Supporting Statement for the Information Collection Requirements (ICR)
Contained in the Clinical Laboratory Improvement Amendments (CLIA)
Regulations 42 CFR Part 493.801, 493.803, 493.1232, 493.1233, 493.1234, 493.1235, 493.1236, 493.1239, 493.1241, 493.1242, 493.1249, 493.1251, 493,1252, 493.1253, 493.1254, 493.1255, 493.1256, 493.1261, 493.1262, 493.1263, 493.1269, 493.1273, 493.1274, 493.1278, 493.1283, 493.1289, 493.1291, and 493.1299

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.

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 Heath Service Act.

This information collection reflects the CLIA requirements due to 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) (formerly the Health Care Financing Administration) or its designee when conducting inspections in order to determine a laboratory's compliance with the CLIA requirements. The information is also used by HHS in determining appropriateness of test classifications.

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

A 60-day Federal Register notice was published on April 13, 2007.

The Clinical Laboratory Improvement Advisory Committee (CLIAC) holds periodic meetings to discuss technical and scientific issues raised by the general public.

9. Payment/Gift To Respondent

There is no payment or gift to respondents.

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. 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 43,035 laboratories are currently affected by this requirement and that each laboratory has a burden of approximately 6 hrs/yr. We determined the number of laboratories subject to this requirement by taking the total number of laboratories, CLIA certified plus exempt (174,856), and subtracting the waived and physician performed microscopy (PPM) laboratories.

43,035 x 6 hrs/yr = **258,210** hrs/yr.

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 43,035 laboratories are affected by this requirement and that each laboratory has a burden of approximately 3 hrs/yr.

43,035 x 3 hrs/yr = **129,105** hrs/yr.

Section 493.1232 Standard: Specimen identification and integrity.

The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.

Section 493.1233 Standard: Complaint investigations.

The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate.

Section 493.1234 Standard: Communications.

The laboratory must have a system in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized individual who orders or receives test results.

Section 493.1235 Standard: Personnel competency assessment policies.

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

Section 493.1236 Standard: Evaluation of proficiency testing performance.

Under this section, all proficiency testing evaluation and verification activities must be documented.

Section 493.1239 Standard: General laboratory 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 general laboratory

system requirements specified at §§493.1231 through 493.1236 and must document all general laboratory systems assessment activities.

Section 493.1249 Standard: Preanalytic 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 preanalytic systems specified at §§493.1241 and must document all preanalytic systems assessment activities.

Section 493.1289 Standard: Analytic 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 analytic systems specified in §§493.1251 through 493.1283 and must document all analytic systems assessment activities.

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 hrs = **7840** hrs/yr.

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

70,455 POL, PPM, and "other" laboratories x 36 hrs/yr = **2,536,380** hrs/yr.

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

11,765 hospital and independent laboratories x 96 hrs/yr = **1,129,440** hrs/yr.

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 hrs x 12 months = 15 hrs/laboratory/yr

82,220 laboratories x 15 hrs/yr = **1,233,300** hrs/yr.

Section 493.1241, Standard: Test request

Under this section, the laboratory must have a written or electronic request soliciting specified information for patient testing from an authorized person. The laboratory may accept oral requests for laboratory tests if it solicits a written or electronic authorization within 30 days of the oral request and maintains the authorization or documentation of its efforts to obtain the authorization.

Section 493.1283, Standard: Test records

Under this section, the laboratory must maintain an information or record system that includes specified information; records of patient testing including, if applicable, instrument printouts, must be retained.

Section 493.1291 Standard: Test report

Under this section, the laboratory must have adequate manual or electronic systems in place to ensure that test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request.

The test report must indicate specified information. The specified information was revised to include: (1) either the patient's name and identification number or a unique patient identifier and identification number; (2) the test report date; and (3) the specimen source, when appropriate.

The laboratory must, upon request, make available to clients a list of test methods employed by the laboratory and, as applicable, the performance specifications established or verified as specified in §493.1253. In addition, information that may affect the interpretation of test results, for example test interferences, must be provided upon request. Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results.

The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminent life-threatening condition, or panic or alert values.

If a laboratory refers patient specimens for testing, the referring laboratory must retain or be able to produce an exact duplicate of each testing laboratory's report. The authorized person who orders a test must be notified by the referring laboratory of the name and address of each laboratory location where the test was performed.

When errors in the reported patient test results are detected, the laboratory must do the following:

(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors.

(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results.

(3) Maintain duplicates of the original report, as well as the corrected report.

These requirements do not impose any additional burden. Laboratories that were regulated previous to the CLIA requirements of 1992 were already subject to these requirements and did not acquire additional burden. Also, the CLIA requirements were patterned after the standards used by accrediting organizations and states with licensure programs, resulting in these CLIA requirements being the minimum standard practice for laboratories. These CLIA requirements were also developed with a great deal of flexibility so that a physician in a physician's office laboratory may use the information normally recorded in the patient's chart to meet them. We have discussed these requirements with professional organizations and members of industry who all agree these requirements are a customary standard of practice. Therefore, any burden is exempt from the PRA.

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 = **2940** hrs.

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:

82,220 non-waived laboratories x 65% = 53,443 laboratories

53,443 laboratories x 0.5 hrs = **26,722** hrs/yr.

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 hrs = **2940** hours/laboratory

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:

82,220 non-waived laboratories x 65% = 53,443 laboratories x 1 hr/yr = **53,443** hrs/yr.

Testing procedures must be reapproved, signed and dated if there is a change in laboratory director. 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:

82,220 non-waived laboratories x 2% = 1,644 laboratories x 1 hr/yr = **1,644** hrs./yr.

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 hr/month x 12 months/yr = 12 hrs/laboratory/yr

The total estimated burden for this requirement is:

82,220 non-waived laboratories x 12 hrs/yr = **986,640** hrs/yr.

Section 493.1253, Standard; Establishment and verification of performance specifications.

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must, before reporting patient test results, demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the specified performance characteristics.

In addition, each laboratory that uses a test system in which performance specifications are not provided by the manufacturer, modifies an FDA-cleared or approved test system or introduces a test system not subject to FDA clearance or approval (includes standardized methods and methods developed in-house) must, before reporting patient test results, establish for each test system the performance specifications for specified performance characteristics.

Based upon the performance specifications verified or established, the laboratory must determine calibration procedures and control procedures. Also, the laboratory must have documentation of the laboratory's performance of all activities specified in this section.

This is a 2-part requirement and will affect laboratories differently depending on whether they are

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

Section 493.1254, 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 min/day x 20 days/month = 100 min/month or 1.7 hrs/month

1.7 hrs/month x 12 months/yr = 20 hrs/yr x 82,220 non-waived laboratories = **1,644,400** hrs/yr.

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/yr.

43,035 non-waived laboratories x 10 hours/yr = **430,350** hrs/yr.

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 min/day x 24 days/month = 120 min/month = 2 hrs/month

2 hrs/month x 12 months/yr = 24 hours/ laboratory/yr.

The total estimated burden for this requirement is:

27,685 laboratories (total number of laboratories minus the number of waived laboratories, PPM laboratories and previously regulated laboratories) x 24 hrs/yr = **664,440** hrs/yr.

§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 min./day x 1 day/month = 2.5 min./month. 2.5 min../month x 12 months/year = 30 min../laboratory/yr. (or .5 hrs/laboratory/yr.)

The estimated total burden for documenting control testing for the reagents above is 27,443 bacteriology laboratories x .5 hrs./yr. = **13,721.5** hrs./yr.

§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 min/day x 8 days/month = 16 min./month = 0.27 hrs./month x 12 months/yr. = 3.24 hrs./laboratory/yr.

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

As mentioned previously, the regulation also requirs 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 min/day x 4 days/month = 4 min./month x 12 months/yr. = 48 min./laboratory/yr. = 0.8 hrs./laboratory/yr.

The total estimated burden for documenting control testing for acid-fast and fluorochrome acid-fast stains is 3,185 mycobacteriology laboratories x 0.8 hrs./yr. = 2,548 hrs./yr.

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

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 3,651 hrs./yr. (from above) = 1,826 hrs./yr.

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 min/day x 26 days/month = 39 min./month = 0.65 hrs./month x 12 months/yr. = 7.8 hrs./laboratory/yr.

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

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

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 6,199 hrs./yr. + 26,669 hrs./yr. = **32,868** hrs./yr.

§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/yr.

The total estimated burden for this requirement is:

9059 mycology laboratories x 0.5 hours/yr. = **4, 530** hours/year.

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:

9059 mycology laboratories x 0.4 hours = **3,624** hours/year.

§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 32,753. Of this total, 5,329 are hospitals, 3,867 are independent laboratories, 17,844 are physician's office laboratories (POLs), and 5,713 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 min./day x 30 days/month = 45 min./month = .75 hrs./month

.75 hrs./month x 12 = 9 hrs./laboratory/yr.

9,196 hospital and independent laboratories x 9 hrs./yr. = 82,764 hrs./yr.

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 23,557 laboratories Therefore, the burden for these laboratories is:

1.5min./day x 20 days/month = 30 min./month = 0.5 hrs./month
0.5hrs./month x 12 months/yr. = 6 hours/laboratory/yr.
23,557 laboratories x 6 hours/yr. = 141,342 hrs./yr.

The total estimated burden is 82,764 hrs./yr. (hospital and independent laboratories) + 141,342hrs./yr. (total POLs and "other")= **224,106**hrs./yr.

§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.

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

10 min./day x 20 days/month = 200 min./month = 3.3 hrs./month/per cytotechnologist
3.3 hrs./month x 12 months/yr = 40 hrs./yr./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:

4478 laboratories x 5 cytotechnologists x 40 hrs/yr = **895,600** hrs/yr.

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

10 min./6 months = .3 hr./yr./per cytotechnologist
4478 laboratories x 5 cytotechnologists x .3 hr/yr/cytotechnologist = **6717** hrs./yr.

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

10 min./day x 20 days/month = 200 min./month = 3.3 hrs./month
3.3 hrs./month x 12 months/yr = 40 hrs./cytotechnologist/yr.
4478 laboratories x 5 cytotechnologists x 40 hrs./yr. = **895,600** hrs./yr.

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

10 min./day x20 days/month = 200 min./month = 3.3 hrs./month
3.3 hrs./month x 12 months/yr = 40 hrs./laboratory/yr.
40 hrs./yr. x 4478 laboratories = **179,120** hrs./yr.

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.

Total total aggregate burden for all of the requirements under #12 in the supporting statement is 11,363,680 hours.

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

There are no program changes. There has been a slight increase in burden based on new calculations for labs under Section 493.1274 Cytology. In the former burden write-up (2004), we only spoke about the 30% of total Cytology labs that we anticipated to be affected by the 2003 CLIA Final Rule. At that time (2004), we estimated that 70% of the Cytology labs were already in compliance; therefore, we did not include all of those hours for that population. We have now calculated the burden using the entire universe of Cytology labs which total 4,478. This is the reason for the burden increase. The number of annual responses shows a decrease of 15,927,295. This is due to the way the numbers were calculated for this submission. Unfortunately, we were unable to duplicate a calculation to show how the prior analyst arrived at 111,354,920 annual responses in the 2004 package. We believe the newly reflected total annual responses (95,427,625) is a more accurate representation.

16. Publication and Tabulation Dates

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

17. Expiration Date

There are no forms involved with the information collection; therefore, this item is not applicable.

18. Certification Statement

There are no exceptions to the certification statement.

C. Collection of Information Employing Statistical Methods

There are no statistical methods connected with this collection.