet the phase-in QC requirements.

Response: We agree that the regulation needs to be revised to include these products, and provisions addressing these products were added in the revisions to the regulations published in the January 19, 1993 technical corrections (58 FR 5215). Since these products are not evaluated by the FDA, they could not be included under § 493.1202(c) but were added to § 493.1202(b) and subject to all applicable standards of subpart K.

Comment: Comments were divided concerning the phase-in of the general QC requirements. Some commenters agreed with the phase-in while others were opposed. Some commenters felt that following manufacturers' instructions should be sufficient to meet the CLIA QC requirements. Others expressed concern that FDA would not complete the review and approval of manufacturers' QC instructions by September 1, 1994. Most commenters opposed the phase-in provision. Some