PAPERWORK REDUCTION ACT SUBMISSION WORKSHEET
Part I: Information Collection Request

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. Agency/Subagency originating request
DHHS/CMS/CMSO/SCG/DLS

2. Title **CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) and the ICRs contained in the supporting regulations in 42 CFR 493.1-.2001 (CMS-R-26)**

3. Type of information collection *(check one)*
(See instructions)
__ New collection (Request for a new OMB Control Number)
X Extension without change of a currently approved collection
__Revision of a currently approved collection
__ Reinstatement without change of a previously approved collection
__Reinstatement with change of a previously approved collection
__Nonmaterial or nonsubstantive change to a currently approved collection (formerly 83C)
__ Existing collection in use without and OMB Control Number

4. OCN: **0938-0612**_____ __ __

5. Type of review requested *(check one)*

a. **X** Regular
b. __ Emergency - Approval requested by: _____/_____/_____
c. __ Delegated

If Emergency, please attach justification.(4000 characters maximum)

6. Requested expiration date *(check one)*

a. **X** Three years from approval date
b. __ Six Months from approval date (Maximum for Emergency reviews)
c. Other

Specify:_____/_____ (mm/yy)
or Number of Months from Approval Date

7. Abstract (4000 characters maximum, attach additional sheets as necessary)
The ICRs referenced in 42 CFR Part 493 outline the requirements necessary to determine an entity's compliance with CLIA. CLIA requires laboratories that perform testing on human beings to meet performance requirements (quality standards) in order to be certified by HHS. HHS conducts inspections to determine a laboratory's compliance with CLIA requirements. CLIA implements the certificate, laboratory standards and inspection requirements.

8. Authorizing Statute(s)

Public Law: Amendment to Public Law Public Health Service Act 353

Congress Number	Sequence Number	Section	Name
100th	**578**		

US Code:

Title	Section	Name
42 CFR	**Part 493**	**Laboratory Requirements**

Executive Order:

Number	Name

Statute:

Title	Subtitle

9. Associated Rulemaking Information
RIN: __ __ __ __ - __ __ __ __

Stage of Rulemaking *(check one)*
a. __ Proposed Rule
b. __ Interim Final or Final Rule

Federal Register Citation
Volume__ __ Page number_____ __ __ __
Publication Date _____/_____/____

For a Proposed Rule, OMB will not consider an ICR complete until the Notice of Proposed Rulemaking has been published.
For a Final Rule, please put the ICR reference number for the ICR reviewed at the proposed rule stage in Box 4.
For ICRs associated with Interim Final or Final rules that are not significant under EO

10. Federal Register Notices & Comments

Federal Register Citation

60-day Notice: Volume__ __ Page number __ __ __ __ __ __ Publication Date _____/_____/_____

30-day Notice: Volume__ __ Page number __ __ __ __ __ __ Publication Date _____/_____/_____

Did the Agency receive public comments on this ICR? _Yes _No
Unless submitted as an Emergency or Associated with Rulemaking, OMB will not consider an ICR complete until the 30-day notice has been published.
12866, please attach a draft of the Federal Register document.

11. Annual Cost to Federal Gov:

$ **0**

12. Does this ICR contain surveys, censuses, or employ statistical methods?
__ Yes (Attach Part B of Supporting Statement) **X** No

13. Is the Supporting Statement intended to be a Privacy Impact Assessment required by the E-Government Act of 2002?
__ Yes **X** No

14. Agency contact:
Name: Raelene Perfetto
Phone: 410-786-6876
E-mail: Raelene.perfetto@cms.hhs.gov

PAPERWORK REDUCTION ACT SUBMISSION WORKSHEET
Part I: Information Collection Request (continued)
Information Collection Budget (ICB)

If a change in burden is due to a Program Change Due to New Statute, identify the Citations for New Statutory Requirements:

Public Law:

Congress Number	Sequence Number	Section	Name

US Code:

Title	Section	Name

Executive Order:

Number	Name

Statute:

Title	Subtitle

If Program Change is due to Agency Discretion, please categorize the reduction. Burden reduction from (select one):

a. __ Cutting Redundancy
b. __ Using Information Technology
c. __ Changing Regulations
d. __ Changing Forms
e. __ Miscellaneous Actions

If Program Change is due to Agency Discretion, please categorize the increase in burden. Burden increase caused by (select one):

a. __ Changing Regulations
b. __ Miscellaneous Actions

Explain the reasons for any program changes or adjustments reported; that is, provide a short statement how the reduction in burden was achieved or why the increase in burden occurred. (If you need more space, please provide a short summary here and elaborate in the Supporting Statement.)

_____
_____
_____
_____
_____