Supporting Statement for the Laboratory Personnel Report (CLIA)
(CMS-209) and Supporting Regulations in
42 CFR 493.1 – 403.201

A. Background

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

The Form CMS-209 is used by CLIA surveyors to collect information about laboratory personnel positions each time a survey is performed.

For this submission, we are making minor revisions to the collection instrument.
We revised the instructions for clarity and removed the references to specific regulations.

B. Justification

1. Need and Legal Basis

   The information collected on this form is used in the administrative pursuit of the Congressionally-mandated program with regard to regulation of laboratories participating in CLIA.

   Legislative regulatory authority for this activity is Public Law 100-578.

   To determine compliance, the Secretary has authorized States [in Section 1864(a) of the Social Security Act] through contracts to conduct inspection of laboratories under CLIA. In order for the State survey agency to report to CMS its findings on facility compliance with the individual standards on which CMS determines compliance, the laboratory completes the Laboratory Personnel Report (CLIA) (CMS-209) form.

   The CMS-209 requires an estimated range from 5 minutes to 45 minutes to complete. There are approximately 16,404 laboratories in the CLIA database that require a State survey for determining CLIA compliance. An average time of 30 minutes for form completion was calculated. Without this form, the surveyor would need access to each individual personnel file and would then need to possibly examine the entire file to obtain qualifying data. Often personnel files may be in a locked area and may not be available to the surveyor in a timely manner resulting in deficiencies and possibly re-inspection of a laboratory, thus increasing the cost of the inspection process. In cases of multiple site laboratories, this process could become even more time consuming as the personnel files may not be at the site being inspected.

The surveyor will provide the laboratory with the CMS-209 form prior to or during the CLIA inspection. The laboratory completes the CMS-209 by recording the personnel data needed to support their compliance with the personnel requirements of CLIA. The CLIA surveyor uses the information submitted on the CMS-209 to verify compliance with the CLIA personnel requirements.

2. Information Users

The CMS-209 form is used by the laboratory to report the names and positions of personnel serving as director, technical consultant, clinical consultant, technical supervisor, general supervisor, cytology general supervisor, cytotechnologist, and testing personnel in the laboratory. Information on the qualifications for moderate or high complexity testing is also collected. Personnel information is not required for non-technical staff (i.e., clerical, billing, phlebotomists, etc.). CLIA surveyors use the information collected on the CMS-209 to verify and document compliance with the CLIA personnel requirements.

3. Improved Information Technology

The signature of the director is required on this form. Since the laboratory director of a laboratory often changes, the current laboratory director's signature is needed to attest to the accuracy of their laboratory's compliance with the CLIA personnel requirements. Currently, the CMS-209 form is available on the Internet at https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS209.pdf and is in a 'fillable' format so that the applicant can more easily download and complete the form.

4. Duplication of Similar Information

This form does not duplicate any information currently collected. It contains information essential to the operation of the CLIA program.

5. Small Businesses

This application form does not significantly affect small businesses. We believe that the number of small business entities is similar to the number of low volume A CLIA certificate of compliance facilities. As of June 2024, there are 6,347 low volume A CLIA certificate of compliance facilities. To reduce impact to small businesses, the form was designed to only collect the information necessary to establish compliance with the CLIA regulations.

6. Less Frequent Collection

Under CLIA, laboratories are required to be inspected once every 2 years. This collection is essential for the CLIA inspection process and cannot be collected less

frequently.

7. Special Circumstances
   There are no special circumstances associated with this collection.

8. Federal Register/Outside Consultation

   The 60-day Federal Register notice published on January 3, 2025 (90 FR 320). There was one comment submitted but it was incomplete.

   The 30-day Federal Register notice published on May 12, 2026 (90 FR 20166).

   No other outside consultation was sought.

9. Payment/Gift to Respondents

   There are no payments or gifts to respondents associated with this collection.

10. Confidentiality

    Data will be kept private to the extent allowed by law.

11. Sensitive Questions

    There are no questions of a sensitive nature associated with these forms.

12. Burden Estimate (Total Hours and Wages)

    This form contains the information necessary for laboratories to demonstrate their compliance with the CLIA personnel qualification regulations. We anticipate the time requirement for completion of this form to range between 5 and 45 minutes. The average length of time to report this information is 30 minutes. Since CLIA inspections are biennial (i.e., a CLIA inspection occurs once every two years), the annual frequency is 0.5 times a year per laboratory respondent. Based on the number of laboratory respondents as 16,404 the following computations are appropriate.

    Hourly Burden computation
    16,404 (laboratories) (biennial review)/2 = 8,202 laboratories per year X 0.50 hours per response = 4,101annual burden hours

    Wage Burden computation for laboratory

    We projected the hourly wage of laboratory staff completing the CMS-209 form to be $58.44. Based on the type of information requested on the form, we assumed that a mid-level Clinical Laboratory Technologists/Technicians would be completing the form with the final sign-off and approval from the laboratory director. According to the U.S.

Bureau of Labor Statistics the mean hourly wage for U.S. Clinical Laboratory Technologists and Technicians in May 2023- (https://www.bls.gov/oes/current/oes292010.htm), was $29.22. We believe the mean hourly wage of a laboratory technologist or technician would be appropriate and would include a 100% fringe.

The cost would be $239,662.44 (4,101 annual hours X $58.44).

Table 1. Wage Burden computation table.

Number of Respondents Annually	*Hours per Response Annually*	*Total Burden Hours Annually*	*Total Cost Annually*
8,202	*0.5*	*4,101*	*$239,662.44*

13. Capital Costs (Maintenance of Capital Costs)

There is no capital cost associated with this collection.

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-13 so the cost to the federal government will be approximately $70.00 per hour. It will take approximately 10 hours for a total cost of $14,000 (hourly wage ($70.00 x 2 (overhead and fringe benefits) X 10 X 10).

15. Program or Burden Changes

The changes in burden are the result of an increase in the hourly wage of laboratory staff completing the CMS-209 form to $58.44 from $52.68 and a decrease in the number of compliance laboratories from 19,163 to 16,404. The burden hours decreased from 4,791 to 4,101. The wage burden decreased from $252,390 to $239,662.44.

16. Publication/Tabulation Dates

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

17. Expiration Date

CMS will display the expiration date on the collection instrument.

18. Certification Statement

There are no exceptions to the certification statement.