

PAPERWORK REDUCTION ACT SUBMISSION WORKSHEET
Part II: Information Collection Detail

This template is intended for staff without an ICRAS account. Please fill out and submit to the appropriate Operating Division to enter into ICRAS. The form mirrors the screens available in the ICRAS 4 system. To request an account to log into ICRAS.

Instructions for filling out the form are available at www.paperworkreduction.gov.

1. Title CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) and the ICRs contained in the supporting regulations in 42 CFR 493.1-2001 (CMS-R-26)		
2. Is this a Common Form? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	3. Obligation to respond (<i>check one</i>) a. <input type="checkbox"/> Voluntary b. <input type="checkbox"/> Required to obtain or retain benefits c. <input checked="" type="checkbox"/> Mandatory	4. Frequency of reporting (<i>check all that apply</i>) a. <input type="checkbox"/> Hourly (24 -7) b. <input type="checkbox"/> Hourly Bus (40 per week) c. <input type="checkbox"/> Daily (7 per week) d. <input type="checkbox"/> Daily Bus (5 per week) e. <input type="checkbox"/> Weekly (52 per year) f. <input type="checkbox"/> Monthly g. <input type="checkbox"/> Yearly h. <input type="checkbox"/> Every Decade i. <input type="checkbox"/> Quarterly j. <input type="checkbox"/> Semi-annually k. <input type="checkbox"/> Biennially l. <input type="checkbox"/> Once m. <input checked="" type="checkbox"/> occasionally (Recordkeeping- Only as Needed)
5. CFR Citation(s) for the information collection under review (if applicable).		
Title CFR 42 Part 493 Section .1-2001 Title _____ Part _____ Section _____ Title _____ Part _____ Section _____ Title _____ Part _____ Section _____		
6. Information Collection Instruments - Send all instruments along with the Part 2 form(s). If more than one Part 2 is completed make sure to identify which instruments are associated with which Part 2 form.		
7. Federal Enterprise Architecture Business Reference Model (Select one Services for Citizens Line of Business and one Subfunction from its group)		
Services for Citizens Line of Business	Subfunction	
None		
Community and Social Services__	Homeownership Promotion __ Community and Regional Development __ Social Services __ Postal Service __ None __	
Correctional Activities__	Criminal Incarceration	

	Criminal Rehabilitation None
Defense and National Security__	Strategic National and Theater Defense __ Operational Defense __ Tactical Defense __ None__
Disaster Management__	Disaster Monitoring and Predication __ Disaster Preparedness and Planning __ Disaster Repair and Restore __ Emergency Response __ None__
Economic Development__	Business and Industry Development __ Intellectual Property Protection __ Financial Sector Oversight __ Industry Sector Income Stabilization __ None__
Education__	Elementary, Secondary, and Vocational Education __ Higher Education __ Cultural and Historic Preservation __ Cultural and Historic Exhibition __ None__
Energy__	Energy Supply __ Energy Conservation and Preparedness __ Energy Resource Management __ Energy Production __ None__
Environmental Management__	Environmental Monitoring and Forecasting __ Environmental Remediation __ Pollution Prevention and Control __ None__
General Science and Innovation__	Scientific and Technological Research and Innovation __ Space Exploration and Innovation __ None__
Health X __	Illness Prevention __ Immunization Management __ Public Health Monitoring __ Health Care Services __ Consumer Health and Safety __ None X __
Homeland Security__	Border and Transportation Security __ Key Asset and Critical Infrastructure Protection __ Catastrophic Defense __ None__
Income Security__	General Retirement and Disability __ Unemployment Compensation __ Housing Assistance __ Food and Nutrition Assistance __ Survivor Compensation __ None__
Intelligence Operations__	Intelligence Planning and Direction/Needs __ Intelligence Collection __ Intelligence Analysis and Production __ Dissemination __ None__
International Affairs and Commerce__	Foreign Affairs __ International Development and Humanitarian Aid __ Global Trade __ None__
Law Enforcement__	Criminal Apprehension __ Criminal Investigation and Surveillance __ Citizen Protection __ Crime Prevention __ Leadership Protection __ Property Protection __ Substance Control __ None__
Litigation and Judicial Activities__	Judicial Hearing __

	Legal Defense ___ Legal Investigation ___ Legal Prosecution and Litigation ___ Resolution Facilitation ___ None ___
Natural Resources ___	Water Resource Management ___ Conservation, Marine and Land Management ___ Recreational Resource Management and Tourism ___ Agricultural Innovation and Services ___ None ___
Transportation ___	Air Transportation ___ Ground Transportation ___ Water Transportation ___ Space Operations ___ None ___
Workforce Management ___	Training and Employment ___ Labor Rights Management ___ Worker Safety ___ None ___

See <http://www.feapmo.gov> for the Business Reference Model categories and definitions.

8. Privacy Act System of Records (if applicable)

Title: _____

Federal Register Citation: Volume _____ Page number _____ Publication date ____/____/____

9. Respondents

- a. Total # **10,121.28** _____
- b. Small Entity # _____
- c. Percent Electronic **0** _____

Affected public (choose one)

- a. ___ Individuals or households
 - b. ___ Private Sector
 - c. State, Local, or Tribal Governments
 - d. ___ Federal Government
- (if Private Sector check all that apply)
- a. ___ Business or other for-profits
 - b. ___ Not-for-profit institutions
 - c. ___ Farms

10. Frequency: How often on average will each respondent respond to the Information Collection?

- Number of Responses per Respondent **4.4830752**
- Per (select the most appropriate time period for this collection)
- a. ___ Hour (24-7) - 8736 per year
 - b. ___ Business Hour (40 per week) - 2080 per year
 - c. ___ Day (7 per week) - 364 per year
 - d. ___ Business Day (5 per week) - 260 per year
 - e. ___ Week - 52 per year
 - f. ___ Month - 12 per year
 - g. Year
 - h. ___ Decade .1 per year
 - i. ___ Quarter - 4 per year
 - j. ___ Half-Year - 2 per year
 - k. ___ Biennial - 0.5 per year

Calculated: Annual Frequency = **4.4830752** times a year (per respondent)

Calculated: Annual Number Of Responses = **45,374.459** a year

11. Hour and Cost Burden

Enter the hours and cost (per response) broken out by reporting, record keeping, and third-party disclosure.

	Time per Response	Hour per response	Annual Hour Burden	Cost per Response	Annual cost Burden
Reporting					
Record keeping			681,820.8	0	0
Third party disclosure					
Total					

12. Allocate the change in burden

	Total Requested	Change Due to New Statute	Change Due to Agency Discretion	Due to Agency Estimate	Change Due Violation	Currently Approved
a. Annual Responses						
b. Annual Hour Burden	hours	hours	hours	hours	hours	hours
c. Annual Cost Burden	\$	\$	\$	\$	\$	\$