Frequently Asked Questions- Reapplication 2022

Please note that all clinical laboratory permits expire on June 30, 2022.

Reapplication submissions are due by 5pm on April 29, 2022, unless an extension is requested and approved.

Reapplication instructions have been posted on the web (effective 4/11/2022) as a Program Updates item on the CLEP landing page https://www.wadsworth.org/regulatory/clep. The posting also includes a copy of the eCLEP Manual, the 2022-2023 Permit Category Descriptions, the Test Volume Reporting Guidelines, and the Ownership Attestation Quick Guide.

Q) I cannot access eCLEP for my laboratory. Can you help?

Q) My laboratory is pending a NYS permit, do we have to complete the permit reapplication?

Q) Is there a User Manual for eCLEP?

Q) Where can I get the Disclosure of Ownership, Controlling Interest and Corporate Membership form? It was not included with the reapplication email.

Q) What do I need to submit for enrollment in a federally-approved Cytopathology Proficiency Testing Program?

Q) Can I have an extension beyond the April 29, 2022 deadline?

Q) Does the completion of the Point-of-Care Testing questions fulfill requirements for renewal of my Limited Service Laboratory Registration?

Q) I submitted my reapplication in eCLEP and have discovered a mistake, how do I make these additional changes?

Q) Where can I get a list of my laboratory's Patient Service Centers (PSCs)?

Q) The reapplication does not include the facility personnel form. Should I send a spreadsheet or list documenting personnel performing testing at my laboratory?

Q) I have not yet received my Gross Annual Receipts Reporting form. When will this be mailed?

Q) I have not received instructions on submitting a Blood Services Activity Report. Where is the form, when is it due and how do I submit?

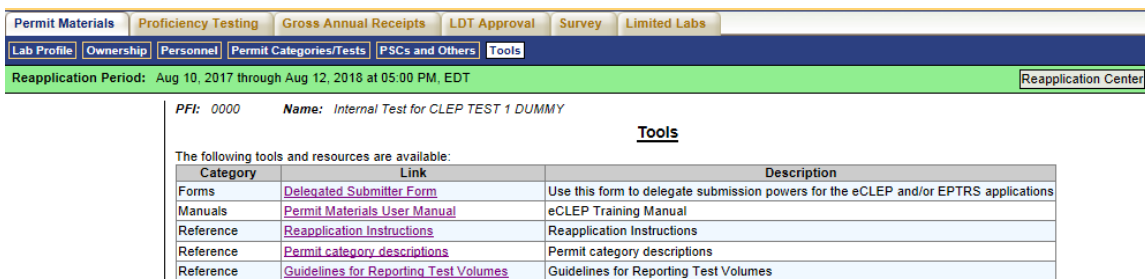**Q) I cannot access eCLEP for my laboratory. Can you help?**

A)
1. Do you have a Health Commerce System account? **If yes, go to question 2.** If no, register for an account at https://commerce.health.state.ny.us. Once registered, contact your laboratory's HCS Coordinator to affiliate your account with the laboratory's HCS record. The laboratory director is a HCS Coordinator. There may be other individuals designated as HCS Coordinators at your laboratory. NOTE: An HCS Coordinator does not have access to eCLEP unless he/she is also a Delegated Submitter.

2. HCS Coordinator instructions after user registers for an account:
   > Log on to the HCS
   > Click on Coord Account Tools – HCS under My Applications
   > Click on User under "Request an account for…"
   > Select Yes, they have a Valid Photo ID
   > Select your organization in the list
   > Enter the user's HCS Id, click Submit
   >> Note: HCS Id to be provided by user
   > Enter the user's information from the Photo ID, click Submit
   >> Note: The information must match exactly. If the ID is not a NYS driver license, please enter the ID number in the Comments field.
   > Enter the user's contact information (fields marked with an asterisk are required), click Submit
   > The user is enrolled on the HCS.

3. Can you access the Health Commerce System? **If yes, go to question 4.** If no, please contact the Commerce Account Management Unit (CAMU) at (866) 529-1890 for login and/or password issues.

4. Does eCLEP appear under the heading My Applications on the left of the screen? **If yes, go to question 7. If no, go to question 5.**

5. Has your account been affiliated with the laboratory's record by your laboratory's HCS Coordinator? Ask your HCS Coordinator to verify. **If yes, go to question 6**. If no, your HCS Coordinator must affiliate your account using their Coordinator Tools in HCS. Proceed to question 5.

6. Has the laboratory director completed and submitted a Delegated Submitter form to grant you permission to access eCLEP on his/her behalf? If Yes, please allow 2-3 business days for this form to be processed. If No, download the Delegated Submitter form from https://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/health-commerce, complete, and submit to clep@health.ny.gov.

7. When you click the word eCLEP under My Applications in the HCS, does it take you to the appropriate laboratory record? If Yes, congratulations! You are appropriately configured for eCLEP access. If No and you should have access to more than one site, please have the HCS Coordinator for each laboratory affiliate your HCS account with each laboratory record. A Delegated Submitter form must be submitted for each laboratory.

Q) My laboratory is pending a NYS permit, do we have to complete the permit reapplication?

A) Yes! All laboratories in applied status are required to submit a permit re-application to maintain enrollment in the Program and remain eligible for a New York State clinical laboratory permit.

Q) Is there a User Manual for eCLEP?

A) Yes, an eCLEP Permit Materials User Manual is available under the Tools section of eCLEP.

The eCLEP Permit Materials Manual is also available at https://www.wadsworth.org/regulatory/clep/clinical-labs/change-permit.

Q) Where can I get the Disclosure of Ownership, Controlling Interest and Corporate Membership form? It was not included with the reapplication email.

A) Laboratories are not required to upload a separate Disclosure of Ownership, Controlling Interest and Corporate Membership Statement, <u>unless they are reporting a change in ownership</u>.

Laboratories reporting a change in ownership must upload a completed Disclosure of Ownership, Controlling Interest and Corporate Membership Statement in the List of Owners upload field in eCLEP. This is found under the Ownership tab, Upload link on the left. The Disclosure form is available on our public website at **https://www.wadsworth.org/regulatory/clep/clinical-labs/change-permit.**

All Laboratories are **required** to provide a list of all owners of the laboratory. Follow the instructions provided in the eCLEP Permit Materials User Manual. The manual is available on our Permit Modifications section of our website at **https://www.wadsworth.org/regulatory/clep/clinical-labs/change-permit** and under the Tools tab on the blue task bar in eCLEP.

Q) What do I need to submit for enrollment in a federally-approved Cytopathology Proficiency Testing Program?

A) The laboratory must upload a copy of their enrollment confirmation from a CMS-approved proficiency testing provider for a test to be taken in 2021 for Cytopathology – Gynecological Testing. The enrollment confirmation must reference the laboratory name and address. The PFI number of the laboratory must be handwritten on the paper if the CLIA number is not already included.
While participants may perform the PT off-site, each laboratory performing gynecological cytopathology is still required under CLIA regulations to enroll in a PAP PT event. Contact your PT vendor for information on 'paper enrollment'. For example, Ordering the 'PAPPT ENROLLMENT ONLY, LABORATORY – PPTENR' Survey from the College of American Pathologists, enables CAP to verify your PT participation at another site and satisfies this requirement.

Q) Can I have an extension beyond the April 29, 2022 deadline?

A) Yes! Please use the new Extension Date Request feature in eCLEP that is described in the eCLEP Permit Materials User Manual, available at https://www.wadsworth.org/regulatory/clep/clinical-labs/change-permit and under the Tools tab on the blue task bar in eCLEP. **Note**: REQUESTED SUBMISSION DATES LATER THAN JUNE 3, 2022 WILL BE REJECTED. Contact clepcert@health.ny.gov if the laboratory is not able to submit a permit reapplication by June 3, 2022.

Q) Does the completion of the Point-of-Care Testing questions fulfill requirements for renewal of my Limited Service Laboratory Registration?

A) No. The Limited Service Laboratory Registration renewal process is separate from the laboratory permit process. Renewal materials for the Limited Service Laboratory Registration are mailed in hard copy via postal service approximately four months prior to the Registration expiration date. Limited Service Laboratory registrations are issued on a rotating basis and therefore have different expiration dates.

Q) I submitted my reapplication in eCLEP and have discovered a mistake, how do I correct the mistake or additional changes?

A) Please submit a request to re-open eCLEP in writing to clepreapp@health.ny.gov. eCLEP will be re-opened in 1-2 business days.

Q) Where can I get a list of my laboratory's Patient Service Centers (PSCs)?

A) Patient Service Center (PSC), Health Fair (HF) and Transfer Station (TS) reapplications are completed in eCLEP under the PSCs and Others Tab. A list of all PSCs on file with CLEP can be generated from the PSC and Others tab in eCLEP. Please refer to page 57 of the eCLEP Manual (available at https://www.wadsworth.org/regulatory/clep/clinical-labs/change-permit).

Q) The reapplication does not include the facility personnel form. Should I send a spreadsheet or list documenting personnel performing testing at my laboratory?

A) Please do not send any facility personnel information at this time. Surveyors will continue to collect the facility personnel information during the on-site survey. If additional information is required, we will contact you.

Q) I have not yet received my Gross Annual Receipts Reporting form. When will this be mailed?

A) The reporting of Gross Annual Receipts (GAR) is now performed in eCLEP. On the eCLEP home page, under Gross Annual Receipts, click on Reporting. An eCLEP Gross Annual Receipt User Manual is available from the menu choices on the left of the GAR Home Page. The Manual is also posted at https://www.wadsworth.org/regulatory/clep/clinical-labs/laboratory-fees. The GAR Report is due on May 15, 2022.

==Submission deadline extensions may be requested using the Extension Request feature in eCLEP.==
Log into the Health Commerce System, click on eCLEP, click on Extension Date Request under Tools.
    Extension Request for: choose "Gross Annual Receipts"

New Date: enter date requested

Reason: provide a brief justification for the extension

Note: REQUESTED SUBMISSION DEADLINE EXTENSIONS LATER THAN JUNE 3, 2022 WILL BE REJECTED. Contact clep@health.ny.gov if the laboratory will be unable to report GAR by June 3, 2022.

Q) I have not received instructions on submitting a Blood Services Activity Report. Where is the form, when is it due and how do I submit?

A) The Blood Service Activity Report is collected and submitted in eCLEP. On the eCLEP home page, under Blood Resources, click on BSAR. Follow the instructions on each page to complete the form and submit the report. The BSAR is due on May 15, 2022.

<mark>Submission deadline extensions may be requested using the Extension Request feature in eCLEP.</mark> Log into the Health Commerce System, click on eCLEP, click on Extension Date Request under Tools.

Extension Request for: choose "Blood Services Activity Report"

New Date: enter date requested

Reason: provide a brief justification for the extension

Note: REQUESTED SUBMISSION DEADLINE EXTENSIONS LATER THAN JUNE 3, 2022 WILL BE REJECTED. Contact clep@health.ny.gov if the laboratory will be unable to submit the BSAR by June 3, 2022.