

procedures. Also, the laboratory must have documentation of the laboratory's performance of all activities specified in this section.

This is a 2-part requirement and will affect laboratories differently depending on whether they are verifying or establishing performance specifications for a test method. In addition, it only applies to new laboratories and new tests instituted in existing laboratories on and after April 24, 2003. Therefore, the number of laboratories needing to meet this requirement will be minimal. While this is a new requirement for some laboratories performing testing using unmodified, moderate complexity test systems approved or cleared by the FDA, it only applies to tests newly introduced into existing laboratories and to all tests in laboratories first established on or after April 24, 2003. In addition, it is common practice for test system manufacturers to perform or provide extensive assistance with this quality control activity when a laboratory buys or leases an instrument or other new test system. Thus, in practice, most of the burden for recording and documenting the quality control requirements are already born by the test system manufacturers. We do not believe that this burden will be shifted to the laboratory. Also, accrediting organizations and States with licensure programs, after which the CLIA requirements were modeled, have traditionally required laboratories to perform these activities. Therefore, while this information collection requirement is subject to the PRA, the burden is exempt as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement are incurred by persons in the normal course of their activities.

Section 493.1256 Control Procedures

These requirements were previously at § 493.1218 and approved under OMB approval number 0938-0612. The burden associated with these requirements involves the documentation of the control results and corrective action taken when control results do not meet the laboratory's acceptability criteria. Therefore, we are revising the paperwork requirements to some extent.

Under paragraph (d), the laboratory must do the following, as applicable:

- In paragraphs (d)(3)(i) and (ii), for each quantitative and qualitative procedure, include two control materials of different concentrations and a positive and negative control material, respectively.

There may be increased reporting for unmodified moderate complexity tests (formerly at § 493.1202(c)) whose manufacturer's instructions did not include these requirements. The burden for the remainder of the tests is captured for this requirement under OMB approval number 0938-0612.

- In paragraph (d)(3)(iii), for each semiquantitative procedure, include a negative control material and, as applicable, a control material with graded or titrated reactivity.

There will be an increase in paperwork burden for unmodified moderate complexity tests (formerly at § 493.1202(c)) whose manufacturer's instructions did not include this requirement and for tests not subject to the specialty requirements formerly at §§ 493.1239(b) or 493.1241(a). The burden for the remainder of these tests for this requirement is captured under OMB approval number 0938-0612.

- In paragraph (d)(3)(v), for each molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting inhibition.

There will be increased burden for recording the additional control results, when needed. The burden of recording the former control results is captured for this requirement under OMB approval number 0938-0612.

- In paragraph (d)(6), when a complete change of reagents is introduced, major preventive maintenance is performed, or any critical part that may influence test performance is replaced, the laboratory must, before resuming patient testing perform control material testing as specified under paragraph (d) of this section.

There will be an increase in burden for tests whose manufacturer's instructions did not include the requirements for control material testing specified under paragraph (d) of this section. The burden for the remainder of the tests is captured for this requirement under OMB approval number 0938-0612.

- Under paragraph (d)(10)(iii), when control materials providing quantitative results are used, statistical parameters for unassayed materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters.

There will be an increase in reporting for moderate complexity tests formerly subject to the phase-in at § 493.1202(c). The burden for the remainder of these tests is captured under OMB approval number 0938-0612.

In paragraph (e)(3), the laboratory must check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use. Therefore, reporting will increase from one to two control results in the subspecialty of histopathology for tests performed using immunohistochemical stains. For mycobacteriology, recording control results will increase from each week of use to each time of use for fluorochrome acid-fast stains. The burden of reporting one control result is captured for these requirements under OMB approval number 0938-0612.

Under the former OMB approval, we allotted 5 minutes per day for the reporting requirements in the former § 493.1218. This time allotment was based on the assumption that most of the previously unregulated laboratories were performing moderate complexity testing and ran a total of four QC samples daily. This time allotted included reporting for the burden associated with all the specialties and subspecialties; therefore, we believe the burden was slightly underestimated.

We are allotting 5 minutes per day to perform this documentation for the specialties and subspecialties (except bacteriology, mycobacteriology, hematology, and histopathology) and are adjusting this burden to reflect the number of laboratories currently affected by this rule. We are addressing the specialties and subspecialties of bacteriology, mycobacteriology, hematology, and histopathology separately. We are assuming laboratories are documenting control activities on an average of 6 days per week. Therefore, the burden for the specialties and subspecialties (except bacteriology, mycobacteriology, hematology and histopathology) can be calculated as 5 min./day × 24 days/month = 120 min./month = 2 hrs./month 2 hrs./month × 12 months/yr. = 24 hours/laboratory/yr. The total estimated burden for this requirement (now at § 493.1256) is 27,685 laboratories (total number of laboratories minus the number of waived laboratories, provider performed microscopy (PPM) laboratories, and previously regulated laboratories) × 24 hrs./yr. = 664,440 hrs./yr.

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Section 493.1261 Standard: Bacteriology

For the subspecialty of bacteriology, in this final rule at paragraph (a), the laboratory must check the following for positive and negative reactivity using control organisms:

- Each day of use for beta-lactamase methods other than Cefinase™.
- Each week of use for Gram stains.