

time we estimated it takes to perform the calibration verification (2 hours), multiplied by the analyst wage per hour (\$17.90).

#### Cost of Verification Materials

Materials used for calibration verification span the reportable range of the method, and target values are assigned independently using accurate test methods. Acceptable materials are proficiency testing material, altered and unaltered previously tested patient specimens, primary standards or reference materials, independent calibrators, or materials for demonstrating linearity or calibration verification kits. For this analysis, we assumed laboratories will purchase calibration verification kits. However, all materials mentioned above may be used as long as the entire reportable range is tested with at least three concentrations and the nominal concentrations are independently assigned with a valid test methodology. Also, we assumed that a laboratory with any multi-test analyzer would buy a product to verify calibration of all tests the analyzer is capable of performing. We may be overestimating the cost because some laboratories do not perform all tests available on an analyzer, or we may be underestimating the cost by not including individual

tests that may not be offered on a multi-test analyzer.

Our evaluation shows the costs were roughly similar for the various calibration verification products. The cost of calibration verification kits was obtained from several different suppliers of calibration verification materials (College of American Pathologists, CASCO NERL Diagnostics, Align, Sigma, R&D Systems, and Streck Laboratories). The average cost for a year's worth of calibration verification materials for comparable products was used as the cost of verification materials for each analyzer type.

#### Reagent Costs

We estimated the cost of reagents from price quotes by analyzer manufacturers (Beckman-Coulter, Dade-Behring, and Roche Diagnostics). This cost varies with test volume. We used the moderate volume estimate provided by these manufacturers for each analyzer type, since most of the laboratories that these changes will affect perform low to moderate test volumes. We calculated the total cost of reagents by multiplying the cost of reagents per test times the number of analytes per analyzer, the minimum number of tests per calibration verification, and the frequency of calibration verification, which we

assumed to be, at a minimum, biannually.

#### Scope of Impact

Based upon these assumptions and estimates, we calculated the total cost of the requirement to perform calibration verification for laboratories that these changes will affect to be \$17.0 million the first year, and the discounted cost will be \$74.5 million by the end of the next 5 years (Table 8).

The impact to an individual laboratory will be proportional to the number of quantitative tests that need calibration verification. Larger laboratories with more analyzers and methods will need to perform calibration verification on more methods than smaller laboratories with fewer methods. Larger laboratories may also have more instrument repairs and reagent changes that may make it necessary to perform calibration verification more than twice a year. Therefore, large laboratories are more likely to incur a greater increase in the cost of calibration verification than small laboratories.

In addition, some manufacturers may furnish calibration verification materials and assist in the performance of calibration verification as part of their service. We cannot estimate the extent that this may happen; therefore, we may have overestimated the total cost.

TABLE 8.—IMPACT OF REQUIREMENT FOR CALIBRATION VERIFICATION

Test category	Laboratories affected for each test category	Labor costs per year	Cost of verification materials per year	Cost of reagents per year	Total costs per laboratory	Total costs per year†
Ther. Drug Monitoring* .....	3,230	\$35.80	\$413.00	\$69.12	\$517.77	\$1.67
Chemistry .....	7,657	35.80	707.00	72.00	815.05	6.24
Hematology .....	12,439	35.80	575.00	10.80	621.60	7.73
Ligands .....	3,404	35.80	207.00	36.00	278.80	0.95
Reproductive .....	930	35.80	158.00	142.80	336.15	0.31
Immunology .....	223	35.80	150.00	142.80	328.10	0.07
Total .....	.....	.....	.....	.....	.....	16.98

\* Therapeutic drug monitoring.

† Cost in millions.

#### e. Documentation of Maintenance and Function Checks

##### Rationale

During the QC phase-in period, laboratories performing commercial, unmodified moderate complexity testing were required to "follow manufacturer's instructions for instrument or test system operation and test performance." Therefore, if the manufacturer had specific instrument maintenance procedures or function checks, the laboratories were required to

perform them. With the completion of the phase-in, these laboratories must perform the maintenance and function checks according to the manufacturer, but also document their performance and results, as appropriate, and ensure that function checks are within the manufacturer's established limits before patient testing is conducted as specified in § 493.1254.

##### Benefits

Documentation of routine instrument maintenance and function checks

provides a record for the laboratory to attest maintenance was performed according to the required schedule and to ensure that instrument function is within acceptable limits whenever patient testing is performed. This documentation is an essential element of good laboratory practice and laboratory quality management.

##### Costs

For those laboratories that have not been documenting maintenance and function checks, the cost to initiate this