

commenters were concerned that manufacturers' QC protocols cleared by the FDA might be less stringent than the CLIA QC requirements. Other commenters disagreed with having two sets of general QC requirements, and other commenters were confused about the phase-in requirements and requested clarification.

*Response:* We implemented a phase-in of the general QC requirements to allow previously unregulated laboratories performing only FDA-approved or cleared, unmodified, and moderate complexity testing sufficient time to implement effective QC programs. During the phase-in, the FDA was to establish a process to review and clear manufacturers' QC instructions for CLIA QC purposes. Under this process, laboratories could meet certain CLIA QC requirements by following the FDA-approved manufacturers' QC instructions. On four occasions, we extended the phase-in of the general QC requirements that are currently in effect until December 31, 2002. However, because the CLIA program is user fee funded, we decided it would be prudent to wait until the phase-in period ended before implementing the FDA QC review. This afforded us the survey experience necessary to determine whether an additional FDA review would be of benefit to laboratories. We realized through our experience inspecting laboratories that an additional FDA review would not be of such benefit. Therefore, in this final rule, we are eliminating the phase-in requirements and establishing minimum general quality system requirements applicable to all nonwaived testing, regardless of complexity. In addition, we are removing all references to the FDA QC clearance process that was not implemented. However, we agree with the commenters that it is essential for laboratories to perform testing according to the manufacturers' test system instructions as required formerly at § 493.1202(c)(1) (now at § 493.1252(a)).

*Comment:* A few comments were received in response to the environmental and safety requirements at § 493.1204. Some commenters indicated that the requirements were too lenient. Others were opposed to exempting moderate complexity testing from the requirements at § 493.1204 during the phase-in, stating that all laboratories should be subject to these requirements.

*Response:* We agree with the commenters and therefore are retaining the requirement formerly at § 493.1204 (now at § 493.1101, subpart J) and applying it to both moderate and high complexity testing. In addition, we are

providing some flexibility to the requirement formerly at § 493.1204(b) (now at § 493.1101(d)) that requires laboratories to post safety precautions. The revisions now require that safety procedures be accessible rather than posted.

*Comment:* We received several comments concerning the requirements at § 493.1205. Most commenters opposed the requirement prohibiting the use of expired reagents. One commenter requested clarification of § 493.1205(c)(1) that requires the laboratory to define criteria for reagent and specimen storage conditions.

*Response:* We understand the concerns expressed regarding the use of rare and expensive reagents and materials beyond their expiration dates. However, the manufacturer has the responsibility for establishing expiration dates that ensure the reagents and materials will perform properly when used for patient testing. In addition, any changes in the labeling of *in-vitro* diagnostics must comply with Food, Drug, and Cosmetic Act requirements. Therefore, we are not making any revisions to the requirement formerly at § 493.1205(e)(1) (now at § 493.1252(d)) prohibiting the use of expired reagents and other materials.

In regard to licensed biological and blood products, any exceptions to dating requirements must be granted by the FDA in the form of an amendment to the product license. In this final rule, we are consolidating all requirements pertaining to the immunohematological testing and distribution of blood and blood products (now at § 493.1271(b)).

We are adding language to the requirement formerly at § 493.1205(c)(1) to clarify how the laboratory establishes and uses its criteria for storing reagents and patient specimens. The requirement now at § 493.1252(b), states that the laboratory must define criteria for those conditions in the manufacturer's test system instructions, when available, that are essential for proper storage of reagents and specimens, and accurate and reliable test system operation and test result reporting. The criteria must be consistent with the manufacturers' instructions, if provided. These conditions must be monitored, documented, and include (1) water quality; (2) temperature; (3) humidity; and (4) electrical tolerances.

*Comment:* One commenter agreed with the requirements at § 493.1211, Procedure manual. Another commenter suggested that the procedure manual requirements be deleted. Two commenters opposed permitting the use of the manufacturer's package insert to satisfy the requirements at

§§ 493.1211(b)(1) through 493.1211(b)(13). Another commenter suggested that laboratories be required to retain each procedure's original specifications and instructions for use as provided by the manufacturer, and maintain a list of any alterations or changes in the procedure manual.

*Response:* We disagree with the commenter who requested that the procedure manual requirements be deleted. All laboratories must maintain and follow procedure manual instructions in order to provide uniform patient testing. Therefore, we are retaining the requirements for a procedure manual now at § 493.1251. Laboratories may use the manufacturer's test system instructions to meet many of the procedure manual requirements, but must supplement them with any laboratory-specific information related to its testing and reporting practices. Examples are the laboratory's procedures for reporting patient test results, including panic values or alert values, corrective actions to follow when test systems become inoperable, and criteria for specimen referral. The use of the manufacturer's test system instructions to meet many of the procedure manual requirements is permitted to ensure that laboratories follow the manufacturer's instructions for patient testing and to minimize the burden on laboratories in developing procedure manuals.

For clarity and consistency, we are reiterating the requirements formerly at §§ 493.1103(a) and 493.1211(b)(14) (now at §§ 493.1242 and 493.1251) that the laboratory have written policies and procedures for specimen submission. In addition, we included language now at § 493.1251(b)(13) to clarify the use of laboratory information systems for entering patient test results.

In addition, we agree with the commenter that laboratories must have copies of test procedures. Therefore, we are retaining the requirement now at § 493.1251(e) that laboratories must maintain a copy of the procedure with the dates of initial use and discontinuance for 2 years after a procedure is no longer used.

*Comment:* Several commenters opposed the requirement at § 493.1211 for the director to approve, date, and sign the procedure manual, approve any change in procedure, or re-approve the manual should there be a change in directorship. One commenter suggested that the requirement be revised to state each procedure must be approved by the director before patient testing.

*Response:* The director is the individual ultimately responsible for the operation and administration of the