

- When each batch (prepared in-house), lot number (commercially prepared), and shipment of antisera is prepared or opened and once every 6 months thereafter.

In paragraph (b), for antimicrobial susceptibility tests, the laboratory must check each batch of media, lot number, and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved reference organisms and, each day tests are performed, the appropriate control organisms must be used to check the procedure.

#### *Former Burden*

In the former regulation, laboratories had to check catalase, coagulase, beta-lactamase, and oxidase reagents using a positive and negative control material each day of use. In addition, the laboratories had to check bacitracin, optochin, ONPG, XV, X, and V disks or strips using a positive and negative control material each week of use. We estimate that most bacteriology laboratories operate an average of 6 days per week; therefore, we allowed an average of 2.5 minutes per day to document the results of control testing for the reagents listed above. This resulted in the former burden, 2.5 min./day  $\times$  24 days/month = 60 min./month = 1 hr./month 1 hr./month  $\times$  12 months/year = 12 hrs./laboratory/yr.

Under the former regulation, the estimated burden for documenting control testing for the reagents above was 27,443 bacteriology laboratories  $\times$  12 hrs./yr. = 329,316 hrs./yr.

#### *Change in Burden*

In this final rule, we are allowing laboratories to check each batch, lot number and shipment of reagents (catalase, coagulase, and oxidase), disks (bacitracin, optochin, ONPG, X, V, and XV), stains, antisera, and identification systems for positive and negative reactivity, and graded reactivity if applicable. For purposes of calculating the burden, we are assuming that laboratories receive a new shipment of reagents on the average of once per month. Since the burden with documenting control testing for susceptibility tests remain the same, we are considering the burden for documenting control testing for this subspecialty to be reduced by 2.5 min./day  $\times$  23 days/month = 57.5 min./month = 0.96 hrs./month 0.96 hrs./month  $\times$  12 months/yr. = 11.5 hours/ laboratory/yr.

The total estimated reduction in burden for this requirement is 27,443 bacteriology laboratories  $\times$  11.5 hrs./yr. = 315,595 hrs./yr.

#### *Burden in This Final Rule*

The estimated burden for documenting control testing for bacteriology reagents under this final rule is 329,316 hrs./yr.—315,595 hrs./yr. = 13,721 hrs./yr.

Section 493.1262 Standard: Mycobacteriology

For the subspecialty of mycobacteriology, in this final rule at paragraph (a), each day of use, the laboratory must check all reagents or test procedures used for mycobacteria identification with at least one acid-fast organism that produces a positive reaction and with an acid-fast organism that produces a negative reaction.

#### *Former Burden*

In the former regulation, we included the requirements to document the results of control testing with the general QC procedures. However, since these documentation requirements are now under the condition, Analytic systems at § 493.1250, we have removed these documentation requirements from the general QC procedures and placed them in the subspecialty of mycobacteriology at § 493.1262.

In the former regulation, the laboratory was required, each day of use, to check all reagents or test procedures for mycobacteria identification with an acid-fast positive control organism (except the iron uptake test, which also requires a negative control). Assuming that only 35.4 percent (see section VII of this final rule, Regulatory Impact Analysis) of mycobacteriology laboratories perform identification procedures, and test an average of twice weekly, the former burden for documenting the positive control reaction for mycobacteria identification reagents and tests can be estimated as 2 min./day  $\times$  8 days/month = 16 min./month = 0.27 hrs./month  $\times$  12 months/yr. = 3.24 hrs./laboratory/yr.

The total estimated burden for documenting the positive control result is 1,127 mycobacteriology laboratories  $\times$  3.24 hrs./yr. = 3,651 hrs./yr.

As mentioned previously, the former regulation also required that the laboratory check positive and negative control materials for fluorochrome acid-fast stains each week of use and check a positive control material for other acid-fast stains each week of use. The former burden for all mycobacteriology laboratories to document these control results is estimated as 1 min./day  $\times$  4 days/month = 4 min./month  $\times$  12 months/yr. = 48 min./laboratory/yr. = 0.8 hrs./laboratory/yr.

The total estimated burden for documenting control testing for acid-fast

and fluorochrome acid-fast stains is 3,185 mycobacteriology laboratories  $\times$  0.8 hrs./yr. = 2,548 hrs./yr.

The former total burden for documenting control testing for mycobacteria identification reagents and tests, and acid-fast, and fluorochrome acid-fast stains was 3,651 hrs./year + 2,548 hrs./year = 6,199 hrs./yr.

#### *Change in Burden*

Since documentation of the positive control reaction was previously required for mycobacteria identification reagents and tests and the number of laboratories performing mycobacteriology remains constant, we also estimated the increase in burden for documenting the negative control material for identification reagents and tests to be one-half the previous burden, which is  $\frac{1}{2}$  of 3,651 hrs./yr. (from above) = 1,826 hrs./yr.

The change in burden for increasing the frequency of acid-fast and fluorochrome acid-fast stains to daily and adding a negative acid-fast stain result is calculated as 1.5 min./day  $\times$  26 days/month = 39 min./month = 0.65 hrs./month  $\times$  12 months/yr. = 7.8 hrs./laboratory/yr.

The total increase in burden for these documentation requirements for acid-fast and fluorochrome acid-fast stains is 3,185 laboratories  $\times$  7.8 hrs./yr. = 24,843 hrs./yr.

The total increase in burden for documenting control testing for mycobacteria identification reagents and tests, acid-fast, and fluorochrome acid-fast stains is 1,826 hrs./yr. + 24,843 hrs./yr. = 26,669 hrs./yr.

#### *Burden in This Final Rule*

The total estimated burden under this final rule for documenting control testing for mycobacteria identification reagents and tests, acid-fast, and fluorochrome acid-fast stains is 6,199 hrs./yr. + 26,669 hrs./yr. = 32,868 hrs./yr.

Section 493.1263 Standard: Mycology

In the former regulation for mycology, each week of use, the laboratory was required to check all procedures for mycological identification (including germ tube test) using an organism that produces a positive reaction. Under this final rule, the requirement is eliminated. This deletion results in the QC requirements for the germ tube test to default to the general QC requirements at § 493.1256(e)(1). The general requirements specify QC testing with each new batch, lot number or shipment of reagents. Because this is a minimal decrease (we estimate the change in frequency from weekly to monthly) in burden for documenting the result of a