Supporting Statement for the Information Collection Requirements (ICR)
Contained in the Clinical Laboratory Improvement Amendments (CLIA) Regulations (CMS-R-26)

A. Background

This is an extension 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, and that are reflected in this revision package.

The previous iteration was revision of the information collection. Based on notice of final rulemaking, CMS-3326-F (88 FR 89976) published on December 28, 2023, we are revising the ICR by adding additional sections. There are no collection instruments.

This final rule addresses recommendations provided by the Centers for Disease Control and Prevention (CDC)'s Clinical Laboratory Improvement Advisory Committee (CLIAC). CMS and CDC incorporated changes in this rulemaking to remove specific regulations already covered in the general requirements and laboratory director responsibilities. The additional requirements include sections 493.1278, 493.1359, 493.1405-1411; 493.1423, 493.1443-1445, 493.1461-1463; 493.1483; 493.1489-1491. These sections include histocompatibility (493.1278) and personnel (493.1359, 493.1405-1411; 493.1423, 493.1443-1445, 493.1461-1463; 493.1483; 493.1489-1491) require laboratories to revise and update policies and procedures applicable to new or amended requirements as follows.

1. Histocompatibility Section 493.1278:

The CLIA regulations include requirements specific to certain laboratory specialties such as microbiology and subspecialties such as endocrinology. The CLIA regulatory requirements for the specialty of histocompatibility at Section 493.1278, including the crossmatching requirements, address laboratory testing associated with organ transplantation and transfusion and testing on prospective donors and recipients. The CLIA regulations governing the specialty of histocompatibility have not been updated since 1992. Many of the changes finalized in this rule remove histocompatibility-specific requirements that we have determined are addressed by the general quality control (QC) requirements. We believe that removing specific requirements for obsolete methods and practices and eliminating redundant requirements will decrease the burden on laboratories performing histocompatibility testing.

2. Personnel Sections 493.1359, 493.1405-1411, 493.1423, 1443-1445, 493.1461-1463 493.1483 and 493.1489-1491:

The CLIA regulations related to personnel requirements were updated with minor changes to the doctoral high complexity laboratory director qualifications in the 2003 final rule, but otherwise have remained unchanged since we published the 1992 final rule with comment period. In the 2018 RFI, we sought public comment and information related to CLIA personnel requirements in the following areas: nursing degrees; physical science degrees; personnel competency assessment (CA); personnel training and experience; and non-traditional degrees. These are areas that the CDC, CMS, interested parties, and State agency surveyors identified as relevant to our efforts to update the CLIA personnel requirements to better reflect current knowledge, changes in the academic context, and advancements in laboratory testing. We also requested input from CLIAC for recommended changes to the CLIA personnel requirements found in subpart M.

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 their 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 60-day Federal Register notice published April 22, 2026 (91 FR 21502). There were no public comments received.

The 30-day Federal Register notice published July 2, 2026 (91 FR 40538).

The Clinical Laboratory Improvement Advisory Committee (CLIAC) holds periodic meetings to discuss technical and scientific issues raised by the general public. The last meeting was held in April 2023. These meetings provide advice and guidance pertaining to general issues related to improvement in clinical laboratory quality and laboratory medicine practice and address specific questions related to possible revision of CLIA standards.

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 **49,646** 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 (**334,078**), and subtracting the waived and physician performed microscopy (PPM) laboratories (**284,432**). The wage rate data is from https://www.bls.gov/ooh/healthcare/clinical-laboratory-technologists-and-technicians.htm.

49,646 x 6 hours/year = **297,876** hours/yr.
6 hours x $29.75 per hour = $178.50 per laboratory
$178.50 x **49,646** laboratories = $**8,861,811**

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 **49,646** laboratories are affected by this requirement and that each laboratory has a burden of approximately 3 hours/year.

49,646 x 3 hours/year = **148,938** hours/year
3 hours x $29.75 per hour = $89.25 per laboratory
$89.25 x **49,646** laboratories = $**4,430,905.50**

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 = $476
$476 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 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 and the number of PPM laboratories in the CMS data base 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
151,075 POL, PPM, and "other" laboratories x 36 hours/year = **5,438,700** hours/year
36 hours x $29.75 = $1071
$1071 x **151,075** POL, PPM, and "other" laboratories = $**161,801,325**

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
18,539 hospital and independent laboratories x 96 hours/year = **1,779,744** hours/year
96 hours x $29.75 = $2,856
$2,856 x **18,539** hospital and independent laboratories = $**52,947,384**

We also assume that it takes approximately 1/2 - 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
169,614 laboratories x 15 hours/year = **2,544,210** hours/year
15 hours x $29.75 = $446.25
$446.25 x 169,614 laboratories = $**75,690,247.50**

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 = $178.50
$178.50 x 490 non-waived laboratories = $87,465

We also estimate that approximately 65% of the non-waived 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 1/2 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:

77,392 non-waived laboratories x 65% = **50,305** laboratories
50,305 laboratories x 0.5 hours = **25,153** hours/year
0.5 hours x $29.75 = $14.88
$14.88 x **50,305** laboratories = $**748,538.40**

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 = $178.50
$178.50 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 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:

77,392 non-waived laboratories x 65% = 50,305 laboratories x 1 hour/year = **50,305** hours/year
1 hour x $29.75 = $29.75
$29.75 x **50,305** laboratories = $**1,496,573.75**

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:

77,392 non-waived laboratories x 2% = 1,548 laboratories x 1 hour/year = **1,548** hours/year
1 hour x $115 per hour = $115
$115 x **77,392** non-waived laboratories = $**8,900,080**

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:

77,392 non-waived laboratories x 12 hours/year = **928,704** hours/year

12 hours x $29.75 = $357
$357 x **77,392** non-waived laboratories = $**27,628,944**

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 **77,392** non-waived laboratories = **1,547,840** hours/year.
20 hours x $29.75 = $595
$595 x **77,392** non-waived laboratories = $**46,048,240**

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 in hours from 5 to 15 with an average of 10 hours/year.

49,626 non-waived laboratories x 10 hours/year = **496,260** hours/year.
10 hours x $29.75= $297.50
$297.50 x **49,626** non-waived laboratories = $**14,763,735**

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:

33,377 laboratories (total number of laboratories minus the number of waived laboratories, PPM laboratories and previously regulated laboratories) x 24 hours/year = **801,048** hours/year.
24 hours x $29.75 = $714
$714 x **33,377** laboratories = $**23,831,178**

§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 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 .5 hours/laboratory/year.)

The estimated total burden for documenting control testing for the reagents above is **19,479** bacteriology laboratories x .5 hours/year = **9,740** hours/year.

0.5 hours x $29.75 = $14.88

$14.88 x **19,479** = $**289,847.52**

§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 = 3.24 hours/laboratory/year.

The total estimated burden for documenting the positive control result is:

401 mycobacteriology laboratories x 3.24 hours/year = **1,299** hours/year.

3.24 hours x $29.75 = $96.39

$96.39 x **401** = $**38,652.39**

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:

1,133 mycobacteriology laboratories x 0.8 hours/year = **906** hours/year.

0.8 hours x $29.75 = $23.80

$23.80 x **1,133** mycobacteriology laboratories = $**26,965.40**

The total burden for documenting control testing for mycobacteria identification reagents and tests, and acid-fast, and fluorochrome acid-fast stains is **1,299** hours/year + **906** hours/year = **2,205** 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 to be one-half of **1,299** hours/year (from above) = **650** hours/year.

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 **1,133** laboratories x 7.8 hours/year = **8,837** hours/year.

The total burden for documenting control testing for mycobacteria identification reagents and tests, acid-fast, and fluorochrome acid-fast stains is **650** hours/year + **8,837** hours/year = 9,487 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 **2,205** hours/year + 9,487 hours/year = **11,692** 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:

9,185 mycology laboratories x 0.5 hours/year = **4,593** hours/year.

0.5 hours x $29.75 = $14.88

$14.88 x **9,185** mycology laboratories = $**136,672.80**

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 = 24minutes= 0.4 hours

The total estimated burden for this requirement is:

9,185 mycology laboratories x 0.4 hours = **3,674** hours/year.

0.4 hours x $29.75 = $11.90

$11.90 x **9,185** mycology laboratories = $**109.301.50**

§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 **18,974**. Of this total, **5,907** are hospitals, **2,116** are independent laboratories, **7,243** are physician's office laboratories (POLs), **1,366** fall into a category of "other", and the remaining **2,342** 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 = .75 hours/month

.75 hours/month x 12 = 9 hours/laboratory/year.
8,023 hospital and independent laboratories x 9 hours/year = **72,207** hours/year.
9 hours x $29.75 = $267.75
$267.75 x **8,023** hospital and independent laboratories = $2,148,158.25

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 **10,951** 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
10,951 laboratories x 6 hours/year = **65,706** hours/year.
6 hours x $29.75 = $178.50
$178.50 x **10,951** laboratories = $**1,954,753.50**

The total estimated burden is **72,207** hours/year (hospital and independent laboratories) **+ 65,706** hours/year (total POLs, "other" and miscellaneous) = **137,913** 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 an average laboratory would employ 5 cytotechnologists.

Therefore, the burden is:

3,191 laboratories x 5 cytotechnologists x 40 hours/year = **638,200** hours/year.
40 hours x 5 cytotechnologists = 200 hours
200 hours x $29.75 = $5,950
$5,950 x **3,191** laboratories = $**18,986,450**

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

10 minutes/6 months = .3 hours/year/per cytotechnologist
3,191 laboratories x 5 cytotechnologists x .3 hours/year/cytotechnologist = **4,787** hours/year.
0.3 hours x 5 cytotechnologist = 1.5 hours
1.5 hours x $29.75 = $44.63
$44.63 x **3,191** laboratories = $**142,414.33**

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
3,191 laboratories x 5 cytotechnologists x 40 hours/year = **638,200** hours/year.
40 hours x 5 cytotechnologists = 200 hours
200 hours x $29.75 = $5,950

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 **3,191** laboratories = **127,640** hours/year.
40 hours x $29.75 = $1,190
$1,190 x **3,191** laboratories = $**3,797,290**

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 493.1278 Standard: Histocompatibility.

The following changes were made in the final rule at Section 493.1278:

1. Revised Section 493.1278(a)(1) to updated language from "an audible alarms system" to "a continuous monitoring and alert system".
2. Revised Section 493.1278(a)(2) to expand the regulatory language to include a requirement that the laboratory must establish and follow written policies and procedures for the storage and retention of patient specimens based on the specific type of specimen because the type and duration of specimen storage are equally important as ease of retrieval.
3. Deleted Section 493.1278(a)(3).
4. Revised Section 493.1278(a)(4) to: redesignate it to 493.1278(a)(3); remove the examples (that is, antibodies, antibody-coated particles, or complement); clarify that these technologies, as well as current and future technologies, are allowed for the isolation of lymphocytes or lymphocyte subsets; clarify the requirement by adding "identification" of lymphocytes, or lymphocyte subsets.
5. Revised Section 493.1278(a)(5) to redesignated it to 493.1278(a)(4).
6. Revised Sections 493.1278(b)(1) through (3) to: delete requirements pertaining to establishing HLA typing procedures as the requirement that the laboratory must establish and have written procedures that ensure quality test results; and delete requirements pertaining to establishing HLA typing procedures as the requirement that the laboratory must establish and have written procedures that ensure quality test results. These requirements are already addressed by the general requirements for all test systems under current regulations at Sections 493.1445(e)(1) and (e)(3)(i) and revision at Section 493.1278(f), respectively, and therefore, are duplicative.
7. Revised Sections 493.1278(b)(4) to: redesignated to paragraph (b)(1); revised to delete the language that states potential new antigens not yet approved by this committee must have a designation that cannot be confused with WHO terminology because new alleles are approved monthly, which makes this requirement obsolete.
8. Revised Sections 493.1278(b)(5)(i) through (iv) to: delete the requirements for preparation of cells or cellular extracts, selecting typing reagents, ensuring that reagents used for typing are adequate, and assignment of HLA antigens as they are already addressed by the general requirements for all test systems under Sections 493.1445(e)(1) and (e)(3)(i), 493.1251, and 493.1252, and therefore, are duplicative.
9. Revised Section 493.1278(b)(5)(v) to: redesignate the provisions at paragraph (b)(5)(v) to paragraph (b)(2); and add "allele" and delete the "re" prefix in the word "retyping" in this paragraph.
10. Revised Section 493.1278(b)(6) to delete requirements for HLA typing control materials procedures as they are addressed by the general requirements regarding quality control materials and procedures for

all test systems under Sections 493.1256(a) through (d) and (f) through (h), and therefore, are duplicative.

11. Revised Sections 439.1278(c) to delete this requirement for control procedures and materials regarding disease related studies because this is addressed by the general requirements for all test systems under §§ 493.1256(d) and 493.1451(b)(4), and therefore, is duplicative.
12. Revised Sections 493.1278(d) to: redesignate the provisions at paragraph (d) to paragraph (c); change the name of this section from "Antibody Screening" to "Antibody Screening and Identification" for clarification as both processes apply to histocompatibility testing; delete the requirements at Sections 493.1278(d)(1) through (3) and (5) through (7), for antibody screening laboratory procedures as they are addressed by the general requirements for all test systems under §§ 493.1445(e)(1) and (e)(3)(i), 493.1251, 493.1252, and 493.1256, and therefore, are duplicative.
13. Revised Sections 493.1278(e)(1) through (3) to: delete these three requirements regarding the laboratory having crossmatch procedures and controls as they are addressed by the general requirements for all test systems under §§ 493.1445(e)(1), 493.1251, 493.1256, and 493.1451(b)(4), and therefore, are duplicative; add the requirements summarized below, at § 493.1278(d), to increase flexibility in the regulations and remove perceived barriers. These requirements include:
    - Defining donor and recipient HLA antigens, alleles, and antibodies to be tested;
    - Defining the criteria necessary to assess a recipient's alloantibody status;
    - Assessing recipient antibody presence or absence on an ongoing basis;
    - Typing the donor at the serological level, to include those HLA antigens to which antibodies have been identified in the potential recipient, as applicable;
    - Describing the circumstances in which a pre- and post-transplant confirmation testing of donor and recipient specimens is required;
    - Making available all applicable donor and recipient test results to transplant team;
    - Ensuring immunologic assessments are based on the test report results obtained from a test report from CLIA certified testing laboratory(ies);
    - Defining time limits between recipient testing and the performance of crossmatch; and
    - Requiring that the test report must specify what type of crossmatch was performed.
14. Revised Sections 493.1278(f) to: redesignate 493.1278(f) to § 493.1278(e); change the terms "transfusion" and "transfused" to "infusion" and "infused", respectively; update paragraph (f)(1) of this Section to state that laboratories performing histocompatibility testing must establish and have written policies and procedures specifying the types of histocompatibility testing. Moved this language to § 493.1278(e); add "identification" after "antibody screening" in the revised § 493.1278(c), as identification is an important part of the process for crossmatching; remove "compatibility testing" because this activity is specific to immunohematology, and crossmatching is a more appropriate description of what we understand is the current histocompatibility procedure used by laboratories; modify the current general requirement to specify that the laboratory must establish and follow written policies and procedures that address the transplant type (organ, tissue, cell) donor type (living, deceased, or paired) and recipient type (high risk vs. non-sensitized); modify the requirement at paragraph (f)(1)(ii) of this Section for laboratory policies and procedures as it would be included in the amended protocol requirements under the proposed regulation at § 493.1278(e)(1)(i) and (iii), and therefore, would be duplicative; replace "the level of" with "type and frequency" at paragraph (f)(1)(iii) of this Section, to clarify this revised requirement refers to the type and frequency of testing practice to support the clinical transplant protocols; removed the examples of antigen and allele level in the regulation as these examples may not be all-inclusive and generally are reflected in guidance rather than regulatory text.
15. Added a new regulation at Section 493.1278(e)(3) for pre-transplant recipient specimens.
16. Revised Sections 493.1278(f)(2) through (3) to delete these requirements for renal and nonrenal transplantation crossmatch procedures.

17. Revised Sections § 493.1278(g) to redesignate it at Section 493.1278(f). This requirement remains unchanged.

Laboratory Costs to Update Policies and Procedures

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

a. Histocompatibility
   - 218 total laboratories
   - One-time cost of 1 to 2 hours per laboratory for this task
   - A management level employee (11-9111) would perform this task at an hourly wage of $66.22per hour: the wage rate would be $132.44 to include overhead and fringe benefits.
   - The burden hours range from 218 to 436 (218 laboratories X 1 or 2 hours)
   - The total cost would range from $**28,871.92 to $57,743.84** (218 laboratories x 1 or 2 hours x $132.44).

Sections 493.1359- 493.1489-1491: Personnel.

The following changes were made in the final rule at Sections 493.1359, 493.1405-1411, 493.1423, 1443-1445, 493.1461-1463, 493.1483, and 493.1489-1491:

1. Revised Section 493.1359(b)(2) by removing the reference to subpart M.
2. Added a new regulation at Section 493.1359(c) to clarify the competency assessment (CA) requirements for PPM laboratories in the Standard for PPM laboratory director (LD) responsibilities, as this testing is moderate complexity per § 493.19(b)(2) and subject to CA.
3. Added a new regulation at Section 493.1359(d) with the same CA intervals as in Sections 493.1413(b)(8) and 493.1451(b)(8) apply to mid-level practitioners for consistency.
4. Revised Section 493.1405 to allow an alternative educational pathway for nontraditional degrees.
5. Deleted Section 493.1406.
6. Revised Section 493.1407(c), so that the LD must be on site at the laboratory at least once every 6 months, with at least a 4-month interval between the two on site visits.
7. Revised Section 493.1411 to allow an alternative educational pathway for nontraditional degrees.
8. Updated the cross-reference at Section 493.1417 from (3)(i) to (3).
9. Revised Section 493.1423 to allow an alternative educational pathway for nontraditional degrees.
10. Added a new regulation at Section 493.1423(7) for blood gas testing personnel (TP) for laboratories performing moderate complexity (MC) testing.
11. Added a new regulation at Section 493.1423(8) to provide a grandfathering provision.
12. Revised Section 493.1443(b)(1)-(6) to allow an alternative educational pathway for nontraditional degrees.
13. Revised Sections 493.1445(c) and (e), so that the LD must be on site at the laboratory at least once every 6 months, with at least a 4-month interval between the two on site visits.
14. Revised Section 493.1449 to allow an alternative educational pathway for nontraditional degrees.
15. Updated the cross-reference at Section 493.1451(c) from (k) to (e).
16. Updated Section 493.1455 cross references from (3)(i) to (3) and from (b)(6) to (b)(5).
17. Revised Section 493.1461 to: remove paragraph at (c)(1)(i) to remove an earned doctoral, master's, or bachelor's degree in "physical science" as a means to qualify; delete the grandfather provisions at (c)(3) through (5), as these requirements had to have been met by February 28, 1992, April 24, 1995, and September 1, 1992, respectively, and individuals can no longer qualify under these provisions; added new regulation at Section 493.1461(c)(4) to specify a new grandfather provision for those individuals who had qualified prior to the publication of the final rule.
18. Deleted Section 493.1462.
19. Revised Section 493.1463(b)(4) from annually evaluating and documenting the performance of all testing personnel to now require the evaluation and documentation of the competency of all testing personnel.
20. Updated the cross-reference at Section 493.1469(a) from (k) to (e).

21. Revised Sections 493.1483(b)(2) and 493.1489(b)(2)(ii)(B)(1), to replace "CAHEA" with CAAHEP (Commission on Accreditation of Allied Health Education Programs) and removed, "or other organization approved by HHS."
22. Revised Sections 493.1483(b)(3) through (5) to remove the grandfather provisions as these requirements had to have been met by September 1, 1992, or September 1, 1994, as individuals can no longer qualify under these provisions. These individuals would be included in the new grandfather provision at § 493.1483(b)(3).
23. Revised Section 493.1489 to: removed paragraph (b)(3) as the February 28, 1992 grandfather provision must have been met by February 28, 1992; redesignated paragraphs (b)(2)(i) and (ii) to paragraphs (b)(3)(i) and (ii), respectively; At § 493.1489(b)(2)(ii)(B)(1), replaced "CAHEA" with "CAAHEP" and removing "or other organization approved by HHS."; revised paragraph (b)(1) to separate the provisions into two paragraphs (that is, paragraph (b)(1) and new paragraph (b)(2)(i)); removed an earned doctoral, master's, or bachelor's degree in "physical science" as a means to qualify. Added new paragraph (b)(2)(ii) to state who may be qualified under § 493.1443(b)(3) or § 493.1449(c)(4) or (5) to allow individuals who do not have a chemical, biological, or clinical science or medical technology or clinical laboratory science degree to be eligible to qualify as a TC using the educational algorithm; move the military provision out of the April 24, 1995, grandfather provision and made it a mechanism that individuals will be able to qualify for moderate complexity testing (§ 493.1423(b)(5)); remove paragraph (b)(4) introductory text and paragraph (b)(4)(i) [the text that currently states "On or before" through "graduated from a [ML] or [CL] training program approved or accredited by ABHES, CAHEA, or other organizations approved by HHS"] per the discussion under § 493.1483(b)(2); the current military requirement at paragraph (b)(4)(ii) is redesignated as paragraph (b)(4).
24. Deleted Section 493.1491.

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
   - **34,082** total laboratories
   - One-time burden per laboratory is 5 to 7 hours
   - A management level employee (11-9111) would perform this task at an hourly wage of $66.22 per hour; the wage rate would be $132.44 to include overhead and fringe benefits.
   - The burden hours range from 170,410 to 238,574 (34,082 laboratories X 5 or 7 hours)
   - The total cost would range from $**22,569,100.40 to $31,596,740.56** (34,082 laboratories x 5 or 7 hours x $132.44).

b. Certificates for Provider-Performed Microscopy, Personnel Regulations
   - **31,982** 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 $66.22 per hour; the wage rate would be $132.44 to include overhead and fringe benefits.
   - The burden hours would range from 7,996 to 15,991 (31,982 laboratories x 0.25 to 0.5 hours).
   - The total cost would range from **$1,058,924.02 to $2,117,848.04** (31,982 laboratories x 0.25 or 0.5 hours x $132.44).

Section 493.1725 - 493.1780, Conditions: Inspections

The burden of these sections is captured under another collection, 0938-0544.

The total aggregate burden for all of the requirements under #12 in the supporting statement is **15,839,779** 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	49, 646	3	148,938	6	297,876
493.803	49, 646	3	148,938	3	148,938
493.1299	490	1	490	16	7,840
	151, 075	12	1,812,900	36	5,438,700
	18, 539	12	222,468	96	1,779,744
	169, 614	12	2,035,368	15	2,544,210
493.1242	490	1	490	6	2,940
	50,305	1	50,305	0.5	25,153
493.1251	490	1	490	6	2,940
	50,305	1	50,305	1	50,305
	1,548	1	1,548	1	1,548
493.1252	77, 392	365	28,248,080	12	928,704
493.1254	77, 392	365	28,248,080	20	1,547,840
493.1255	49, 626	52	2,580,552	10	496,260
493.1256	33, 377	365	12,182,605	24	801,048
493.1261	19, 479	12	233,748	0.5	9,740
493.1262	401	365	146,365	3.24	1,299
	401	365	146,365	1.62	650
	1,133	365	413,545	0.8	906
	1, 133	365	413,545	7.8	8,837
493.1263	9,185	12	110,220	0.5	4,593
	9,185	12	110,220	0.4	3,674
493.1269	8,023	365	2,928,395	9.0	72,207
493.1274	3,191	365	1,164,715	200	638,200
	3,191	365	1,164,715	1.5	4,787
	3,191	365	1,164,715	200	638,200
	3,191	365	1,164,715	40	127,640
SUBTOTAL			**84,892,820**		**15,584,778**
One-time Burden for Collection of Information CMS-3326-F Sections 493.1278, 493.1359, 493.1405-1411; 493.1423, 493.1443-1445, 493.1461-1463; 493.1483; 493.1489-1491					
CFR Section	**Number of Respondents**	**Burden per response**	**Total Annual Responses**	**Annual Frequency per Response**	**Annual Burden Hours**
493.1278	218	1	218	2	436
493.1359-493.1489-1491*	34,082	1	34,082	7	238,574
493.1359-493.1489-1491**	31,982	1	31,982	0.5	15,991

SUBTOTAL		**66,282**		**255,001**
TOTAL BURDEN		**84,959,102**		**15,839,779**

* Certificates of Compliance (CoC) and Accreditation (CoA) ** Certificates for Provider-Performed Microscopy

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. Ten 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 $ 9,718 to $15,022 (hourly wage ($48.59 or 75.11 x 2 (overhead and fringe benefits) X 10 X 10).

15. Program/Burden Changes

There was no increase in burden hours in this extension package. The labor costs were updated.

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.