Frequently Asked Questions- Reapplication 2020

PLEASE NOTE THAT ALL CLINICAL LABORATORY PERMITS EXPIRE ON JUNE 30, 2020. AN APPLICATION TO RENEW MUST BE SUBMITTED IN ORDER TO ALLOW TESTING TO CONTINUE BEYOND JUNE 30, 2020.

Reapplication submissions are due by 5pm on June 12, 2020, unless an extension is requested and approved. Under no circumstances will an extension be granted beyond June 26, 2020.

Reapplication instructions have been posted on the web 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 2020-2021 Permit Category Descriptions and the Test Volume Reporting Guidelines.

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

3. Does eCLEP appear under the heading My Applications on the left of the screen? **If yes, go to question 6. If no, go to question 4.**

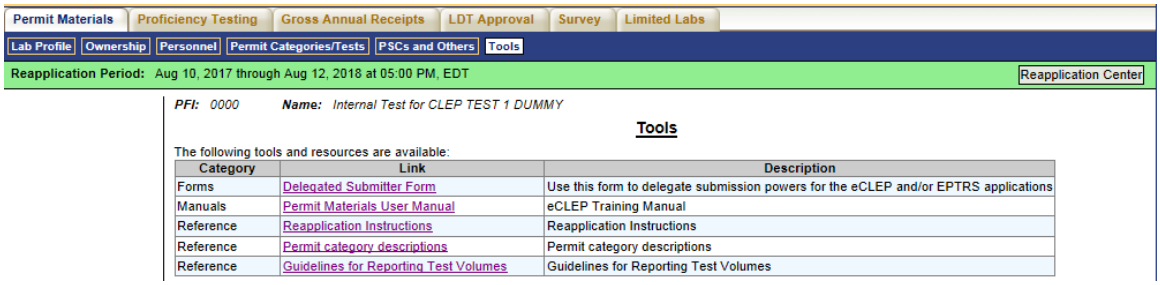
4. Has your account been affiliated with the laboratory's record by your laboratory's HCS Coordinator? Ask your HCS Coordinator to verify. **If yes, go to question 5**. If no, your HCS Coordinator must affiliate your account using their Coordinator Tools in HCS. Proceed to question 5.

5. 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.

6. 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) 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, unless they are reporting a change in ownership.

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 2020 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 June 12, 2020 deadline?

A) Yes! Please submit your request in writing to clep@health.ny.gov. No extensions will be granted beyond June 26, 2020.

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 approximately three 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 make these additional changes?

A) Please submit your request in writing to clep@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)?

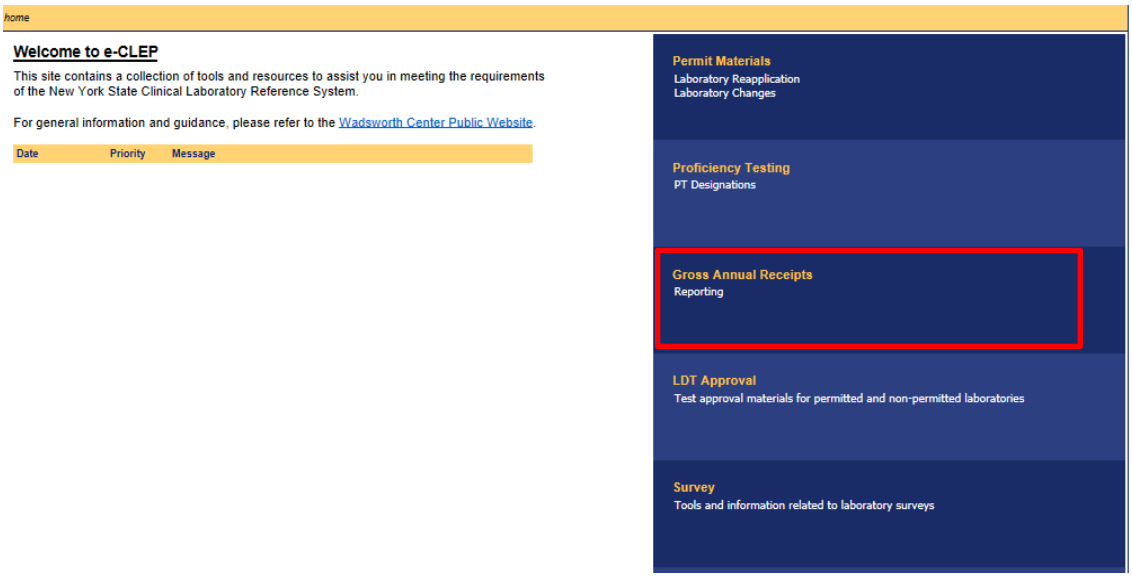
A) Patient Service Center (PSC), Health Fair (HF) and Transfer Station (TS) reapplications are completed in eCLEP under the PSCs and Others Tab. No hard-copy reapplications were mailed to laboratories. A list of all PSCs on file with CLEP can be generated from the PSC and Others tab in eCLEP. Please refer to page 59 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. From the eCLEP home page, click on the words "Gross Annual Receipts" on the right of the page. 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.



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