

performing bacteriology testing to be \$2,274 the first year. By multiplying this number by the total number of bacteriology laboratories (27,443), we estimate the total savings for bacteriology laboratories to be \$62.4 million the first year and the overall savings over the next 5 years to be approximately \$273.7 million for bacteriology.

For mycology, we estimate the total cost savings the first year per laboratory will be \$153, and the change will affect 9,059 mycology laboratories with total savings of \$1.4 million. We estimate overall savings will be \$6.1 million for the next 5 years.

Although the increase in QC requirements for mycobacteriology will result in increased costs for microbiology laboratories conducting this testing, the impact will not affect all laboratories to the same extent, as previously explained. In fact, laboratories previously following professional standards of practice for mycobacteriology will not be impacted at all by these QC changes. Mycobacteriology laboratories will likely incur increased QC costs for acid-fast and/or fluorochrome stains, an estimated maximum increase of \$1,501 per laboratory the first year, and \$4.8 million overall, assuming laboratories use both methods of staining, and did not previously test controls each time of use. Since only 35.4 percent of mycobacteriology laboratories perform organism identification, the impact of increasing the QC requirements for certain identification tests will affect significantly fewer laboratories. We calculated this increase to cost \$2,752 per laboratory the first year, with a maximum cost of \$3.1 million overall. However, as explained previously in the Mycobacteriology subsection of the Methodology section, we believe this cost impact is overestimated for the increased QC for biochemical identification tests. Evidence shows that with newer technology, fewer laboratories use the older conventional tests, and this is expected to further decrease as technology continues to improve. In addition, laboratories offering limited services may not use as many biochemical identification tests if they only identify a limited number of organisms. Last, since professional standards and an accreditation organization already recommend or require negative control organisms, many laboratories may already be including the controls we are now requiring in this regulation. Therefore, the combined annual estimate of increased QC costs for mycobacteriology laboratories of \$7.9 million overall and

the next 5 year estimate of \$34.6 million are likely inflated to some degree.

To summarize, the total savings in QC testing costs that will result from the changes in the microbiology requirements is the sum of the savings in the subspecialties of bacteriology and mycology, minus the cost increases in the subspecialty of mycobacteriology, a minimum total cost savings for microbiology laboratories of \$55.9 million the first year. The savings projected over the next 5 years are approximately \$245.2 million.

Alternative Approaches

For bacteriology and mycology, one alternative approach would be to continue to require QC testing for all reagents at the same frequencies as specified in the February 1992 regulations. However, there are no data that support continuing these frequencies to ensure the quality of patient testing. We believe if the previous frequencies were maintained, the total financial costs in labor and materials would far exceed the possible benefits in detecting problems with reagents. Another approach we considered is QC testing less frequently than with every batch, lot number and shipment of reagents (catalase, coagulase, beta-lactamase, oxidase, and germ tube test), disks and strips (bacitracin, optochin, ONPG, X, V, and XV), stains (lactophenol cotton blue), and antisera. However, because damage or improper handling of each batch, lot, or shipment can result in compromised reagent integrity, we did not consider this to be acceptable. We also considered leaving the requirement for monthly testing of antisera in place, but since there are no data to support this frequency, and the ASM data showed the reagents are relatively stable, we considered QC testing every 6 months adequate for these relatively expensive reagents with extended shelf lives.

For mycobacteriology, we considered not requiring a negative control with daily use of identification reagents, and not requiring QC daily for acid-fast stains, and each time of use for fluorochrome stains. However, the expense of increasing these requirements is relatively small because so few laboratories are impacted and in practice the incremental impact of adding a second control is relatively small. We cannot quantify the impact on error rates of not implementing these changes, but false positive tests in mycobacteriology can result in considerable extra expense in patient care.

b. Changes in Required QC Frequency for Syphilis Serology, Immunology, and Hematology

Syphilis Serology

We estimated that the reduction in frequency for syphilis serology QC testing may affect 7,634 laboratories (Certificate of Compliance (3,068), Certificate of Accreditation (4,070), and State-exempt (496)) (OSCAR, 2001 and the States of New York and Washington). Laboratories will be required to run controls each day patient specimens are tested, rather than each time they are tested. For laboratories testing patient specimens more than once a day, this change will result in a cost savings. However, we cannot estimate the amount of savings, because we do not know how many of these laboratories conduct testing more than once per day.

Immunology

There are a total of 20,665 laboratories (Certificate of Compliance (9,728), Certificate of Accreditation (10,285), and State-exempt (652)) performing immunology testing that may be affected by the reduction in the frequency for immunology QC testing. Under this final rule, laboratories must perform control procedures each day of testing, rather than concurrent with each testing event. We do not know how many of these laboratories test patient specimens more than once per day for each immunology procedure; therefore, we cannot estimate the cost savings if control procedures are performed less frequently. However, these provisions for the frequency of control testing do not supercede manufacturers' instructions or laboratory specifications that may require control testing more frequently; for example, each time patient specimens are tested.

Hematology

For hematology, we are reducing the required frequency for control testing from once each 8 hours of operation to once each day of testing. There are a total of 32,753 laboratories (Certificate of Compliance (16,332), Certificate of Accreditation (15,477), and State-exempt (944)) that perform hematology testing to which this change may apply. We do not know the exact number of laboratories that this change will affect because this change will only impact laboratories performing testing longer than 8 hours per day. However, we expect it will affect most hospital laboratories and many independent laboratories, since the majority of hospitals and independent laboratories operate 24 hours per day. For these