

process will depend on the labor needed to develop a documentation system. Subsequent costs will be for the labor necessary to maintain documentation, the number of instruments involved and the extent to which documentation is not currently being done. We have no data to estimate the total cost to fulfill this requirement; however, it will be of minimal impact.

#### f. Control Procedures

##### **Rationale**

The intent of the CLIA regulation was to impose the same requirements on all U.S. laboratories, regardless of testing site, in order to assure the public that minimum standards for quality testing were met wherever testing was performed. Under the QC phase-in requirements, laboratories performing testing using unmodified moderate complexity test systems approved or cleared by the FDA were required to test two levels of control materials each day of testing. Since many laboratories had never been regulated, they were given a phase-in period to allow them to become accustomed to meeting requirements for QC. During the phase-in, laboratories, could through the guidance in Appendix C of the State Operations Manual (SOM), use test system internal checks and controls, for example, built in procedural or electronic checks, as a substitute for one or both levels of traditional external liquid controls.

With the completion of the QC phase-in, all laboratories performing nonwaived testing are subject to the requirements specified in § 493.1256 for control procedures. The minimal number of control materials and frequency for control testing remains unchanged, two levels of control materials at least once each day of testing. We will continue to allow flexibility for laboratories to follow control procedures determined to be equivalent to testing two levels of external controls each day of testing.

We are acknowledging that laboratory technology has become simpler since the initial CLIA regulations were promulgated, and simplification and improvements are continuing. These technological advances may allow for control procedures equivalent to the traditional daily evaluation of two levels of external control materials, for example, the use of internal checks and internal controls or performance of control procedures at a frequency other than daily.

Additionally, laboratories must now meet some requirements for control use and acceptability that were not included

for FDA-cleared, unmodified moderate complexity testing during the phase-in period. This includes testing controls in the same manner as patient specimens, rotating control testing among all operators who perform specific tests, and verifying the criteria for control results acceptability for quantitative tests.

##### **Benefits**

The requirements for control procedures between those in effect during the phase-in and this final rule are similar. While enforcement was permissive during the phase-in, there were no specific guidelines for laboratories to follow. With this final rule, laboratories will have guidance on what control procedures are acceptable (criteria will be specified in the SOM). In addition, the regulatory language is more specific, providing laboratories more detailed descriptions of what is required. Also, with the recognition that technology has and continues to improve, manufacturers will have more incentive to continue simplifying and improving technology to further reduce the cost of QC.

##### **Costs**

Most information on the prevalence of the reliance on internal checks and controls in lieu of using traditional external controls is anecdotal (American Association for Clinical Chemistry, 1999). A study by the Pacific Northwest Laboratory Medicine Sentinel Monitoring Network (LaBeau, et al, 1999), demonstrates that the majority of the 83 laboratories completing the survey used mechanisms other than daily testing of traditional external liquid controls for a total of 184 nonwaived tests. These control mechanisms included built-in controls, procedural controls, electronic control cartridges or devices, and control strips. Although external controls were used with 85 percent of these tests, the frequency varied. Only 15 percent used external controls daily, while the majority of the laboratories (64 percent) used external controls with each kit or lot of reagents. However, this study sample size is too small to draw general conclusions about the use of control procedures in most laboratories. Since we anticipate maintaining the status quo allowing the use of internal checks and internal controls, and the testing of external control materials at the frequency currently being performed in most laboratories for unmodified moderate complexity testing, there will be no impact on the cost.

All laboratories must now verify control results acceptability for

quantitative testing. Laboratories affected by the completion of the QC phase-in might incur costs to establish this practice, since this is a new requirement. This verification is simply done through repetitive testing to ensure that the laboratory's results are within the control manufacturer's statistical parameters for the particular test system in use. We have no data on the current prevalence of this activity for those laboratories that this change may affect. For laboratories that have not been performing this verification, the costs they will incur will be for the reagents and controls for replicate testing and for the labor in testing and evaluating the statistical parameters. In many cases, replicate control testing can be done concurrent with patient testing, if the control results are within the manufacturer's stated range, reducing the cost of this requirement. Laboratories not performing this verification will use controls at an increased rate; however, they may offset this cost by the ability to use more internal or procedural QC. We have insufficient data to estimate the total costs for this requirement.

##### **Alternative Approaches**

In revising these regulations, we considered maintaining the QC phase-in requirements for QC. These phase-in requirements were intended to temporarily exempt most previously unregulated laboratories from the more stringent QC requirements such as calibration verification and method verification. Previously unregulated laboratories have had sufficient time to become familiar with regulatory requirements. Although few studies have been done linking the performance of QC procedures with patient results (Astles, et al, 1998), the standards specified in this final rule are generally considered to be basic quality requirements. Also, to maintain the phase-in requirements would create a permanent inappropriate discrepancy between what is required among the laboratories having different types of certificates and between moderate and high complexity testing. Accredited laboratories, with the exception of those accredited by COLA, and State-exempt laboratories are already required to meet more stringent QC practices than those allowed during the phase-in. We believe the completion of the QC phase-in requirements is in the best interest of the public to ensure the minimum quality laboratory standards regardless of testing site and the type of testing performed.