Supporting Statement for the Information Collection Requirements (ICR)
Contained in the Clinical Laboratory Improvement Amendments (CLIA) Regulations
(OMB Control number: 0938-0612; CMS-R-26)

A. Background

This is a revision package. The Clinical Laboratory Improvement Amendments of 1988 (CLIA) section 353 of the Public Health Service Act requires the Department of Health and Human Services (HHS) to establish certification requirements for any entity, with certain exceptions contained in the regulation, that performs testing on human beings to meet performance requirements based on test complexity and risk factors related to erroneous test results in order to be certified by HHS.

This information collection reflects a series of records required to be maintained by laboratories participating in the CLIA program and are based upon the publication of a final quality assessment rule on January 24, 2003, and the publication of the final fee, histocompatibility, personnel, and alternative sanction rule on December 28, 2023 (88 FR 89976). Included in the revisions are amendments to the histocompatibility and personnel regulations under CLIA to address obsolete regulations and update the regulations to incorporate technological changes, which are reflected in this revision package.

This is a revision of the information collection. Based on notice of proposed rulemaking, CMS-3478-P (91 FR 64480) published on October 8, 2026, we are revising the ICR. There are no collection instruments.

CMS and CDC incorporated changes in this proposed rulemaking to update the CLIA regulations to advance technology innovation and reduce undue burdens on laboratories. These sections include virtual access (493.2, 493.43(a)(1), 493.55(a)(3), 493.1101(e), 493.1105(a)-(b)(7), 493.1231(a), 493.1251(b)(2), 493.1256(a), 493.1283(a)(5), and 493.1291(a)(2)), gynecologic cytology proficiency testing (493.855(a)-(b) and 493.945(a)-(b)), personnel qualification requirements (493.2, 493.1273(c), 493.1359(c)-(d), 493.1405(b), 493.1407(c), 493.1411(b), 493.1417(b)-(c), 493.1423(b), 493.1443(b), 493.1445(c), 493.1449(c), 493.1449(f), 493.1449(i), 493.1455(a)-(c), 493.1461(c), 493.1461(e), 493.1463(a)-(c), 493.1489(b), and 493.1495(b)-(c)), and other changes (493.2, 493.35(b)(3), 493.39(b), 493.41, 493.43(b)(3), 493.45(b)(2), 493.51(a), 493.53(b), 493.55(b)(3), 493.57(a)(2), and 493.63(a), 493.555(c)(6), 493.801(b), 493.807(a)-(b), 493.931(b)-(c), 493.933 (b)-(c), 493.1100(a)-(b), and 493.1291(c)(2)). Laboratories may need to revise and update policies and procedures applicable to new or amended requirements as follows.

1. Virtual Access Sections (493.2, 493.43(a)(1), 493.55(a)(3), 493.1101(e), 493.1105(a)-(b), 493.1231(a), 493.1251(b)(2), 493.1256(a), 493.1283(a)(5), and 493.1291(a)(2)):

The CLIA regulations at 42 CFR §§ 493.35(a), 493.43(a), and 493.55(a)(2) require laboratories to file a separate application for each laboratory location unless it meets a regulatory exception. Additionally, the CLIA statute and regulations for cytology state that cytology slide preparations must be evaluated on the premises of a laboratory certified to conduct testing in the subspecialty of cytology (42 U.S.C § 263a(f)(4)(B)(vi), 42 CFR § 493.1274(a)). CMS exercised enforcement discretion to ensure laboratories were able to review data, results, and pathology slides/images remotely during the PHE. On May 11, 2023, at the end of the PHE, CMS issued memo QSO-23-15-CLIA [1] titled Clinical Laboratory Improvement Amendments of 1988 (CLIA) Post-PHE Guidance that continued the enforcement discretion to allow staff to remotely review digital laboratory data, digital results, and digital images. On 09/23/2025, CMS revised QSO-23-15-CLIA to end the temporary enforcement discretion for the subspecialty of cytology. The pathology community has expressed its desire to make this enforcement discretion a permanent provision. CMS is proposing to codify this enforcement discretion and update applicable CLIA regulations for virtual access.

2. Gynecologic Cytology Proficiency Testing Sections (493.855(a)-(b) and 493.945(a)-(b)):

1 QSO-23-15-CLIA, https://www.cms.gov/files/document/qso-23-15-clia.pdf.

Current gynecologic cytology proficiency testing regulations at 42 C.F.R. § 493.945 specify glass slides for testing. In 2024, FDA approved the first digital cytology screening system. Proficiency testing is designed to be performed in the same manner as patient specimens to ensure quality and accurate results. Therefore, CMS proposes to add digital images to the cytology proficiency testing programs to allow for technological advancements and to align with the manner in which patient specimens are tested.

3. Personnel Updates Sections (493.2, 493.1273(c), 493.1359(c)-(d), 493.1405(b), 493.1407(c), 493.1411(b), 493.1417(b)-(c), 493.1423(b), 493.1443(b), 493.1445(c), 493.1449(c), 493.1449(f), 493.1449(i), 493.1455(a)-(c), 493.1461(c), 493.1461(e), 493.1463(a)-(c), 493.1489(b), and 493.1495(b)-(c)):

On December 28, 2023, the "Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories" final rule (88 FR 89976), which updated 42 C.F.R. part 493, subpart M's requirements related to personnel qualifications and responsibilities, appeared in the *Federal Register*. Since the December 28, 2024, effective date of the updated personnel regulations, CMS has received substantial feedback from interested parties about the revised personnel qualification requirements. After consideration of this feedback, CMS proposes standardizing laboratory director requirements to require one year of experience directing or supervising laboratory testing or 20 CE credit hours in laboratory practice that cover the laboratory director responsibilities regardless of education background. CMS proposes removing certain definitions and language that limit background, education, experience, and training to human-only. Based on feedback from interested parties, CMS proposes to add two new regulations for testing personnel that may perform histopathology grossing and Mohs dermatology laboratory directors who perform testing in dermatopathology laboratory science. In addition, CMS proposes correcting cross-references, and other minor non-substantive errors found by stakeholders.

4.Other Changes Sections (493.2, 493.35(b), 493.39(b), 493.41, 493.43(b)(3), 493.45(b)(2), 493.51(a), 493.53(b), 493.55(b)(3), 493.57(a)(2), 493.63(a), 493.555(c)(6), 493.801(b), 493.807(a)-(b), 493.931(b)-(c), 493.933(b)-(c), 493.1100(a)-(b), and 493.1291(c)(2)):

The other changes in this proposed rule fall into six main categories: editorial changes, SARS-CoV-2 reporting, certificate notification requirements, test report requirements, enforcement changes, and public consultation. The regulations contain errors in spelling, cross-references, and other minor non-substantive issues. CMS proposes to correct these issues to ensure the regulations are accurate. SARS-CoV-2 reporting was required for laboratories during the COVID-19 PHE. The COVID-19 PHE terminated on May 11, 2023, along with the reporting requirements in the CLIA regulations. CMS proposes to remove these reporting requirements specific to SARS-CoV-2. CMS transitioned all laboratories to electronic notifications on March 1, 2026, to increase efficiency and reduce spending. CMS proposes to require laboratories to notify CMS if their email address has changed, similar to the requirement for addressing changes. CMS proposes to require the CLIA number and laboratory name from the CLIA certificate on test reports to reduce fraud. CMS is proposing to update enforcement regulations to reduce burden. The CLIA statute states that the Secretary shall consult with appropriate private organizations and public agencies in carrying out this section (42 U.S.C. § 263a(q)). In addition, the CLIA regulations state that HHS will establish a Clinical Laboratory Improvement Advisory Committee (CLIAC) (42 C.F.R. § 493.2001(a)). The CDC was directed to inactivate CLIAC by the Secretary on March 31, 2025. CMS proposes revising the regulations at 42 C.F.R. § 493.2001(a) to align with this directive and to provide that a CLIAC "may" be established and used, rather than requiring its use. CLIAC is not specifically required by statute.

B. Justification

1. Need and Legal Basis

The information required is necessary to determine an entity's compliance with the Congressionally-

mandated program with respect to the regulation of laboratory testing (CLIA). In addition, laboratories participating in the Medicare program must comply with CLIA requirements as required by section 6141 of OBRA 89. Medicaid, under the authority of section 1902(a)(9)(C) of the Social Security Act, pays for services furnished only by laboratories that meet Medicare (CLIA) requirements.

Legislative authority for these requirements and the supporting regulations is found in Section 353 of the Public Health Service Act.

2. Information Users

The information required is used by the Centers for Medicare and Medicaid Services (CMS) or its designee, such as a CMS agent or CMS approved laboratory accreditation organization, when conducting inspections in order to determine a laboratory's compliance with the CLIA requirements. Laboratory compliance is assessed every 2 years with an on-site inspection. During an on-site survey, each Condition-level laboratory requirement under Part 493 is assessed for compliance. The information is also used by HHS in determining appropriateness of test classifications. Test classifications within the CLIA program consist of Waived, Moderate and High Complexity. Test complexity determines certain compliance requirements that a CLIA certified laboratory must follow.

3. Improved Information Technology

This regulation does not prescribe how the facility should prepare or maintain necessary records. Facilities are free to take advantage of any technological advances that they find appropriate for their needs.

4. Duplication of Similar Information

These requirements do not duplicate any current information collection. They contain information required by the statute which supersedes any previous requirements.

5. Small Businesses

These requirements impact small businesses that are operating as laboratories regulated under CLIA. However, the general nature of the requirements allows flexibility for facilities to meet the requirements in a way consistent with their existing operations.

6. Less Frequent Collection

The laboratory must maintain these records on an ongoing basis in order to maintain its CLIA certification and approval to participate in the Medicare or Medicaid programs.

7. Special Circumstances

There are no special circumstances associated with this collection.

8. Federal Register Notice/Outside Consultation

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) Virtual Access, Gynecologic Cytology Proficiency Testing (PT), Personnel Updates, and Other Changes proposed rule was published in the Federal Register on October 8, 2026 (91 FR 64480).

9. Payment/Gift To Respondent

There is no payment or gift to respondents. A laboratory must have a current CLIA certificate and in good standing to receive Medicare reimbursement.

10. Confidentiality

We make no pledges of confidentiality.

11. Sensitive Questions

There are no questions of a sensitive nature.

12. Burden Estimate

Sections 493.35 - 493.63, Notification and certification requirements.

The burden attributed to these sections is addressed in another collection, 0938-0581.

Sections 493.551-493.557, Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program.

The burden attributed to these sections is addressed in another collection, 0938-0686.

Section 493.801, Condition; Enrollment in proficiency testing (PT).

Under CLIA, laboratories must enroll and participate successfully in PT for the tests specified in the regulation as required analytes and for which approved PT is available. Laboratories must analyze five challenges, for each test they perform, in three PT events per year. We estimate that **33,955** laboratories are currently affected by this requirement and that each laboratory has a burden of approximately 6 hours/year. We determined the number of laboratories subject to this requirement by taking the total number of laboratories, CLIA certified plus exempt (**307,038**), and subtracting the waived and provider-performed microscopy (PPM) laboratories (**273,083**). The wage rate data is from https://www.bls.gov/ooh/healthcare/clinical-laboratory-technologists-and-technicians.htm.

33,955 x 6 hours/year = **203,730** hours/yr.
6 hours x $29.75 x **33,955** laboratories = $**6,060,968**

The CLIA proficiency testing regulations were modified by CMS-3355-F, and laboratories are required to detect and identify microbiology organisms to the highest level performed on patient specimens. We estimate that the number of laboratories that were not currently reporting microbiology organisms to the highest level that they report results on patient specimens to be about 10 percent of laboratories with a specialty in microbiology (13,265), which is 1,327. We estimate it would take 20 minutes for a laboratory to fill in this information on the PT submission form. The PT submission form is developed and supplied to the laboratories by the PT programs and is not a CMS form. Each laboratory would report this information 3 times a year, which would take approximately 1 hour in total. The total annual burden is 1,327 hours (1,327 laboratories X 1 hour). Clinical Laboratory Technologists/Technicians (29-2010) would perform this task at an hourly wage of $29.75 as published in 2024 by the Bureau of Labor Statistics (https://data.bls.gov/oes/#/industry/000000). The wage rate would be $59.50, including overhead and fringe benefits. The total cost would be $78,957 (1,327 hours X $59.50).

1,327 x 1 hours/year = **1,327** hours/yr.
1 hour x $59.50 x **1,327** laboratories = $**78,957**

If this proposed rule (CMS-3478-P) is finalized, we expect approximately 3,229 CLIA certified laboratories performing testing in the subspecialty of cytology to be affected. We are able to determine how many laboratories have adopted digital imaging for screening as the primary method of patient testing. We estimate the number of laboratories to be about 25 percent of 3,229 laboratories, which is 807 laboratories. We estimate it would take 0.5 hours for a laboratory to fill in this information on the PT submission form. A management-level employee (11-9111) would perform this task at an hourly wage of $56.71 per hour, as published by the 2024 Bureau of Labor Statistics. The wage rate would be $113.42, to include overhead and fringe benefits. The total cost would be $45,765 (807 × 0.5 hours × $113.42).

807 x 0.5 hours/year = 404 hours/yr.
0.5 hours x $113.42 per hour x **807** laboratories = $**45,765**

Section 483.803, Condition; Successful participation.

Each laboratory performing testing for analytes listed in Subpart I is required to enroll with an approved PT program and must document the receipt and handling of the PT samples and reporting of results. We estimate that **33,955** laboratories are affected by this requirement and that each laboratory has a burden of approximately 3 hours/year.

33,955 x 3 hours/year = **101,865** hours/year

3 hours x $29.75 per hour x **33,955** laboratories = $**3,030,484**

Section 493.1299 Standard: Postanalytic systems assessment.

Under this section, the laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the postanalytic systems specified in §493.1291 and must document all postanalytic systems assessment activities.

This burden reflects the current number of laboratories that need to meet these requirements. Each laboratory must develop and implement assessment systems that address all the criteria in the total testing process. This process includes documenting problems identified during the laboratory's quality assessment review, and the corrective actions taken to resolve the problems identified and to prevent their recurrence.

The burden for documenting the written policies and procedures applies only to new laboratories entering the CLIA program each year.

Depending on the size and volume of testing of the laboratory, we assume a one-time burden of 8-24 hours, or an average burden of 16 hours, for the laboratory to develop its written policies and procedures. We assume that 1000 new laboratories will enter the CLIA program each year. Approximately 51% will request a certificate of waiver, therefore, only 490 new laboratories will need to develop an assessment process.

490 laboratories x 16 hours = **7,840** hours/year
16 hours x $29.75 x **490** laboratories = $233,240

The ongoing burden for laboratories involves evaluating data to determine if there are problems, documenting the problems identified, taking corrective actions, and revising policies based on the evaluations, as necessary. A smaller laboratory, such as a physician's office laboratory (POL) or a laboratory that only performs PPM tests, that is directly involved in the patient's care, may use patient outcomes to evaluate its testing process. We assume that it takes a laboratory approximately 2-10 hours once a month, depending on the size and volume of testing, to evaluate the data and document these evaluations. We are estimating the burden for this requirement based on the concept that it will take a POL or a PPM laboratory from 2 to 4 hours once a month and a hospital or independent laboratory from 6 to 10 hours once a month to meet this requirement. We determined the number of POLs and PPM laboratories by using the number of POLs and the number of PPM laboratories in the CMS database and adding a proportionate number of the same categories from the exempt laboratories.

Therefore, the burden for a POL or a PPM laboratory for this requirement is:

2-4, or an average of 3 hours x 12 months = 36 hours/year
46,618 POL, PPM, and "other" laboratories x 36 hours/year = **1,678,248** hours/year
36 hours x $29.75 x **46,618** POL, PPM, and "other" laboratories = $**49,927,878**

We determined the number of hospital and independent laboratories based on how laboratories classified themselves on the CLIA application. This includes exempt laboratories.

6-10, or an average of 8 hours x 12 months = 96 hours/year
11,775 hospital and independent laboratories x 96 hours/year = **1,130,400** hours/year
96 hours x $29.75 x **11,775** hospital and independent laboratories = $**33,629,400**

We also assume that it takes approximately 0.5 - 2 hours, or an average of 1.25 hours, for the non-waived laboratory (CoC, CoA, or PPM certified laboratory) to revise its policies based on its quality assessment evaluations. This burden can be calculated as:

1.25 hours x 12 months = 15 hours/laboratory/year
58,396 laboratories x 15 hours/year = **875,940** hours/year
15 hours x $29.75 x **58,396** laboratories = $**26,059,215**

Section 493.1242, Standard: Specimen submission, handling and referral.

Under this section, the laboratory must establish and follow written policies and procedures for specified procedures.

The laboratory must document the date and time it receives a specimen.

If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraph (a) of this section.

The burden reflects the current number of laboratories that need to meet these requirements.

We assume that it takes a laboratory approximately 6 hours to write its procedures for specimen submission and handling. We also determined that this is a one-time burden to the laboratory.

We estimate that approximately 1000 laboratories may enter the CLIA program in a given year. Of these, approximately 51% will be waived.

Therefore, the initial burden to a non-waived laboratories is:

490 non-waived laboratories x 6 hours = **2,940** hours

6 hours x $29.75 x 490 non-waived laboratories = $87,465

We also estimate that approximately 65% of the non-waived laboratories (CoC, CoA, and PPM certified laboratories) will decide to include new tests in a given year. This estimate would apply to all non-waived laboratories. New procedures would be required for these new tests. We assume that it would take 0.5 hour to write the procedures for one test. There is no way to determine how many tests a laboratory may choose to add to its test menu.

However, if the laboratories include at least one new test per year, the burden is:

58,396 non-waived laboratories x 65% = **37,957** laboratories

37,957 laboratories x 0.5 hours = **18,979** hours/year

0.5 hours x $29.75 x **37,957** laboratories = $**564,610**

Section 493.1251, Standard: Procedure manual.

Under this section, a written procedure manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. The procedure manual must include specified information when applicable. The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in §493.1105(a)(2).

The burden reflects current CLIA certification. The preparation of a procedure manual is a one-time burden for laboratories. We allow a laboratory to use the manufacturer's package insert and instrument manuals to assist in the development of its procedure manual. Laboratories currently registered in the CLIA program are covered under the initial burden estimate for this requirement.

We assume that 1000 laboratories may enter the CLIA program in a given year, and that 51% of these will be laboratories with a certificate of waiver. The initial burden for preparing the procedure manual for these non-waived laboratories includes evaluating written instructions and assembling procedure protocols. We estimate that this task takes 6 hours.

The one-time burden for new laboratories is:

490 non-waived laboratories x 6 hours = **2,940** hours/laboratory

6 hours x $29.75 x 490 = $**87,465**

The laboratory must update its procedure manual when changes are made in test procedures. We allow the laboratory to use the manufacturer's protocols when developing its procedure manual. Therefore, we estimate that it would take approximately one hour to update the procedure manual for new tests. We assume that approximately 65% of the non-waived laboratories (CoC, CoA, and PPM certified laboratories) will make some changes in their test menus in a given year and that this requirement affects non-waived laboratories. The estimated burden for this requirement is:

58,396 non-waived laboratories x 65% = **37,957** laboratories x 1 hour/year = **37,957** hours/year

1 hour x $29.75 x **37,957** laboratories = $**1,129,221**

Testing procedures must be reapproved, signed and dated if there is a change in laboratory director. Lab Director Salary is determined by search under physician at https://www.bls.gov/ooh/healthcare/physicians-and-surgeons.htm

We estimate that approximately 2% of the laboratories may change directors in a given year. We assume that it would take an average of 1 hour for the director to review all testing procedures in the laboratory.

Therefore, the burden for this requirement is:

58,396 non-waived laboratories x 2% = **1,168** laboratories x 1 hour/year = **1,168** hours/year
1 hour x $115 x 1,168 non-waived laboratories = $**134,320**

Section 493.1252, Standard: Test systems, equipment, instrumentation, reagents, materials, and supplies.

Under this section, the laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. These conditions must be monitored and documented and, if applicable, include specified information. Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate specified information.

We are calculating this burden to address the laboratories currently affected and assume that all non-waived laboratories are affected. We assume that an average time to perform this documentation to be one hour/month.

The ongoing burden for laboratories for this burden is:
1 hour/month x 12 months/year = **12** hours/laboratory/year

The total estimated burden for this requirement is:
58,396 non-waived laboratories x 12 hours/year = **700,752** hours/year
12 hours x $29.75 x **58,396** non-waived laboratories = $**20,847,372**

Section 493.1254, Standard: Equipment maintenance and function checks.

For unmodified manufacturer's equipment, instruments, or test systems and for equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must perform and document the maintenance activities specified.

The burden for the documentation of the maintenance and function checks performed for the current number of CLIA laboratories affected can be calculated as:

5 minutes/day x 20 days/month = 100 minutes/month or 1.7 hours/month
1.7 hours/month x 12 months/year = 20 hours/year x **58,396** non-waived laboratories = **1,167,920** hours/year.
20 hours x $29.75 x **58,396** non-waived laboratories = $**34,745,620**

Section 493.1255, Standard: Calibration and calibration verification procedures.

Under this section, the laboratory must perform and document the calibration activities specified and perform and document the calibration verification activities specified according to the manufacturer's instructions, at a minimum. Laboratories have the option to develop a more frequent schedule for calibration. The burden associated with these requirements may differ widely due to variation in the complexity of test systems. We are estimating a range of hours from 5 to 15, with an average of 10 hours/year.

33,955 non-waived laboratories x 10 hours/year = **339,550** hours/year.
10 hours x $29.75 x **33,955** non-waived laboratories = $**10,101,613**

Section 493.1256, Standard: Control procedures.

The burden associated with this requirement involves the documentation of the control results and corrective action taken when control results do not meet the laboratory's performance specifications. Under the current OMB approval, we allotted 5 minutes per day for these reporting requirements. 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 4 quality control samples daily. This time allotted included the reporting for the burden

associated with all the specialties and subspecialties and we believe the burden was slightly underestimated. We are allowing 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. We are addressing the specialties and subspecialties of bacteriology, mycobacteriology, hematology and histopathology separately. Daily or weekly controls must be recorded regardless of whether the controls are an internal system check or a traditional check. 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, mycology, hematology and histopathology) can be calculated as:

5 minutes/day x 24 days/month = 120 min/month = 2 hours/month
2 hours/month x 12 months/year = 24 hours/ laboratory/year.

The total estimated burden for this requirement is:

16,960 laboratories (total number of laboratories minus the number of waived laboratories, PPM laboratories and previously regulated laboratories) x 24 hours/year = **407,040** hours/year.
24 hours x $29.75 x **16,960** laboratories = $**12,109,440**

If this proposed rule (CMS-3478-P) is finalized, we expect approximately 33,955 CLIA certified laboratories to be affected. Certificate of Compliance (CoC) = 16,960; Certificate of Accreditation (CoA) = 16,995 (Data from Quality, Certification and Oversight Reports (QCOR) as of August 4th, 2025). We expect approximately 40% of the 33,955 CoC and CoA laboratories to utilize virtual access (hospital, independent, industrial, public health, and pharmacy laboratories) and incur costs. The on-going burden for the approximate 13,582 laboratories involves quality control procedures that monitor the accuracy and precision of the complete analytic process including testing performed via virtual access. We estimate this burden to be 2.4 hours per year. A management-level employee (11-9111) would perform this task at an hourly wage of $56.71 per hour as published by the 2024 Bureau of Labor Statistics.[2] The wage rate would be $113.42 to include overhead and fringe benefits. Total cost would be approximately $**3,697,129** (13,582 × 2.4 ×113.42).

0.5 minutes/day x 24 days/month = 12 minutes /month
12 minutes /month x 12 months/year = 2.4 hours/ laboratory/year.

The total estimated burden for this requirement is:

13,582 laboratories x 2.4 hours/year = **32,597** hours/year.
2.4 hours x $113.42 x **13,582** laboratories= $**3,697,129**

§493.1261 Standard: Bacteriology.

For the subspecialty of bacteriology, 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.
- 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.

The information collection requirement is under paragraph (c), which requires that the laboratory document all control procedures performed, as specified in the section.

Total Estimated Burden: Laboratories have 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; therefore, we allow an average of 2.5 minutes per day to document the results of control testing for the

2 https://data.bls.gov/oesprofile/

reagents listed above. This results in a burden of 2.5 minutes/day x 1 day/month = 2.5 minutes/month. 2.5 minutes/month x 12 months/year = 30 minutes/laboratory/year (or 0.5 hours/laboratory/year).

The estimated total burden for documenting control testing for the reagents above is **9,168** bacteriology laboratories x 0.5 hours/year = **4,584** hours/year.
0.5 hours x $29.75 x **9,168** = $**136,374**

§493.1262 Standard: Mycobacteriology.

Under this section, for 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 an acid-fast organism that produces a negative reaction. For antimycobacterial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimycobacterial agent(s) before, or concurrent with, initial use, using an appropriate control organism(s). The laboratory must document all control procedures performed, as specified in this section.

For the subspecialty of mycobacteriology, in the 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.

The laboratory is 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 of mycobacteriology laboratories perform identification procedures, and test an average of twice weekly, the burden for documenting the positive control reaction for mycobacteria identification reagents and tests can be estimated as 2 minutes/day x 8 days/month = 16 minutes/month = 0.27 hours/month x 12 months/year = 3.2 hours/laboratory/year.

The total estimated burden for documenting the positive control result is:
432 mycobacteriology laboratories x 3.2 hours/year = **1,382** hours/year.
3.2 hours x $29.75 x **432** = **$41,126**

As mentioned previously, the regulation also requires 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 burden for all mycobacteriology laboratories to document these control results is estimated as 1 minute/day x 4 days/month = 4 minutes/month x 12 months/year = 48 minutes/laboratory/year = 0.8 hours/laboratory/year.

The total estimated burden for documenting control testing for acid-fast and fluorochrome acid-fast stains is:

1,219 mycobacteriology laboratories x 0.8 hours/year = **975** hours/year.
0.8 hours x $29.75 x **1,219** mycobacteriology laboratories = $**29,012**

The total burden for documenting control testing for mycobacteria identification reagents and tests, and acid-fast, and fluorochrome acid-fast stains is **1,382** hours/year + **975** hours/year = **2,357** hours/year.

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 burden for documenting the negative control material for identification reagents and tests can be estimated as 1 minutes/day x 8 days/month = 8 minutes/month = 8 mins/month x 12 months/year = 1.6 hours/laboratory/year.

The total estimated burden for documenting the positive control result is:
432 mycobacteriology laboratories x 1.6 hours/year = **691** hours/year.
1.6 hours x $29.75 x **432** = $**20,563**

The 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 minutes/day x 26 days/month = 39 minutes/month = 0.65

hours/month x 12 months/year = 7.8 hours/laboratory/year.

The total burden for these documentation requirements for acid-fast and fluorochrome acid-fast stains is:

1,219 laboratories x 7.8 hours/year = **9,508** hours/year.

7.8 hours x $29.75 x **1,219** = $**282,869**

The total burden for documenting control testing for mycobacteria identification reagents and tests, acid-fast, and fluorochrome acid-fast stains is **691** hours/year + **9,508** hours/year = **10,199** hours/year.

Total Estimated Burden

The total estimated burden for documenting control testing for mycobacteria identification reagents and tests, acid-fast, and fluorochrome acid-fast stains is **2,357** hours/year + **10,199** hours/year = **12,556** hours/year.

§493.1263 Standard: Mycology.

The general requirements specify QC testing with each new batch, lot number or shipment of reagents. For purposes of calculating the burden we estimate that laboratories receive a new shipment of reagents on average of once per month. Therefore, we are considering the burden for this subspecialty to be the following amount:2.5 minutes x 12 times/year = 30minutes= 0.5 hours/year.

The total estimated burden for this requirement is:

8,643 mycology laboratories x 0.5 hours/year = **4,322** hours/year.

0.5 hours x $29.75 x **8,643** mycology laboratories = $**128,565**

Under current regulations, QC requirements for lactophenol cotton blue 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. For purposes of calculating the burden, we estimate that laboratories receive a new shipment of reagents on average of once per month.

Therefore, we are considering the burden for this subspecialty to be the following amount:

2 minutes x 12 times/year = 24 minutes= 0.4 hours

The total estimated burden for this requirement is:

8,643 mycology laboratories x 0.4 hours = **3,457** hours/year.

0.4 hours x $29.75 x **8,643** mycology laboratories = $102,852

§493.1269 Standard: Hematology.

Regulations for the specialty of hematology, include two levels of control materials each day of testing under §493.1256.

Burden: Hospital and Independent Laboratories

The total number of laboratories performing hematology testing is **18,849**. Of this total, **6,072** are hospitals, **2,199** are independent laboratories, **6,594** are POLs, **1,454** fall into a category of "other", and the remaining **2,530** represent various miscellaneous categories self-identified by the laboratory on their CLIA application.

Most hospitals and independent laboratories typically operate 24 hours per day for 30 days a month.

Therefore, the burden for these laboratories is:

1.5 minutes/day x 30 days/month = 45 minutes/month = 0.75 hours/month

0.75 hours/month x 12 = **9 hours/laboratory/year**.

8,271 hospital and independent laboratories x 9 hours/year = **74,439** hours/year.

9 hours x $29.75 x **8,271** hospital and independent laboratories = **$2,214,560**

Burden: POLs, Other, and Miscellaneous

POLs have operating hours that can range from 8 to 10 hours a day, 5 days a week (20 days a month). These laboratories are required to run control materials each day of testing. In estimating the burden for this category of laboratories, we include the POLs, the "other" category, and the remaining miscellaneous categories for a total of **10,578** laboratories.

Therefore, the burden for these laboratories is:

1.5 minutes/day x 20 days/month = 30 minutes/month = 0.5 hours/month
0.5 hours/month x 12 months/year = **6 hours/laboratory/year.**
10,578 laboratories x 6 hours/year = **63,468** hours/year.
6 hours x $29.75 x **10,578** laboratories = $**1,888,173**

The total estimated burden is **74,439** hours/year (hospital and independent laboratories) **+ 63,468** hours/year (total POLs, "other" and miscellaneous) = **137,907** hours/year.

§493.1273 Standard: Histopathology

We cannot estimate the laboratory burden because we do not know the number of laboratories that perform immunohistochemical stains or how often the staining is performed. Additionally, many of the laboratories performing immunohistochemical stains were already testing both a positive and negative control material, and some immunohistochemical stains can be checked for a negative reaction on the same slide that contains positive reactive cells. We expect this requirement only affects a limited number of laboratories, and the burden is small.

Section 493.1274, Standard: Cytology.

The requirements for this subspecialty and the burden associated with these requirements were first introduced in the March 14, 1990 regulations and were not new to previously regulated cytology laboratories. Most laboratory professionals express improvements in their laboratories due to these requirements and agree that the documentation enhances their quality assessment programs. Also, laboratory computerization and instrument automation are moving toward decreasing the burden in cytology laboratories. The wage rate for Cytotechnologist is found at https://www.onetonline.org/link/summary/29-2011.02.

We are estimating the burden associated with cytotechnologist workload recording as:

10 minutes/day x 20 days/month = 200 minutes/month = 3.3 hours/month/per cytotechnologist
3.3 hours/month x 12 months/year = 40 hours/year/cytotechnologist

The number of cytotechnologists per laboratory varies from many laboratories with 1 cytotechnologist to a few laboratories with as many as 50 cytotechnologists. We are estimating that an average laboratory would employ 5 cytotechnologists.

Therefore, the burden is:

3,229 laboratories x 5 cytotechnologists x 40 hours/year = **645,800** hours/year.
40 hours x 5 cytotechnologists = 200 hours
200 hours x $29.75 x **3,229** laboratories = $**19,212,550**

We are estimating the burden associated with establishing and reviewing each cytotechnologist's workload as:

10 minutes/6 months = 0.3 hours/year/per cytotechnologist
3,229 laboratories x 5 cytotechnologists x 0.3 hours/year/cytotechnologist = **4,844** hours/year.
0.3 hours x 5 cytotechnologist = 1.5 hours
1.5 hours x $29.75 x **3,229** laboratories = $**144,094**

We are estimating the burden associated with documenting the review of at least 10 percent of the negative and high risk cases as:

10 minutes/day x 20 days/month = 200 minutes/month = 3.3 hours/month
3.3 hours/month x 12 months/year = 40 hours/cytotechnologist/year

3,229 laboratories x 5 cytotechnologists x 40 hours/year = **645,800** hours/year.
40 hours x 5 cytotechnologists = 200 hours
200 hours x $29.75 x **3,229** laboratories = $**19,212,550**

We are estimating the burden associated with establishing and documenting an annual statistical evaluation as:

10 minutes/day x 20 days/month = 200 minutes/month = 3.3 hours/month
3.3 hours/month x 12 months/year = 40 hours/laboratory/year.
40 hours/year x **3,229** laboratories = **129,160** hours/year.
40 hours x $29.75 x **3,229** laboratories = $**3,842,510**

Some cytology laboratories that introduce new methods or instrumentation will have an increase in burden associated with the requirements at sections 493.1253, 493.1254 and 493.1255; however, we have included cytology laboratories in each section in the total number of laboratories affected by these requirements.

Section 493.1283(a)(5) Standard: Test records.

Under this section, a laboratory utilizing virtual access must record the identity of the person performing the test, the software version used if applicable, and the device. If this proposed rule (CMS-3478-P) is finalized, we expect approximately 33,955 CLIA certified laboratories to be affected. Certificate of Compliance (CoC) = 16,960; Certificate of Accreditation (CoA) = 16,995 (Data from Quality, Certification and Oversight Reports (QCOR) as of August 4th, 2025). We expect approximately 40% of the 33,955 CoC and CoA laboratories to utilize virtual access (hospital, independent, industrial, public health, and pharmacy laboratories) and incur costs. The on-going burden for the approximate 13,582 laboratories involves updating software with new personnel, software versions, and devices on an ongoing basis. We estimate this burden to be 0.6 hours per year. A management level employee (11-9111) would perform this task at an hourly wage of $56.71 per hour as published by the 2024 Bureau of Labor Statistics.[3] The wage rate would be $113.42 to include overhead and fringe benefits. Total cost would be approximately $**924,282** (13,582 × 0.6 ×113.42).

3 minutes/month x 12 months = 36 minutes/laboratory/year

The total estimated burden for this requirement is:

13,582 laboratories x 0.6 hours/year = **8,149** hours/year.
0.6 hours x $113.42 x **13,582** laboratories = $**924,282**

Section 493.1299 Standard: Postanalytic system quality assessment.

Under this section, the laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in § 493.1291 and must document all postanalytic systems assessment activities.

This burden reflects the current number of laboratories that need to meet these requirements. Each laboratory must develop and implement assessment systems that address all the criteria in the total testing process. This process includes documenting problems identified during the laboratory's quality assessment review, and the corrective actions taken to resolve the problems identified and to prevent their recurrence.

The burden for documenting the written policies and procedures applies only to new laboratories entering the CLIA program each year.

Depending on the size and volume of testing of the laboratory, we assume a one-time burden of 8-24 hours, or an average burden of 16 hours, for the laboratory to develop its written policies and procedures. We assume that 1000 new laboratories will enter the CLIA program each year. Approximately 51% will request a certificate of waiver, therefore, only 490 new laboratories will need to develop an assessment process.

490 laboratories x 16 hours = **7,840** hours/year

3 https://data.bls.gov/oesprofile/

16 hours x $29.75 x **490** laboratories = $**233,240**

The ongoing burden for laboratories involves evaluating data to determine if there are problems, documenting the problems identified, taking corrective actions and revising policies based on the evaluations, as necessary. A smaller laboratory, such as a physician's office laboratory (POL) or a laboratory that only performs PPM tests, that is directly involved in the patient's care, may use patient outcomes to evaluate its testing process. We assume that it takes a laboratory approximately 2-10 hours once a month, depending on the size and volume of testing, to evaluate the data and document these evaluations. We are estimating the burden for this requirement based on the concept that it will take a POL or a PPM laboratory from 2 to 4 hours once a month to meet this requirement and a hospital or independent laboratory from 6 to 10 hours to meet this requirement. We determined the number of POLs and PPM laboratories by using the number of POLs (14,250) and the number of PPM laboratories (24,441) and all "others" (7,927) in the CMS database this includes exempt laboratories.

Therefore, the burden for a POL or a PPM laboratory for this requirement is:

2-4 hours, or an average of 3 hours x 12 months = 36 hours/year
46,618 POL, PPM, "other" x 36 hours/year = **1,678,248** hours/year
36 hours x $29.75 x **46,618** POL, PPM, and "other" laboratories = $**49,927,878**

We determined the number of hospital (6554) and independent laboratories (5221) based on how laboratories classified themselves on the CLIA application. This includes exempt laboratories.

6-10 hours, or an average of 8 hours x 12 months = 96 hours/year
11,775 hospital and independent laboratories x 96 hours/year = **1,130,400** hours/year
96 hours x $29.75 x **11,775** hospital and independent laboratories = $**33,629,400**

We also assume that it takes approximately 0.5 - 2 hours, or an average of 1.25 hours, for the laboratory to revise its policies based on its quality assessment evaluations. This burden can be calculated as:

1.25 hours x 12 months = 15 hours/laboratory/year
58,396 laboratories x 15 hours/year = **875,940** hours/year
15 hours x $29.75 x 58,396 laboratories = $**26,059,215**

Sections 493.2, 493.43(a)(1), 493.55(a)(3), 493.1101(e), 493.1105(a)-(b), 493.1231(a), 493.1251(b)(2), §493.1256(a), 493.1283(a)(5), and 493.1291(a)(2): Virtual Access.

The following changes were proposed in CMS-3478-P:

1. Section 493.2 is amended by revising and adding a definition.
2. Section 493.43 is amended by revising paragraph (a).
3. Section 493.55 is amended by revising paragraph (a)
4. Section 493.1101 is amended by revising paragraph (e).
5. Section 493.1105 is amended by revising paragraph (a) introductory text, (a)(3) introductory text, (a)(7), and (b).
6. Section 493.1231 is amended by adding paragraph (a).
7. Section 493.1251 is amended by revising paragraph (b)(2).
8. Section 493.1256 is amended by revising paragraph (a).
9. Section 493.1283 is amended by adding paragraph (a)(5).
10. Section 493.1291 is amended by revising paragraph (a)(2).

Laboratory Costs to Update Policies and Procedures

We are estimating the burden associated with updating policies and procedures related to personnel regulations as:

a. Virtual Access
   - Total number of labs – 13,582.
   - One-time burden of 4 to 6 hours per laboratory for this task.

- A management level employee (11-9111) would perform this task at an hourly wage of $56.71 per hour: the wage rate would be $113.42 to include overhead and fringe benefits.
- The burden hours range from 54,328 to 81,492 (13,582 laboratories X 4 or 6 hours)
- The total cost would range from $**6,161,882 to $9,242,823** (54,328 or 81,492 x $113.42).

Sections 493.855(a) and (b) and 493.945(a)-(b): Gynecologic Cytology Proficiency Testing.
The following changes were proposed in CMS-3478-P:

1. Section 493.855 is amended by revising paragraphs (a) and (b).
2. Section 493.945 is amended by revising paragraphs (a), (b) introductory text, (b)(1) and (2), (b)(3)(i), (b)(3)(ii)(B), (b)(3)(ii)(C) introductory text, (b)(3)(ii)(D) introductory text, (b)(3)(ii)(E), (b)(3)(ii)(F) introductory text, and (b)(3)(ii)(G) introductory text

Laboratory Costs to Update Policies and Procedures
We are estimating the burden associated with updating policies and procedures related to gynecologic cytology proficiency testing as:

b. Gynecologic Cytology Proficiency Testing
   - Total number of labs – 807.
   - One-time burden of 1 to 1.5 hours per laboratory for this task.
   - A management level employee (11-9111) would perform this task at an hourly wage of $56.71 per hour: the wage rate would be $113.42 to include overhead and fringe benefits.
   - The burden hours range from 807 to 1,211 (807 laboratories X 1 or 1.5 hours)
   - The total cost would range from $**91,530 to $137,352** (807 or 1,211 x $113.42).

Sections 493.2, 493.1273(c), 493.1359(c)-(d), 493.1405(b), 493.1407(c), 493.1411(b)(6)(i), 493.1417(b)-(c), 493.1423(b)(7), 493.1443(b), 493.1445(c), 493.1449(c), 493.1449(f), 493.1449(i), 493.1455(a)-(c), 493.1461(c), 493.1461(e), 493.1463(a)-(c), 493.1489(b), and 493.1495(b)-(c): Personnel.
The following changes were proposed in CMS-3478-P:

1. Section 493.2 is amended by adding, revising, and rescinding definitions.
2. Section 493.1273 is amended by revising paragraph (c).
3. Section 493.1359 (c)(1-5) and (d) are rescinded.
4. Section 493.1405 is amended by revising paragraph (b):
5. Section 493.1407 is amended by revising paragraph (c).
6. Section 493.1411 is amended by revising paragraph (b)(6)(i).
7. Section 493.1417 is amended by revising paragraph (b) and adding paragraph (c).
8. Section 493.1423 is amended by revising paragraph (b)(7)
9. Section 493.1443 is amended by revising paragraphs (b)(2) and (3) and adding paragraph (b)(6):
10. Section 493.1445 is amended by revising paragraph (c).
11. Section 493.1449 is amended by revising paragraph (c)(4)(i)(C)(2) and (f)(2)(i)(B)(3), adding paragraph (f)(4); and revising paragraph (i)(2)(ii).
12. Section 493.1455 is amended revising paragraph (a) and (b) and adding paragraph (c).
13. Section 493.1461 is amended by rescinding paragraph (c)(3), redesignating paragraph (c)(4) as (c)(3), and revising paragraph (e) introductory text.
14. Section 493.1463 is amended by rescinding paragraphs (a)(3) and (c), redesignating paragraphs (a)(4) as (a)(3), and revising paragraph (b)(4).
15. Section 493.1489 is amended by revising paragraph (b).
16. Section 493.1495 is amended by revising paragraph (b)(5) and (6) and rescinding paragraphs (b)(7) and (c).

Laboratory Costs to Update Policies and Procedures
We are estimating the burden associated with updating policies and procedures related to personnel regulations as:

a. Certificates of Compliance (CoC) and Accreditation (CoA), Personnel Regulations
   - **33,955** total laboratories
   - One-time burden per laboratory is 2.25 to 4.5 hours

- A management level employee (11-9111) would perform this task at an hourly wage of $56.71 per hour; the wage rate would be $113.42 to include overhead and fringe benefits.
- The burden hours range from 76,399 to 152,798 (33,955 laboratories X 2.25 or 4.5 hours)
- The total cost would range from $**8,665,175 to $17,330,349** (76,399 or 152,798 x $113.42).

b. Certificates for Provider-Performed Microscopy, Personnel Regulations
- **24,441** total laboratories
- One-time burden of 0.25 to 0.5 hours per laboratory for this task
- A management level employee (11-9111) would perform this task at an hourly wage of $56.71 per hour; the wage rate would be $113.42 to include overhead and fringe benefits.
- The burden hours would range from 6,110 to 12,221 (24,441 laboratories x 0.25 to 0.5 hours).
- The total cost would range from $**692,996 to $1,386,106** (6,110 or 12,221 x $113.42).

Sections 493.2, 493.35(b)(3), 493.39(b), 493.41, 493.43(b)(3), 493.45(b)(2), 493.51(a), 493.53(b), 493.55(b)(3), 493.57(a)(2), and 493.63(a), 493.555(c)(6), 493.801 (b), 493.807(a)-(b), 493.931 (b)-(c), 493.933 (b)-(c), 493.1100(a)-(b), 493.1291(c)(2): Other Changes.

The following changes were proposed in CMS-3478-P:

1. Section 493.2 is amended by revising a definition.
2. Section 493.35 is amended by revising paragraph (b)(3).
3. Section 493.41 is rescinded.
4. Section 493.43(b) is amended by revising paragraph (b)(3).
5. Section 493.45 is amended by revising paragraph (b)(2).
6. Section 493.51 is amended by revising paragraph (a).
7. Section 493.53 is amended by revising paragraphs (b)(3) and (4) and adding paragraph (b)(5).
8. Section 493.55(b) is amended by revising paragraph (b)(3).
9. Section 493.57(a) is amended by revising paragraph (a)(2).
10. Section 493.63 is amended by revising paragraphs (a)(3) and (4) and adding paragraph (a)(5).
11. Section 493.555 is amended by rescinding paragraph (c)(6).
12. Section 493.801 is amended by revising paragraph (b) introductory text.
13. Section 493.807 is amended by revising paragraph (a) and rescinding paragraph (b).
14. Section 493.931 is amended by revising Table 1 to paragraph (b) and Table 2 to paragraph (c).
15. Section 493.933 is amended by revising Table 1 to paragraph (b) and Table 2 to paragraph (c).
16. Section 493.1100 is amended by rescinding paragraphs (a) and (b).
17. Section 493.1291 is amended by revising paragraph (c)(2).

Laboratory Costs to Update Policies and Procedures

We are estimating the burden associated with updating policies and procedures related to other changes as:

a. Certificates of Compliance (CoC) and Accreditation (CoA), Other Changes
- **33,955** total laboratories
- One-time burden per laboratory is 0.5 to 1.0 hour
- A management-level employee (11-9111) would perform this task at an hourly wage of $56.71 per hour; the wage rate would be $113.42 to include overhead and fringe benefits.
- The burden hours range from 16,978 to 33,955 (33,955 laboratories X 0.5 or 1 hour)
- The total cost would range from $**1,925,645 to $3,851,176** (16,978 or 33,955 x $113.42).

b. Certificates for Provider-Performed Microscopy, Other Changes
- **24,441** total laboratories
- One-time burden of 0.25 to 0.5 hours per laboratory for this task
- A management-level employee (11-9111) would perform this task at an hourly wage of $56.71 per hour; the wage rate would be $113.42 to include overhead and fringe benefits.
- The burden hours would range from 6,110 to 12,221 (24,441 laboratories x 0.25 to 0.5 hours).
- The total cost would range from $**692,996 to $1,386,106** (6,110 or 12,221 x $113.42).

c. Certificates of Waiver, Other Changes

- **248,642** total laboratories
- One-time burden of 0.25 to 0.5 hours per laboratory for this task
- A management-level employee (11-9111) would perform this task at an hourly wage of $56.71 per hour; the wage rate would be $113.42 to include overhead and fringe benefits.
- The burden hours would range from 62,161 to 124,321 (248,642 laboratories x 0.25 to 0.5 hours).
- The total cost would range from **$7,050,301 to $14,100,488** (62,161 or 124,321 x $113.42).

Section 493.1725 - 493.1780, Conditions: Inspections

The burden of these sections is captured under another collection, 0938-0544.
Number of Respondents x Annual Frequency per Response = Total Annual Responses
Burden per Response x Total Annual Responses = Annual Burden Hours

The total aggregate burden for all of the requirements under #12 in the supporting statement is **8,726,395** hours.

CFR Section	Number of Respondents	Burden per response	Total Annual Responses	Annual Frequency per Response	Annual Burden Hours
493.35-493.63					
493.801	33,955	2 hours	101,865	3	203,730
	1,327	20 mins	3,981	3	1,327
	807	0.5 hours	807	1	404
493.803	33,955	3 hours	33,955	1	101,865
493.1299	490	16 hours	490	1	7,840
	46,618	3 hours	559,416	12	1,678,248
	11,775	8 hours	141,300	12	1,130,400
	58,396	1.25 hours	700,752	12	875,940
493.1242	490	6 hours	490	1	2,940
	37,957	0.5 hours	37,957	1	18,979
493.1251	490	6 hours	490	1	2,940
	37,957	1 hour	37,957	1	37,957
	1,168	1 hour	1,168	1	1,168
493.1252	58,396	1 hour	700,752	12	700,752
493.1254	58,396	5 mins	14,015,040	240	1,167,920
493.1255	33,955	10 hours	33,955	1	339,550
493.1256	16,960	5 mins	4,884,480	288	407,040
	13,582	0.5 mins	3,911,616	288	32,597
493.1261	9,168	2.5 mins	110,016	12	4,584
493.1262	432	2 mins	41,472	96	1,382
	1,219	1 min	58,512	48	975
	432	1 min	41,472	96	691
	1, 219	1.5 mins	380,328	312	9,508
493.1263	8,643	2.5 mins	103,716	12	4,322
	8,643	2 mins	103,716	12	3,457
493.1269	8271	1.5 mins	2,977,560	360	74,439
	10578	1.5 mins	2,538,720	240	63,468

493.1274	3229	10 mins	3,874,800	1200	645,800
	3229	0.3 hours	16,145	5	4,844
	3229	10 mins	3,874,800	1200	645,800
	3229	10 mins	774,960	240	129,160
493.1283	13,582	3 mins	162,984	12	8,149
SUBTOTAL			**40,225,672**		**8,308,176**
One-time Burden for Collection of Information CMS-3478-P:**Virtual Access** Sections 493.2, 493.43(a)(1), 493.55(a)(3), 493.1101(e), 493.1105(a)-(b), 493.1231(a), 493.1251(b)(2), §493.1256(a), 493.1283(a)(5), and 493.1291(a)(2); **Gynecologic Cytology Proficiency Testing** Sections 493.855(a) and (b) and 493.945(a)-(b); **Personnel** Sections 493.2, 493.1273(c), 493.1359(c)-(d), 493.1405(b), 493.1407(c), 493.1411(b)(6)(i), 493.1417(b)-(c), 493.1423(b)(7), 493.1443(b), 493.1445(c), 493.1449(c), 493.1449(f), 493.1449(i), 493.1455(a)-(c), 493.1461(c), 493.1461(e), 493.1463(a)-(c), 493.1489(b), and 493.1495(b)-(c); and **Other Changes** Sections 493.2, 493.35(b)(3), 493.39(b), 493.41, 493.43(b)(3), 493.45(b)(2), 493.51(a), 493.53(b), 493.55(b)(3), 493.57(a)(2), and 493.63(a), 493.555(c)(6), 493.801 (b), 493.807(a)-(b), 493.931 (b)-(c), 493.933 (b)-(c), 493.1100(a)-(b), 493.1291(c)(2).					
Section	**Number of Respondents**	**Burden per response**	**Total Annual Responses**	**Annual Frequency per Response**	**Annual Burden Hours**
Virtual Access	13,582	6 hours	13,582	1	81,492
Gynecologic Cytology Proficiency Testing	807	1.5 hours	807	1	1,211
Personnel	33,955	4.5 hours	33,955	1	152,798
	24,441	0.5 hours	24,441	1	12,221
Other Changes	33,955	1 hour	33,955	1	33,955
	24,441	0.5 hours	24,441	1	12,221
	248,642	0.5 hours	248,642	1	124,321
SUBTOTAL			**379,823**		**418,219**
TOTAL BURDEN			**40,605,495**		**8,726,395**

13. Capital Costs (Maintenance of Capital Costs)

There are no capital costs.

14. Cost to Federal Government

Congress intended for the CLIA program to be self-funding, and laboratories are assessed user fees to fund the operation of the program. Eight full-time employees (FTE) in the Division of Clinical Laboratory Quality and Improvement (DCLIQ) will oversee the revised requirements. The FTEs are GS-12 to 13 so the cost to the federal government will range from $ 48.59 per hour to $75.11 per hour. It will take approximately 10 hours for a total cost of $7,774 to $12,018 (hourly wage ($48.59 or $75.11 x 2 (overhead and fringe benefits) X 8 X 10).

15. Program/Burden Changes

This decrease of **7,179,291** hours from the previous collection is a result of a combination of issues. Following the end of the SARS-CoV-2 Public Health Emergency (PHE), the number of laboratories for each certificate type decreased. There are 27,040 fewer labs than in the previous collection, including 15,691 fewer CoC and CoA labs. The previous collection also contained errors in the number of labs included in the calculations. At §493.1256, both CoC and CoA were included in the previous collection. Based on a review of historical collections, this should include only CoC labs. At §493.1261, all microbiology labs were included in the previous collection instead of only those with the subspecialty of bacteriology. In addition, the data now available is more specific. At §493.1299, the previous collection included all labs instead of only non-waived labs. Waived labs are not subject to §493.1299 but were not previously separated out in the data.

16. Publication and Tabulation Dates

There are no publication and tabulation dates associated with this collection.

17. Expiration Date

CMS will display the expiration date.

18. Certification Statement

There are no exceptions to the certification statement.