

TABLE 2.—IMPACTS DUE TO REGULATORY CHANGES: ANNUAL IMPACTS OVER 5 YEARS—Continued

	Savings (costs) <sup>†</sup>					
	Year 1	Year 2	Year 3	Year 4	Year 5	5-Year total
Hematology .....	Unknown .....	Unknown .....	Unknown .....	Unknown .....	Unknown .....	Unknown
Total .....	18.8–27.6 .....	17.5–25.7 .....	16.4–24.1 .....	15.3–22.5 .....	14.4–21.1 .....	82.5–121.0

<sup>†</sup> In millions of dollars.

Changes discounted at 7 percent compounded annually after Year 1.

### B. Introduction

The changes in this final rule will have some impact upon nearly all laboratories performing nonwaived testing. The nature and magnitude of the specific effects on any particular laboratory will depend upon the volume and types of testing performed and the QC requirements it met under the former regulation. The most significant impact will be on laboratories performing unmodified moderate complexity testing approved or cleared by the FDA that have been following the minimal QC requirements provided during the QC phase-in period. With the completion of the phase-in, these laboratories may now be required to follow more stringent QC procedures.

#### QC Phase-in Requirements

Under the February 28, 1992 final rule with comment period implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA), many laboratories that had never been regulated were required for the first time to establish and perform minimum QC and quality assurance practices. Most previously unregulated laboratories were performing primarily waived or moderate complexity testing using unmodified commercial test systems. Acknowledging the burden of coming under regulation for the first time, we created a phase-in period that allowed laboratories performing unmodified moderate complexity testing approved or cleared by the FDA to perform less stringent QC procedures than laboratories performing modified moderate complexity or high complexity testing. In addition, our intent was that when the phase-in period was complete, all laboratories performing nonwaived testing would be subject to the same QC requirements. This final rule is ending the phase-in period for QC that had been extended to December 31, 2002. The QC requirements for laboratories performing unmodified moderate complexity testing are now essentially equivalent to the requirements for modified moderate complexity, and high complexity testing.

As part of the QC phase-in, the FDA was to establish a process for review and clearance of manufacturers' test system instructions for compliance with certain CLIA QC requirements. This provision would have allowed laboratories to meet the CLIA QC requirements by following the manufacturers' FDA-approved or cleared instructions. 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 process beyond that already in place as part of premarket 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, this prospective provision was removed in this rule.

#### Moderate Complexity Testing

With implementation of this final rule, laboratories performing unmodified, FDA approved or cleared moderate complexity testing must now, as applicable—

- Augment procedure manual instructions;
- Monitor laboratory environmental conditions that affect reagent storage and test system operation;
- Verify or establish performance specifications for newly introduced test systems;
- Record or document equipment maintenance and function checks;
- Perform calibration verification; and
- Follow control procedures that monitor the accuracy and precision of the testing process.

These changes will primarily impact Certificate of Compliance and COLA-accredited laboratories, because these laboratories perform the bulk of the commercial, unmodified moderate complexity testing that was subject to the QC phase-in requirements.

#### Moderate and High Complexity Testing

This final rule updates requirements and recognizes the improvements in technology and stability of reagents by reducing the frequency of QC testing in several specialty and subspecialty areas that include both moderate and high complexity testing. For the following specialties and subspecialties, we reduced the frequency of QC testing, relieving laboratory burden and lowering the cost per test:

- Decreased frequency of QC testing for bacteriology and mycology reagent checks.
- Decreased frequency of QC testing for general immunology and syphilis serology to daily testing from concurrent with patient testing.
- Decreased frequency for hematology QC testing to each day of use from each 8 hours of operation.

For the subspecialty of mycobacteriology, we increased the frequency of QC testing for the following:

- Added a requirement for testing negative controls to check stains and reagents.
- Increased frequency for checking fluorochrome and acid fast stains.

#### Laboratory Director

We are completing the phase-in qualification requirements for high complexity laboratory director that allows individuals with a doctoral degree to qualify based on training and experience in lieu of board certification until February 24, 2003. With the implementation of this final rule on February 24, 2003, board certification will be required. To ensure a smooth transition to the new provisions for directors of high complexity testing who are not board certified (but who have doctoral degrees), we will not be holding facilities out of compliance with the provisions of the rule concerning directors who are not board certified until the effective date of this new rule, to the extent the facilities are otherwise in compliance with the requirements for laboratory directors. This new final rule permits those individuals who qualified under the