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

A. Background

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 collection is in order of the regulation however, there are some sections that are not addressed as in previous years when they were considered usual and customary.

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.

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.

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 on June 8, 2020 (85 FR 34735). There were no public comments received.

The 30-day Federal Register notice published on [August 14, 2020 (85 FR 49654).

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 November 2019. 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 34579laboratories 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 (266336), and subtracting the waived and physician performed microscopy (PPM) laboratories (231757). The wage rate date is from https://www.bls.gov/ooh/healthcare/medical-and-clinical-laboratory-technologists-and-technicians.htm.

34, 579 x 6 hours/year = **207, 474** hours/yr.
6 hours x $25.54 per hour = $153.24 per laboratory
$153.24 x 34,579 laboratories = $5,298,885.96

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 34, 579 laboratories are affected by this requirement and that each laboratory has a burden of approximately 3 hours/year.

34, 579 x 3 hours/year = **103, 737** hours/year
3 hours x $25.54 per hour = $76.62 per laboratory
$76.62 x 34,579 laboratories = $2,649,442.98

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 will need to develop an assessment process.

490 labs x 16 hours = **7,840** hours/year
16 hours x $25.54 = $408.64
$408.64 x 490 laboratories = $200,233.60

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
152, 625 POL, PPM, and "other" laboratories x 36 hours/year = **5,494,500** hours/year
36 hours x $25.54 = $919.44
$919.44 x 152,625 POL, PPM, and "other" laboratories = $140,329,530.00

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
15,675 hospital and independent laboratories x 96 hours/year = **1,504,800** hours/year
96 hours x $25.54 = $2,451.84
$2,451.84 x 15,675 hospital and independent laboratories = $38,432,592.00

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
168,300 laboratories x 15 hours/year = **2,524,500** hours/year
15 hours x $25.54 = $383.10
$383.10 x 168,300 laboratories = $64,475,730.00

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 $25.54 = $153.24
$153.24 x 490 non-waived laboratories = $75,087.60

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:

66,033 non-waived laboratories x 65% = 42,921 laboratories
42,921 laboratories x 0.5 hours = **21461** hours/year
0.5 hours x $25.54 = $12.77
$12.77 x 42,921 laboratories = $548,101.17

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 $25.54 = $153.24
$153.24 x 490 = $75,087.60

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:

66,033 non-waived laboratories x 65% = 42,921 laboratories x 1 hour/year = **42,921** hours/year
1 hour x $25.54 = $25.54
$25.54 x 42,921 laboratories = $1,096,202.34

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:

66,033 non-waived laboratories x 2% = 1,321 laboratories x 1 hour/year = **1,321** hours/year
1 hour x $100 per hour = $100
$100 x 66,033 non-waived laboratories = $6,603,300.00

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:

66,033 non-waived laboratories x 12 hours/year = **792,396** hours/year

12 hours x $25.54 = $306.48

$306.48 x 66,033 non-waived laboratories = $20,237,793.80

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 66,033 non-waived laboratories = **1,320,660** hours/year.

20 hours x $25.54 = $510.80

$510.80 x 66,033 non-waived laboratories = $33,729,656.40

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.

34,579 non-waived laboratories x 10 hours/year = **345,790** hours/year.

10 hours x $25.54 = $255.40

$255.40 x 34,579 non-waived laboratories = $8,831,476.60

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:

18,689 laboratories (total number of laboratories minus the number of waived laboratories, PPM laboratories and previously regulated laboratories) x 24 hours/year = **448,536** hours/year.

24 hours x $25.54 = $612.96

$612.96 x 18,689 laboratories = $11,455,609.40

§493.1261 Standard: Bacteriology.

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

- Each day of use for beta-lactamase methods other than Cefinase™.
- Each week of use for Gram stains.
- 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 20,961 bacteriology laboratories x .5 hours/year = **10,481** hours/year.
0.5 hours x $25.54 = $12.77
$12.77 x 20,961 = $267,671.97

§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 438 mycobacteriology laboratories x 3.24 hours/year = 1,419 hours/year.
3.24 hours x $25.54 = $82.75
$82.75 x 438 = $36,244.50

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 1,237 mycobacteriology laboratories x 0.8 hours/year = 990 hours/year.
0.8 hours x $25.54 = $20.43
$20.43 x 1,237 mycobacteriology laboratories = $25,271.91

The total burden for documenting control testing for mycobacteria identification reagents and tests, and acid-fast, and fluorochrome acid-fast stains is 1,419 hours/year + 1,237 hours/year = 2,656 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 1,419 hours/year (from above) = 710 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 1,237 laboratories x 7.8 hours/year = 9,649 hours/year.

The total burden for documenting control testing for mycobacteria identification reagents and tests, acid-fast, and fluorochrome acid-fast stains is 710 hours/year + 9,649 hours/year = 10,359 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 2,656 hours/year + 10,359 hours/year = **13,015** 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:

10,092 mycology laboratories x 0.5 hours/year = 5,046 hours/year.
0.5 hours x $25.54 = $12.77
$12.77 x 10,092 mycology laboratories = $128,874.84

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:

10,092 mycology laboratories x 0.4 hours = **4,037** hours/year.
0.4 hours x $25.54 = $10.22
$10.22 x 10,092 mycology laboratories = $103,140.24

§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 20,130. Of this total, 5,912 are hospitals, 2,219 are independent laboratories, 8,254 are physician's office laboratories (POLs), and 3,746 fall into a miscellaneous category of others. 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.
8,131 hospital and independent laboratories x 9 hours/year = 73,179 hours/year.
9 hours x $25.54 = $229.86
$229.86 x 8,131 hospital and independent laboratories = $1,868,991.66

Burden: POLs

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 and the "other" category for a total of 12,000 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
12,000 laboratories x 6 hours/year = 72,000 hours/year.
6 hours x $25.54 = $153.24
$153.24 x 12,000 laboratories = $1,838,880

The total estimated burden is 73,179 hours/year (hospital and independent laboratories) + 72,000 hours/year (total POLs and "other") = **145,179** 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:

3,432 laboratories x 5 cytotechnologists x 40 hours/year = **686,400** hours/year.
40 hours x 5 cytotechnologists = 200 hours
200 hours x $25.54 = $5,108
$5,108 x 3,432 laboratories = $17,530,656.00

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

as:

10 minutes/6 months = .3 hours/year/per cytotechnologist
3,432 laboratories x 5 cytotechnologists x .3 hours/year/cytotechnologist = **5,148** hours/year.
0.3 hours x 5 cytotechnologist = 1.5 hours
1.5 hours x $25.54 = $38.31
$38.31 x 3,432 laboratories = $131,479.92

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
3,432 laboratories x 5 cytotechnologists x 40 hours/year = **686,400** hours/year.
40 hours x 5 cytotechnologists = 200 hours
200 hours x $25.54 = $5,108.00

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 3,432 laboratories = **137,280** hours/year.
40 hours x $25.54 = $1,021.60
$1,021.60 x 3,432 laboratories = $ 3,506,131.20

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.

We no longer require laboratories to, at least once each month, have each individual performing tests evaluate a previously tested specimen as an unknown to verify his or her ability to reproduce test results. Therefore, there is no reporting burden for this activity

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 **14,514,802** hours.

CFR Section	Number of Respondents	Total Annual Responses	Annual Frequency per Response	Annual Burden Hours
493.35-493.63				
493.801	34,579	103,737	3	207,474
493.803	34,579	103,737	3	103,737
493.1299	490	490	1	7,840
	152,625	1,831,500	12	5,494,500
	15,675	188,100	12	1,504,800
	168,300	2,019,600	12	2,524,500
493.1242	490	490	1	2,940
	66,033	51,464	1	21,461
493.1251	490	490	1	2,940
	66,033	79,175	1	42,921
	66,033	79,175	1	1,321
493.1252	66,033	24,102,045	365	792,396
493.1254	66,033	24,102,045	365	1,320,660

493.1255	34,579	1,798,108	52	345,790
493.1256	18,689	6,821,485	365	448,536
493.1261	20,961	251,532	12	10,481
493.1262	1,237	451,505	365	13,015
493.1263	10,092	121,104	12	5,046
	10,092	12,424	12	4,037
493.1269	20,130	7,347,450	365	145,179
493.1274	3,432	1,252,680	365	686,400
	3,432	1,252,680	365	5,148
	3,432	1,252,680	365	686,400
	3,432	1,252,680	365	137,280
TOTALS		**74,476,376**		**14,514,802**

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.

15. Program/Burden Changes

This reduction of 460,719 hours from the previous collection is a direct result from the slight decrease in enrollment of laboratories into the CLIA program. It is not related to any statute or regulatory change.

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.