

change. On the other hand, in mycobacteriology, negative control organisms are now required for biochemical identification tests. Although this could result in some initial expense if new organisms must be purchased, significant cost should not be incurred, since in some cases the same organism may be used as a control for more than one test, and some of the organisms used for negative controls may be organisms already used as positive controls for different biochemical tests.

For estimating labor costs (the larger component of the QC cost for many tests), we used the 2000 mean wage per hour for a staff medical technologist (Ward-Cook and Tannar, 2001), divided by 60 minutes per hour to calculate the cost per minute (\$0.30). The cost of labor is the sum of the time required to perform QC and maintain the QC records, multiplied by the calculated wage per minute. The total cost of QC per test is the sum of the labor and material costs.

Bacteriology

We estimate that the QC changes for bacteriology will affect 27,443 laboratories, consisting of 26,610 laboratories in the CMS OSCAR (2001) database and an additional 833 bacteriology laboratories in exempt States. The changes pertain to reagents commonly used to identify bacteria. Although these reagents are primarily used for high complexity culture and identification procedures that may not be performed in a number of physician office laboratories or laboratories that perform only moderate complexity testing, we included all bacteriology laboratories in our estimates because some physician office laboratories perform high complexity culture and identification procedures, and at least one of the reagents may be used for moderate complexity tests. We realize the number of bacteriology laboratories that these QC changes affect may be overestimated.

As recommended by ASM, we are reducing QC testing to every batch, lot number, and shipment, for 10 commercial bacteriology reagents. Under the previous QC requirements for catalase, coagulase, oxidase, and beta-lactamase, QC testing was additionally required each day of use. The previous QC requirements for bacitracin, optochin, ONPG, X, V, and XV strips and disks were to test each week of use after initial testing of each batch, lot number, and shipment of reagent. For antisera (including *Salmonella* and *Shigella* antisera), we are reducing the QC testing requirements from every

month of use, to every 6 months after initial QC testing.

Mycobacteriology

We expect the QC changes will affect a total of 3,185 mycobacteriology laboratories in various degrees, depending upon the services they provide. This includes 2,903 laboratories in the CMS OSCAR (2001) database and 282 laboratories in exempt States. Based on estimates of the levels of mycobacteriology testing performed in the U.S. (CDC, 1995), all mycobacteriology laboratories perform acid-fast stains and could be impacted by the changes to the QC requirements for this testing. However, according to the estimates above, only 35.4 percent (1,127) of mycobacteriology laboratories perform mycobacterial organism identification, including 24.4 percent that perform acid-fast stains, primary culture, and identification (at least of *M. tuberculosis* complex), and 11.0 percent that perform acid-fast stains, primary culture, identification, and drug-susceptibility testing. Therefore, this number represents the maximum number of laboratories that could be fully impacted by all QC changes for this subspecialty.

For acid-fast stains, we are now requiring positive and negative control organisms to be QC tested each day of use rather than each week of use. In addition, we are now requiring that fluorochrome acid-fast stains be QC tested each time of use rather than each week of use. Although not all mycobacteriology laboratories perform both types of stains on a daily basis, the specific percentage of laboratories performing each type of stain is unavailable. We conservatively estimated that the QC change will affect all mycobacteriology laboratories for both staining procedures and will require the laboratories to perform QC testing for each procedure at least daily. However, professional standards of practice recommend QC for acid-fast stains each time of use, and the QC changes will not impact laboratories following these guidelines.

For conventional biochemical reagents and test procedures for mycobacterial identification from culture, we are now requiring that a negative control organism be tested in addition to a positive control organism each day of use. Based on the biochemical tests used for mycobacterial identification as listed in *Essential Procedures for Clinical Microbiology* (Eisenburg, 1998), we estimate 10 additional negative controls for biochemical tests may be performed by each laboratory depending on the

organism to be identified. However, our estimates of the additional QC required and number of laboratories that these changes will impact could be inflated for several reasons. First, many mycobacteriology laboratories now use molecular methods for organism identification in lieu of conventional biochemical tests (we are not changing the QC requirements for molecular methods). According to an ASM survey presented to the CLIAC in 1999, 78 percent of the responding laboratories performing mycobacterial identification used molecular methods. It is likely that this percentage will increase in the future as new technology continues to be developed. Second, a significant number of mycobacteriology laboratories only identify *M. tuberculosis* and do not use biochemical tests to identify additional species of mycobacteria. Last, professional standards and at least one accreditation organization already recommend or require a negative control in addition to a positive control for each identification test; therefore, the increase in the requirement will not impact laboratories already meeting these standards. Since sufficient data are not available to quantify these considerations, we estimate a maximum of 35.4 percent of mycobacteriology laboratories will have to perform additional QC for conventional biochemical tests.

Mycology

We are reducing the QC testing for the germ tube test by eliminating the positive control each week of use after initial testing of positive and negative controls with every batch, lot number, and shipment. We are also reducing the QC testing for lactophenol cotton blue from checking this stain for intended reactivity each day of use, to requiring QC testing only with each batch, lot number, and shipment. We do not expect the QC changes to affect all 18,117 laboratories performing mycology testing (17,784 mycology laboratories in the CMS OSCAR (2001) database and 333 mycology laboratories in exempt States), since the impact of decreasing the QC testing will differ among laboratories depending on the testing performed and the numbers of positive cultures obtained by these laboratories. For both the germ tube test and the lactophenol cotton blue stain, we conservatively estimate that the reduction in QC testing will affect 50 percent of the total laboratories (9,059), those being hospital and independent laboratories that would perform the high complexity culture procedures that require the use of these reagents.