eCLEP Manual

Permit Materials Module

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Introduction

The purpose of this manual is to provide clinical laboratories with the information needed to begin using the web-based, electronic clinical laboratory information management tool, eCLEP. It includes the following major sections:

- **Getting Started: An Overview** introduces a laboratory to eCLEP.
- **Requirements for Use** provides hardware and software specifications and configuration settings required to access eCLEP.
- **Navigating in eCLEP** provides detailed directions for accessing eCLEP and entering data.
- **Reapplication Submissions** provides detailed instructions for submitting the clinical laboratory permit reapplication.
- **Open Mode Submissions** provides detailed instructions for submitting changes in facility information outside of the permit reapplication period.

Getting Started: An Overview

The New York State Department of Health (NYSDOH) has developed eCLEP to enable clinical laboratories to exchange information electronically in place of mailing paper forms. This web-based application supports the inquiry, maintenance, and reporting requirements as defined by the Wadsworth Center Clinical Laboratory Evaluation Program (CLEP) and acts as a single repository for the data. eCLEP has evolved to support the submission of permit reapplications and notification of laboratory changes, as well as provide each clinical laboratory the ability to check their laboratory licensure status 24/7.

***Note**: the eCLEP application does not service Limited Service Laboratories. Please see our website at https://www.wadsworth.org/regulatory/clep/limited-service-lab-certs for information on Limited Service Laboratories*.

eCLEP offers many advantages over existing paper-based processes, including:

Persistent Data – The system displays general laboratory information as found in the Clinical Laboratory Evaluation Program's licensure database. The most current information is displayed, eliminating redundant data entry.

Data Validation – User entries are validated for incorrectly formatted and incomplete submissions at every step, eliminating submission failures and reducing the need for follow-up communications to correct minor errors such as missing entries.

Delegating Submission – The Laboratory Director may delegate the electronic submission of Laboratory information.

Documented Delivery – Permit reapplications and changes to laboratory information are electronically transmitted; the time of the submission and username submitting the data is recorded.

Requirements for Use

To enter information into the eCLEP system, your laboratory must have a personal computer that is minimally configured as follows:

- Pentium processor or higher
- DSL or a broadband Internet connection (The laboratory is responsible for obtaining Internet access with an Internet Service Provider (ISP)).
- Printer (optional)

Browser Requirements and Configuration

Access to the Health Commerce System and eCLEP requires 256-bit encryption, browser setting to accept cookies and enabling of Javascript.

Supported browsers on desktop computers include: Microsoft Internet Explorer, Google Chrome and Safari (Mac OS only). Support browsers on mobile devices include: Google Chrome (iOS5.1/Android 4.0 or later) and Safari (iOS5.1 or later). The Health Commerce System supports the current and two previous versions supported browsers.

Limited support is available for the following browsers: Mozilla Firefox (desktop/mobile) and WebKit-based browsers. Microsoft Internet Explorer Mobile and Safari for Windows are not supported.

Roles and Responsibilities

This section describes the different levels of eCLEP users and their access and data submission privileges in the system. It also gives instructions on how to request access to the system.

eCLEP users at the laboratory will belong to one of two roles. Below is a description of the roles, followed by the user qualifications:

A **Laboratory Director** is an individual who is responsible for the administration of the technical and scientific operation of a clinical laboratory or blood bank, including the supervision of procedures, reporting of results and responsibilities specified in Section 19.3 of 10 NYCRR (New York Codes, Rules and Regulations) and Article 5 Title V Section 571 of the Public Health Law. Such person shall possess a Certificate of Qualification issued pursuant to Part 19 of 10 NYCRR. A Director is authorized to **view**, **enter**, **attest, and submit** laboratory information electronically using the eCLEP system.

An **Assistant Director** is a person who has been designated by the Laboratory Director to serve as an Assistant Director in one or multiple categories or subcategories of testing. Such person shall possess a Certificate of Qualification issued pursuant to Part 19 of 10 NYCRR. A responsible Assistant Director holding a Certificate of Qualification is authorized to **view**, **enter, attest,** and **submit** laboratory information electronically using the eCLEP system.

A **Delegated Submitter** is a person who has been given written authorization by the Laboratory Director to electronically submit laboratory information on behalf of the Laboratory Director. A Delegated Submitter is authorized to **view**, **enter, attest,** and **submit** laboratory information electronically using the eCLEP system.

HCS Access Permissions

Before logging on to eCLEP to submit data, you will need access to the New York State Health Commerce System (HCS) at https://commerce.health.state.ny.us.

The New York State Department of Health assigns a NYSDOH HCS Account ID (User ID) and password to each individual who has been granted access to the HCS.

As the HCS contains confidential information, safeguard your HCS User ID and password by not revealing them to other users. Violation of the security and use agreement (e.g. sharing your User ID and password with someone else) will result in the temporary suspension of your account privileges and repeat offenses may result in the permanent removal of the account. Also, do not leave your computer logged on to the HCS unattended. For security purposes, there are **session timeouts after one hour of inactivity** and **system timeouts after eight hours of total connectivity**.

Clinical Laboratory Directors and HCS Coordinators without HCS accounts

Clinical Laboratory Directors without HCS accounts may begin the HCS account application process with the HCS Affiliation Request form available at www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/health-commerce. After completing the form, scan and email to CLEPHCS@health.ny.gov or fax it to 518-449-6901.The Laboratory Director will receive an e-mail from camu@its.ny.gov which will include a bar-coded PDF document to sign and have notarized. This form must be returned to the Commerce Account Management Unit (CAMU) to complete the affiliation process. Laboratory directors are expected to complete and submit this form promptly. An amended permit reflecting the change in directorship will not be issued until the laboratory director's HCS account has been verified.

The HCS Affiliation Request form is also used to establish HCS Coordinators at your laboratory.

Requesting HCS Accounts for Other Individuals

The Laboratory Director or HCS Coordinator for the laboratory can electronically request an account for additional laboratory staff. The Laboratory Director or HCS Coordinator needs to log into the Health Commerce System at https://commerce.health.state.ny.us, select the Coordinator's Account Tools (left side under My Applications), then click on the appropriate 'Request an Account for…' link.

Delegated Submitter

The Laboratory Director may delegate data submission privileges to a staff member who already has an HCS account by signing and completing a Delegated Submitter Request form. The form is available at www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/health-commerce.

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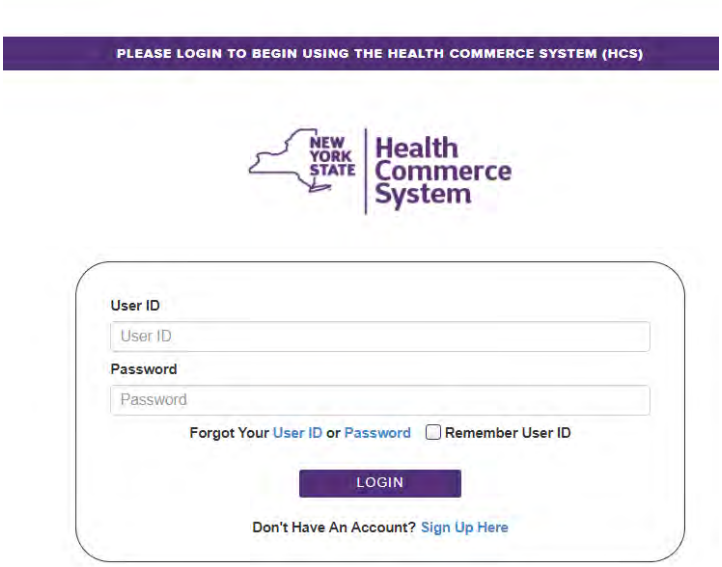
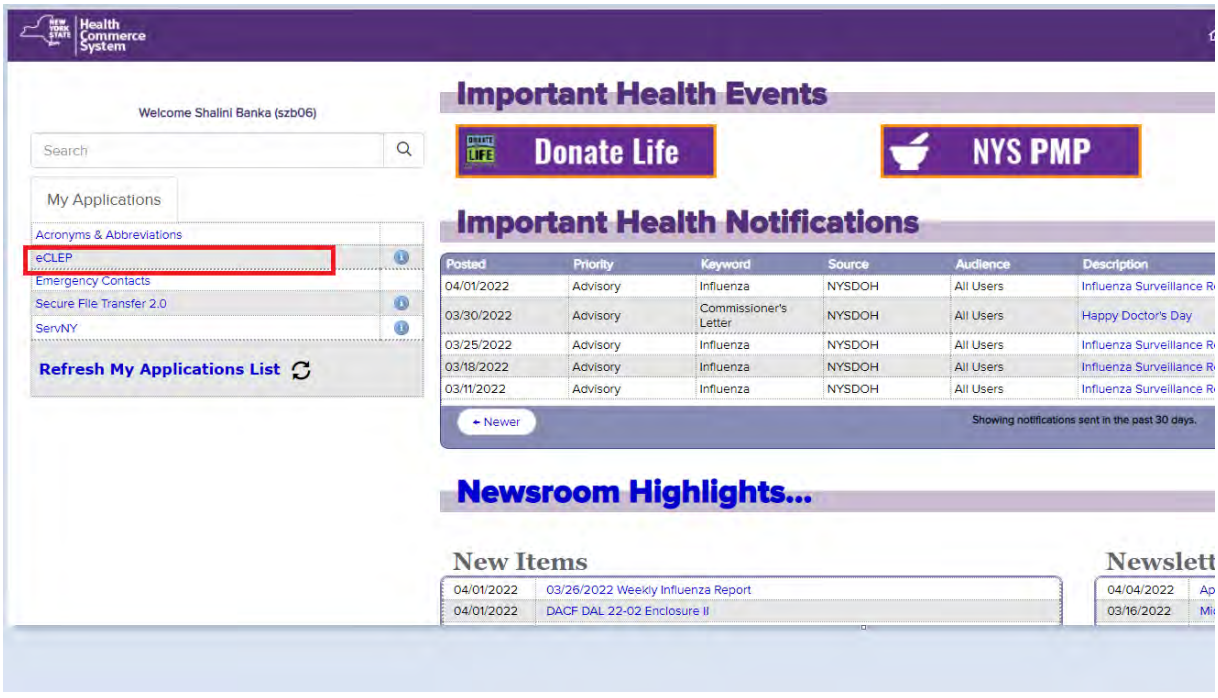
Accessing eCLEP and the Permit Materials Module

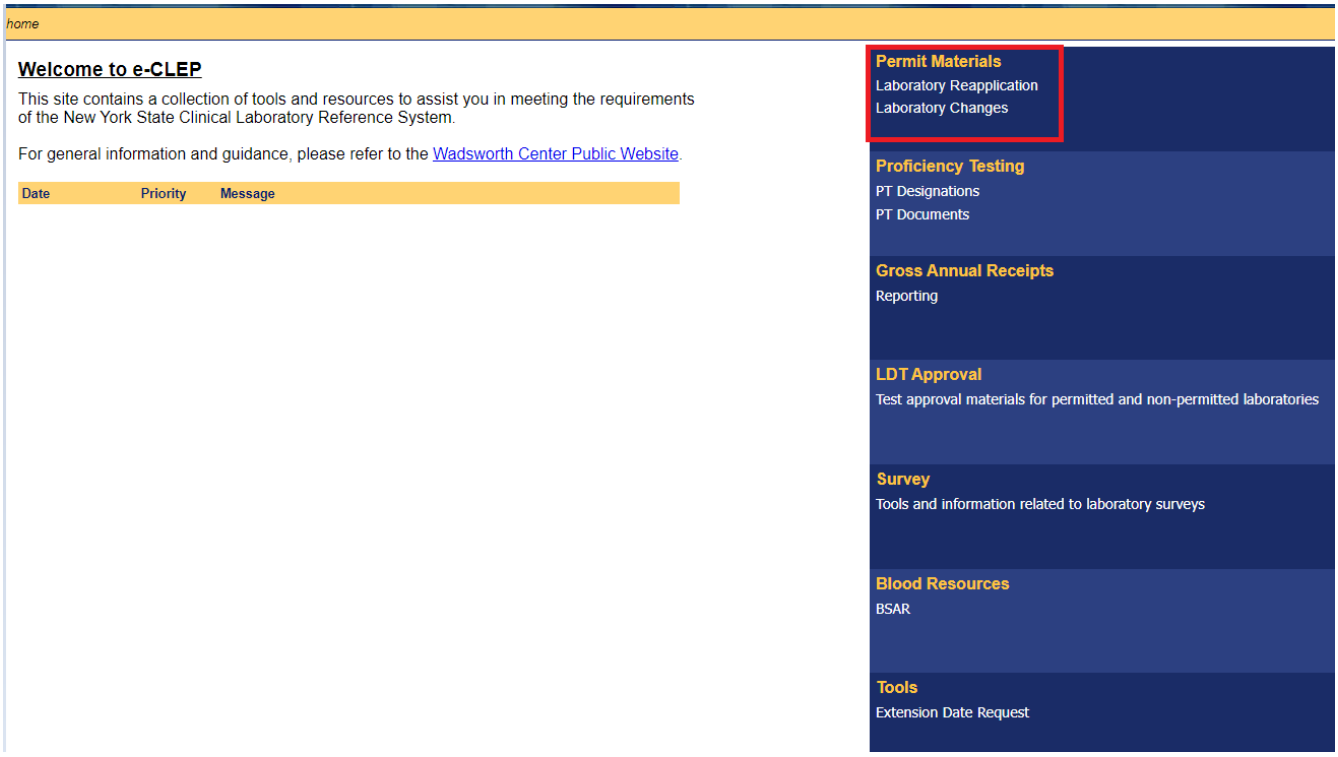
1. To access the eCLEP Home Page enter the following web address into an Internet browser:
   https://commerce.health.state.ny.us
2. Enter your User ID and Password into the **HCS Login screen** and click **Sign In**:



3. The **HCS Homepage** displays. Look for **eCLEP** in the left frame under **My Applications**:

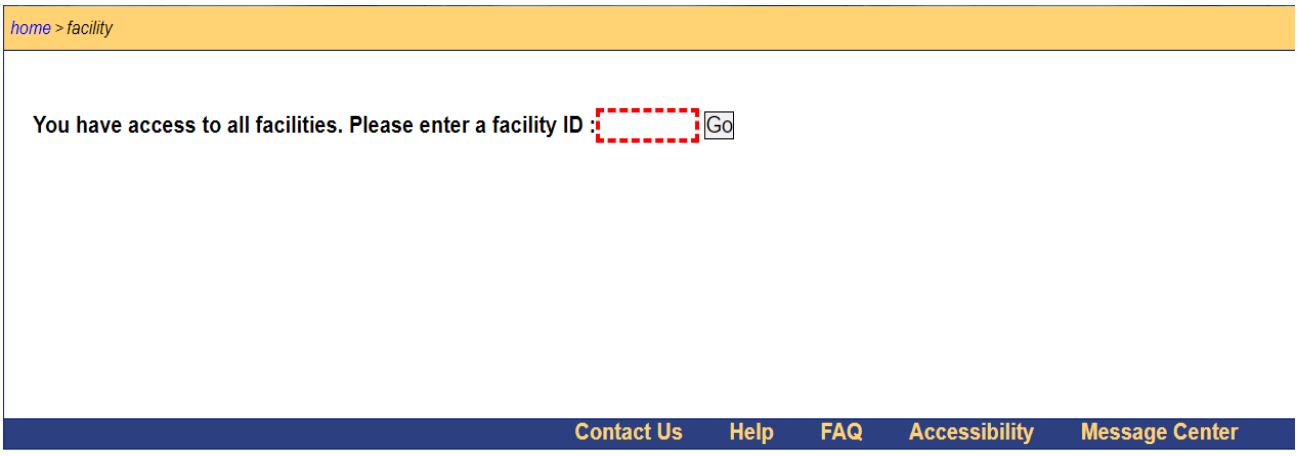


4. Click on **eCLEP** in the left frame and the eCLEP Home Page will display. Click on **Permit Materials**, Laboratory Reapplication / Laboratory Changes area at the upper right



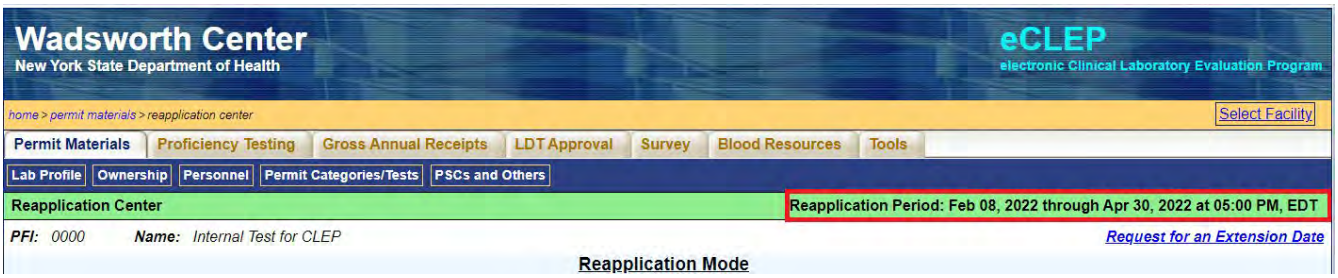
5. HCS account holders affiliated with more than one laboratory will be required to enter an appropriate 4-digit numeric Permanent Facility Identifier **(PFI)**.

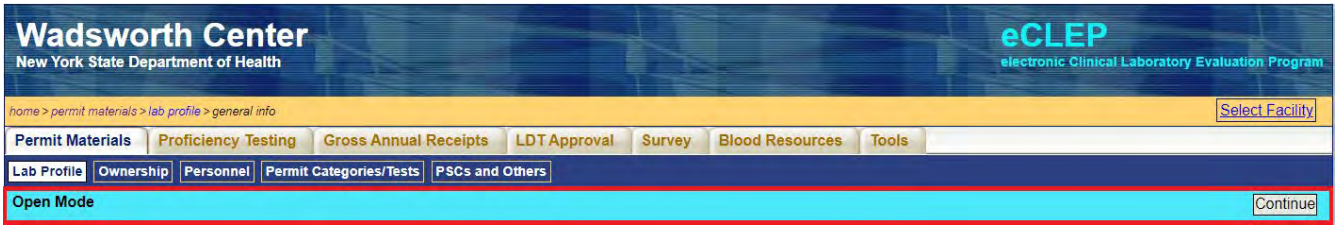
   (An alphanumeric PFI denotes a Limited Service Laboratory (LSL). LSLs are not serviced by the eCLEP application.)



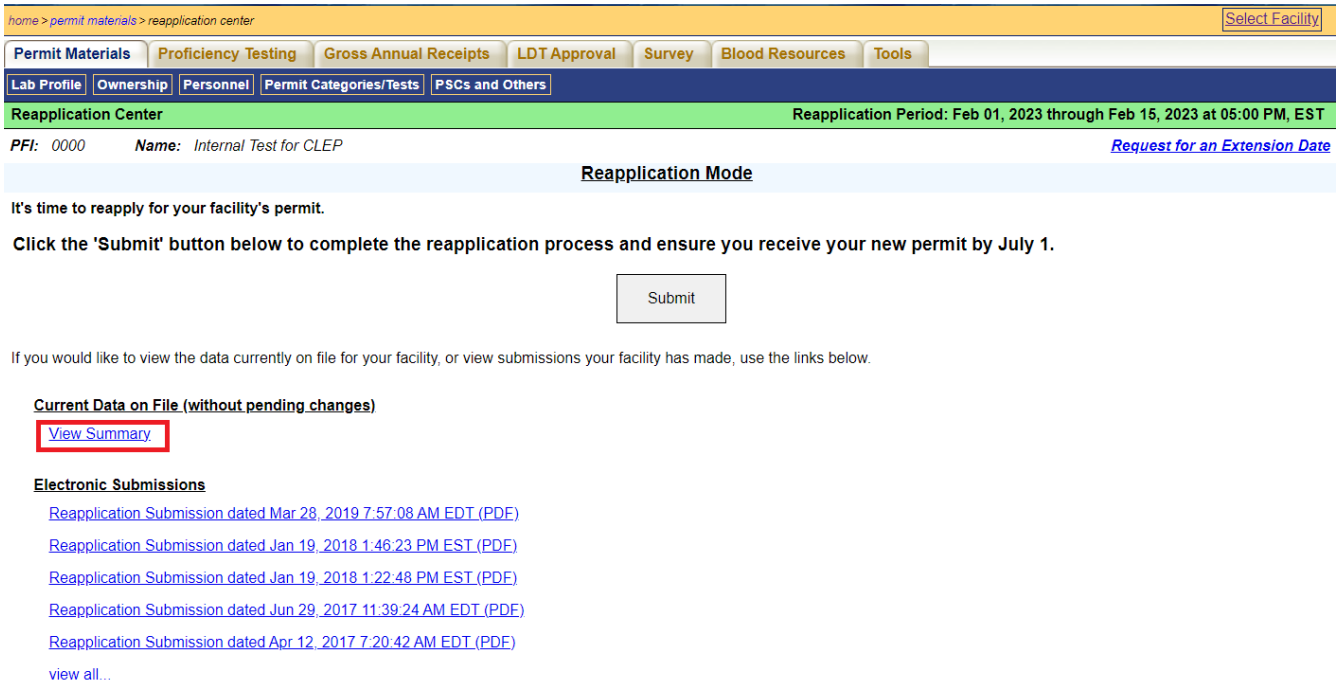
6. Most users, however, will be brought directly to the **Reapplication Mode or Open Mode** page. The reapplication period occurs in April, actual dates will vary year to year. Open Mode is available the rest of the year, provided there are no laboratory information changes submissions pending.

   Note: Reapplication mode is denoted by the presence of green bar at the top of the screen with the dates of the reapplication period; Open mode is denoted by the presence of teal bar at the top of the screen.

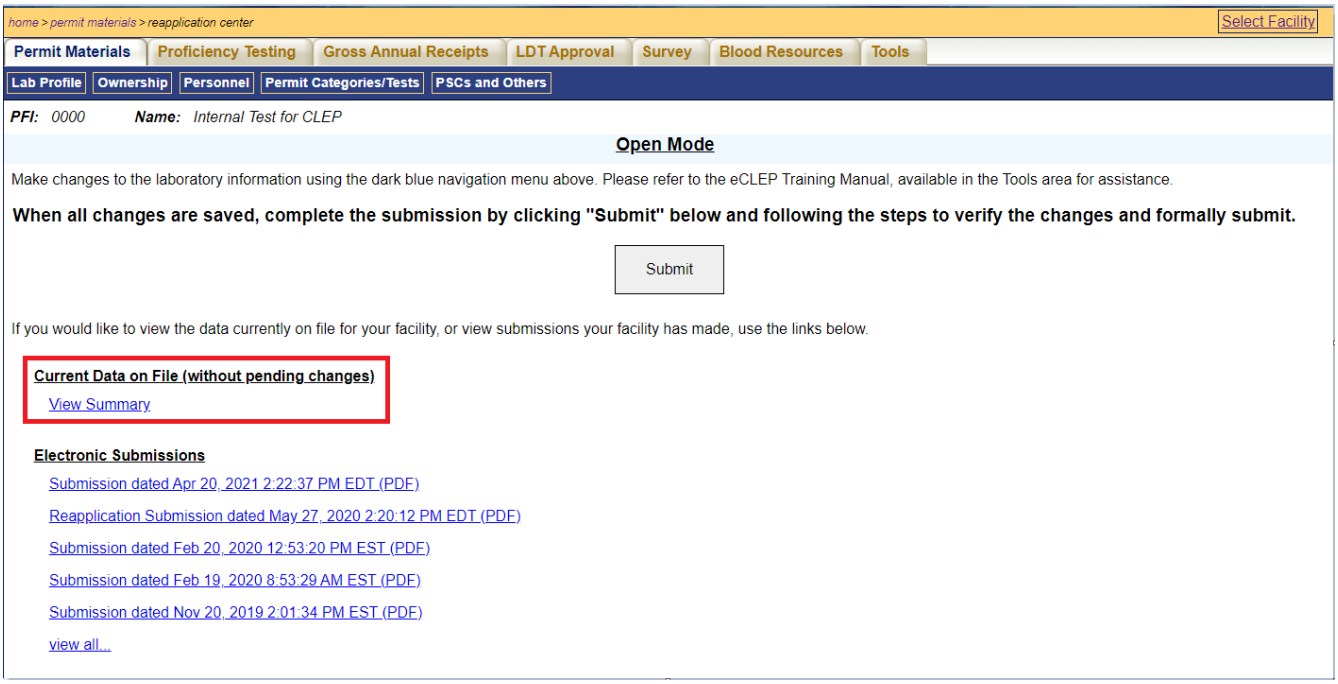




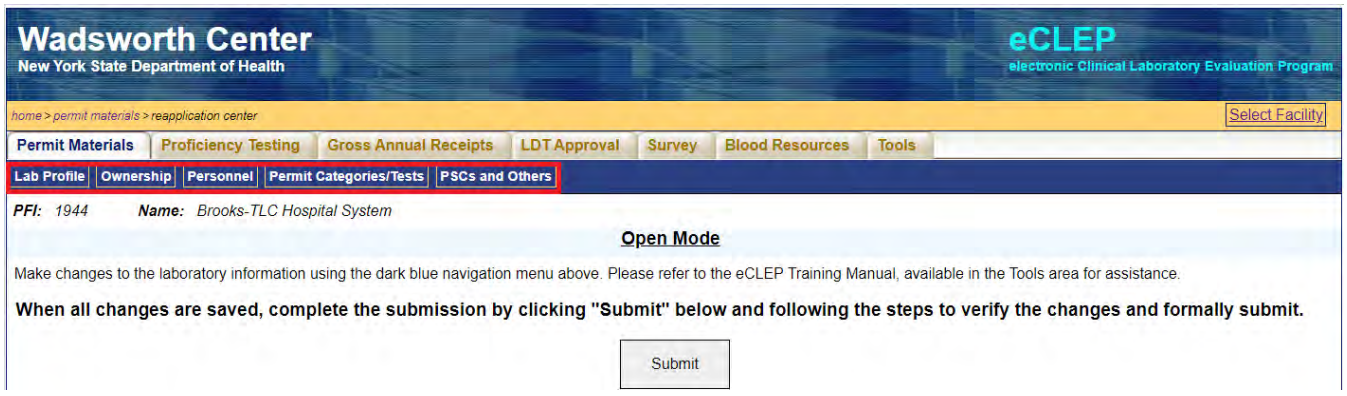
7. On the **Reapplication Mode or Open Mode** page, you may want to review the Current Data on File (without pending changes) using the "**View Summary**" link and print it out to use as a worksheet. Reapplication Mode Screenshot:



Open Mode Screenshot:



8. Make changes to laboratory information as required using the links on the dark blue menu bar (Lab Profile, Ownership, Personnel, Permit Categories/Tests, and PSCs and Others).



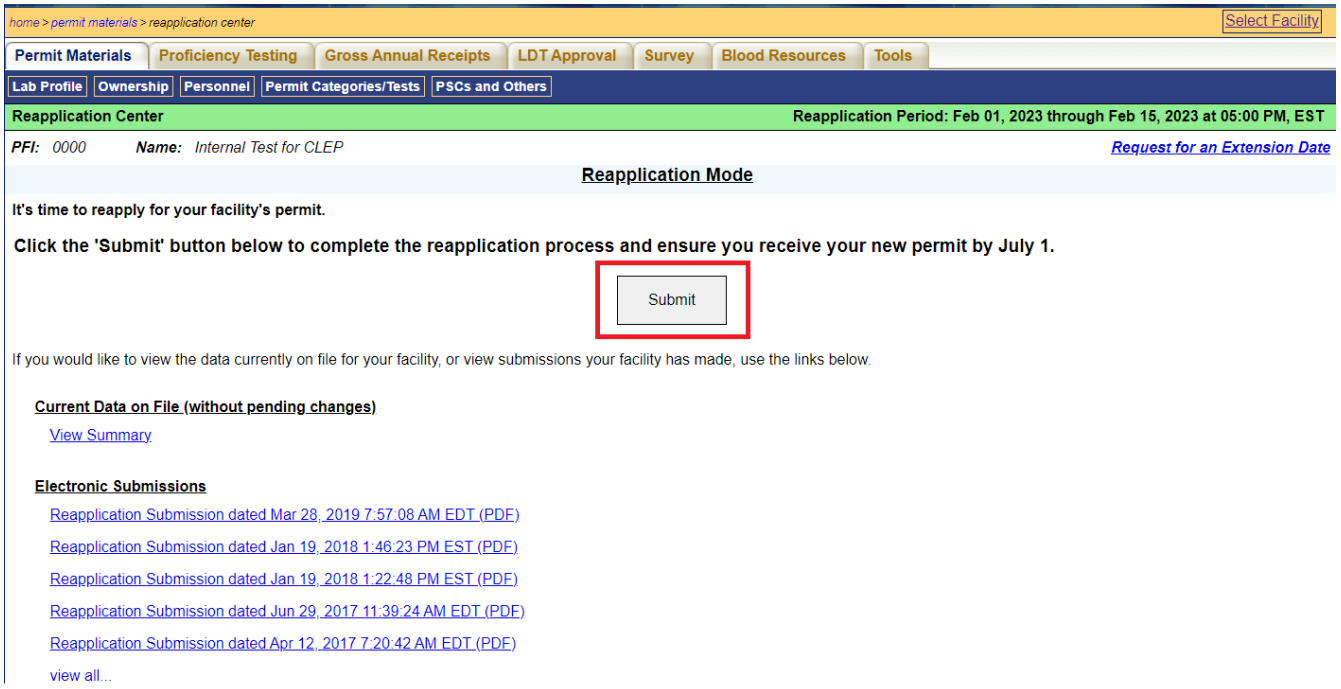
Reapplication Mode Submissions

NOTE: All eCLEP submissions are reviewed by the Clinical Laboratory Evaluation Program prior to acceptance. The Program reserves the right to request additional information, request re-submission to obtain missing information, or to reject the request in total if the eCLEP submission is not acceptable. eCLEP submission does not constitute approval by the Program.

We suggest that you first review the information on file for your laboratory and make any necessary revisions prior to beginning the reapplication submission. If you have already been navigating through the sections on the blue menu bar, click on the **Reapplication Center** button on the green menu bar to return to the main Reapplication Mode page.

Alternatively, you may start the reapplication submission process before revising facility information, however; once you begin navigating through the sections indicated on the blue bar to provide required information, you must return to the main Reapplication Mode page to continue with the submission process.

Click **Submit** to begin the reapplication submission process.



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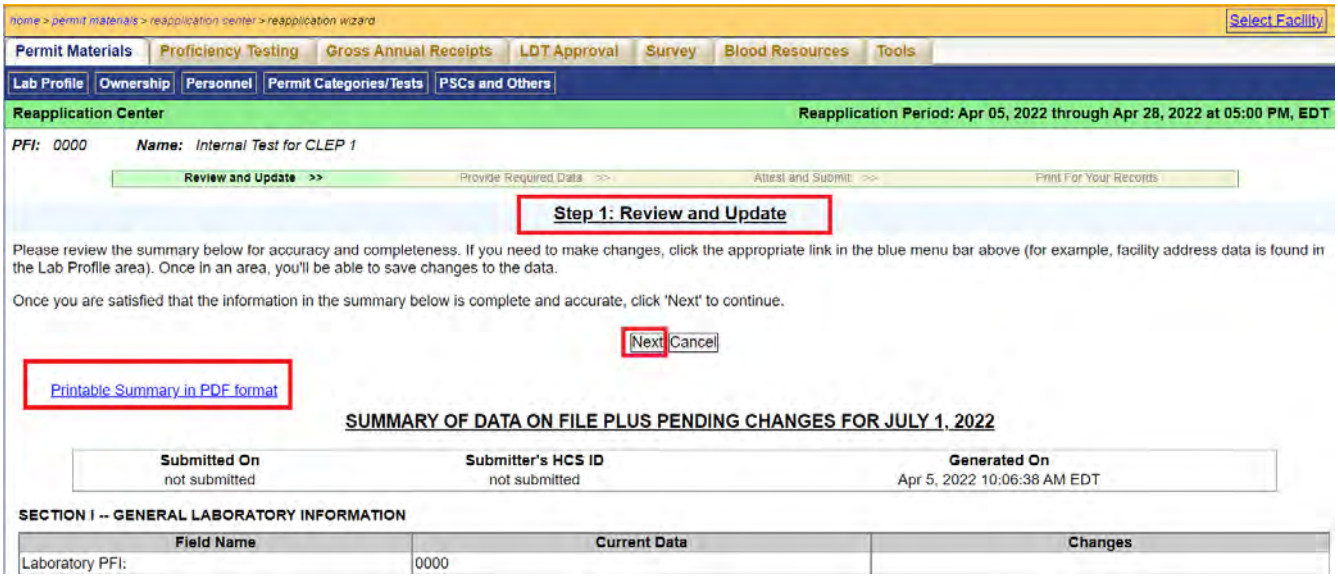
The **Step 1: Review and Update** page displays the data on file in the Laboratory Licensure database (and any pending changes already entered via eCLEP) for your facility. Review and click **Next**. A printable version of this information is available by clicking the "**Printable Summary in PDF Format**" link.



The **Step 2: Provide Required Data** page will list sections/subsections that you will have to visit in order to complete the reapplication. Required information that must be completed before you will be able to submit include:

- laboratory contact person
- owner declaration and Disclosure of Ownership and Controlling Interest Statement upload
- facility e-mail
- test volume, if applicable
- POC testing, if applicable
- PSCs and Others tab, if applicable

You may proceed to the areas with outstanding data requirements by either method below, or a combination of these two methods.

a) Navigate to each section by clicking the links in the blue menu bar near the top, e.g. **Lab Profile, Ownership, Personnel, Permit Categories/Tests, PSCs and Others**.

b) If there are no, or few, owner/personnel/testing changes during this reapplication, you may navigate directly to the sections with outstanding data requirements by clicking the underlined links in the **How to Resolve** column.

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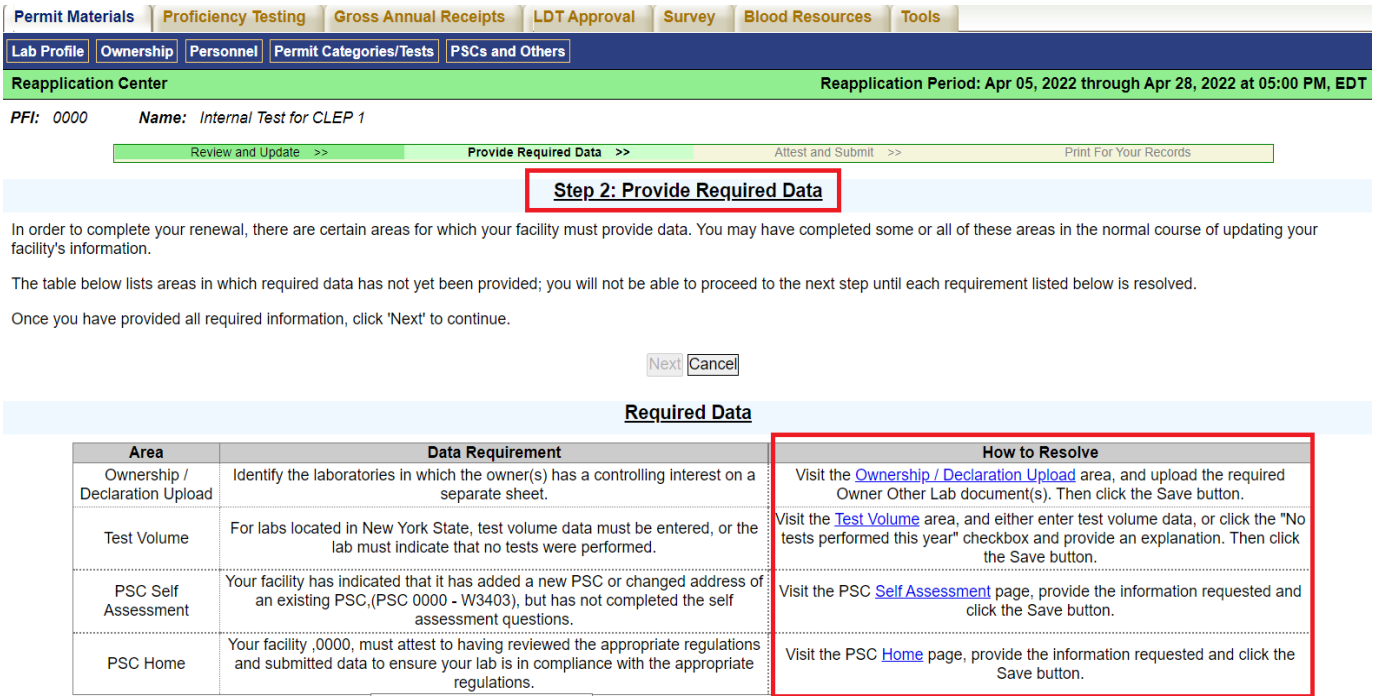
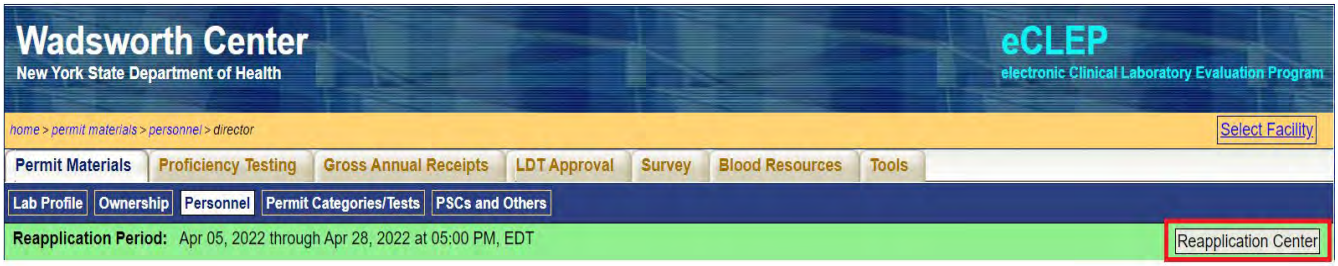
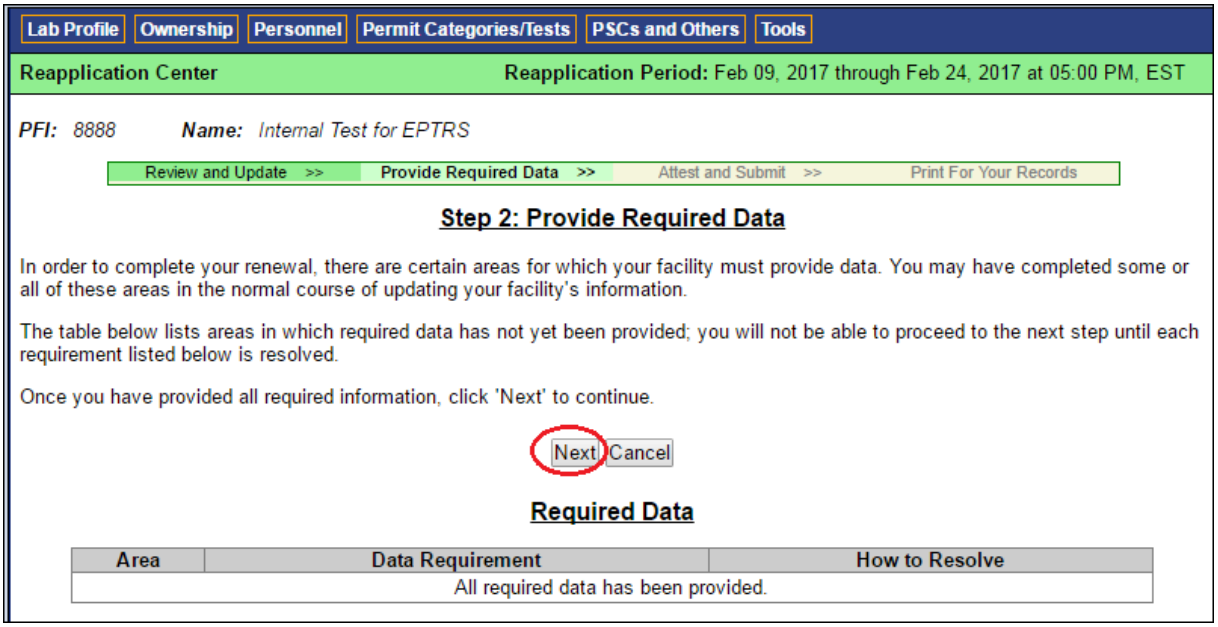


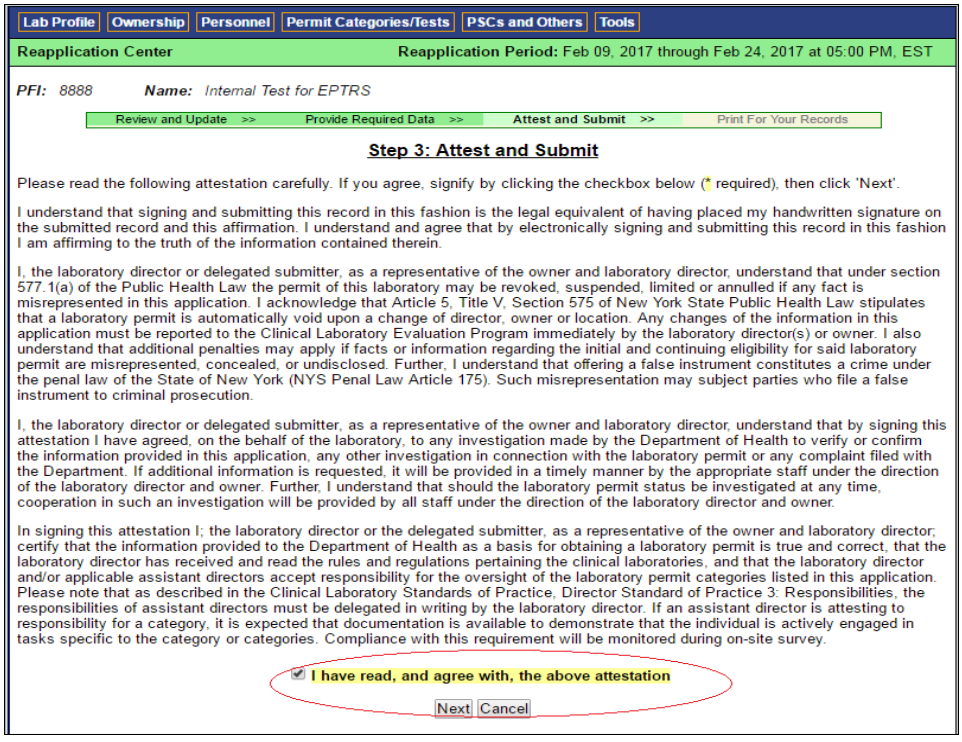
To return to the **Step 2: Provide Required Data** page to resolve further outstanding data requirements, or to verify that all data requirements have been resolved, click the button on the green bar at the top of the screen from any page to get back to the main Reapplication Mode page.



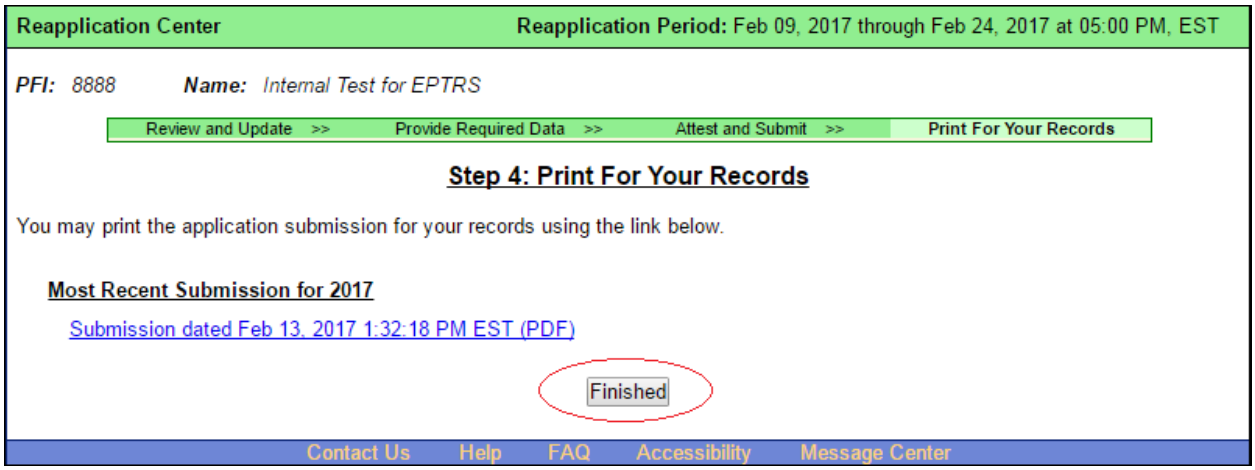
Click **Submit**, and then click **Next** on the **Step One: Review and Update** page. The **Step 2: Provide Required Data** page will list any outstanding data entry requirements. If there are no outstanding data entry requirements, the Required Data table will read "All required data has been provided." Only after all data requirements have been resolved will you be able to proceed to **Step 3: Attest and Submit** by clicking **Next**.



Please read the **Step 3: Attest and Submit** page in its entirety and click the checkbox to signify that you have read, and agree with, the attestation; then click **Next**.



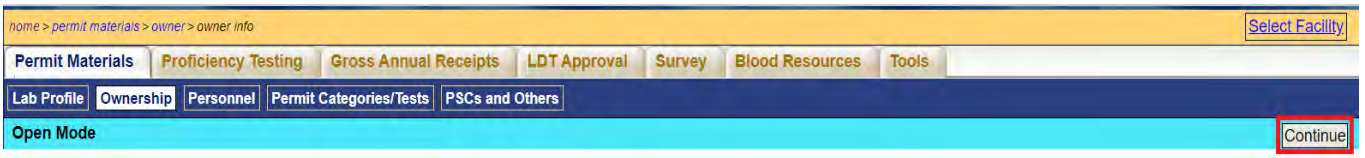
The **Step 4: Print for Your Records** page allows access to the eCLEP summary in PDF format. Click on the **Submission dated [date, time] (PDF)** and print or save this document for your records, if desired. Then click **Finished**. You will be directed to the main Read-Only mode page.



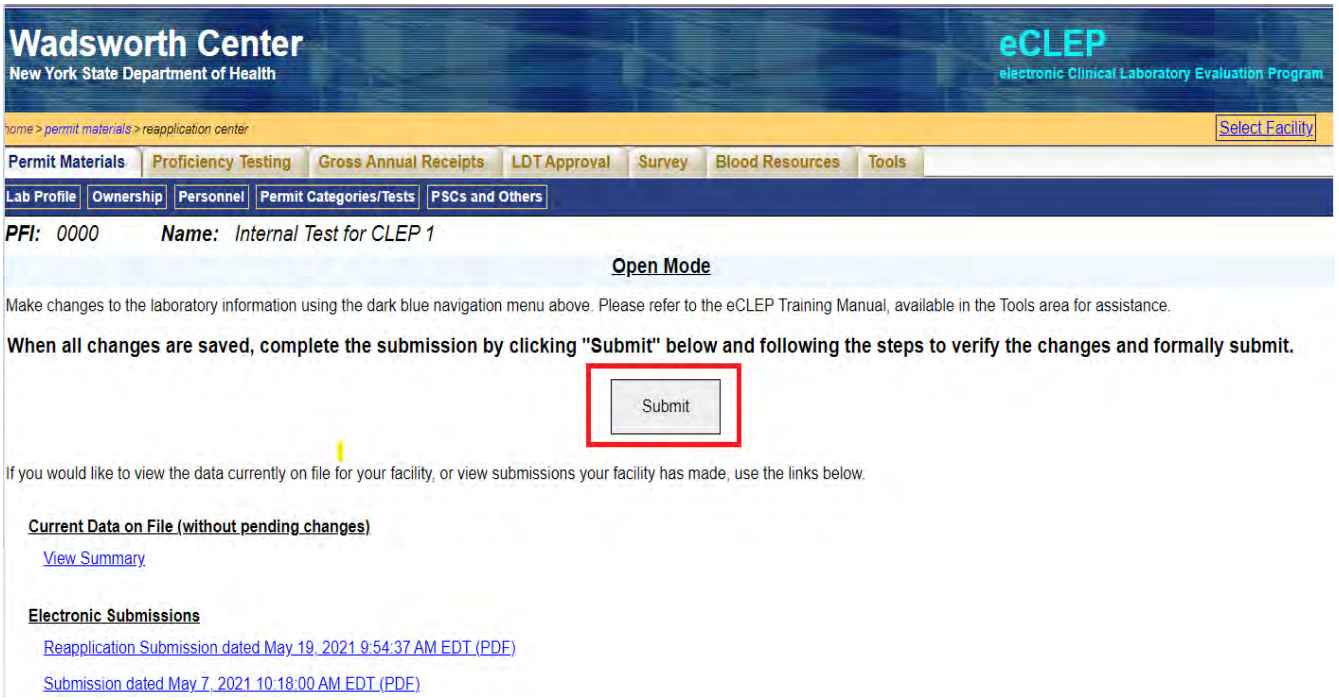
Open Mode Submissions

NOTE: All eCLEP submissions are reviewed by the Clinical Laboratory Evaluation Program prior to acceptance. The Program reserves the right to request additional information, request re-submission to obtain missing information, or to reject the request in total if the eCLEP submission is not acceptable. eCLEP submission does not constitute approval by the Program.

Enter laboratory changes as necessary by navigating the blue menu bar. Click on the **Continue** button to begin the Open Mode submission process.



Click **Submit** to begin the Open Mode submission process.



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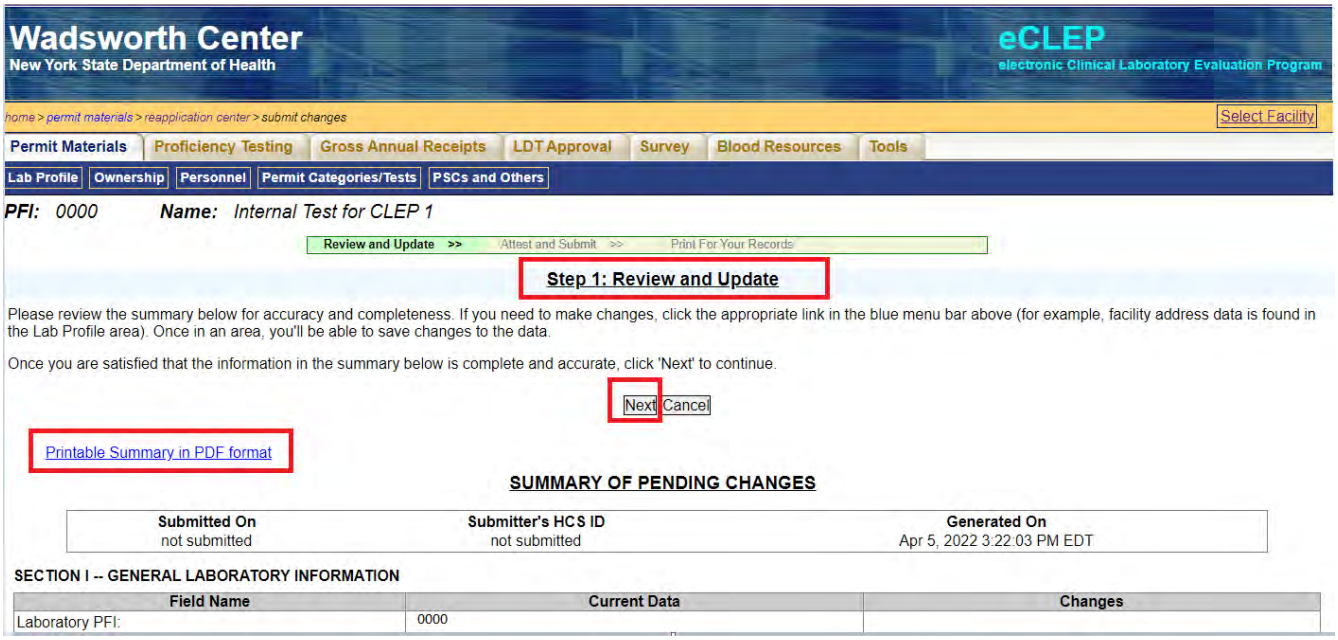
The **Step 1: Review and Update** page displays the data on file in Laboratory Licensure database (and any pending changes already entered via eCLEP) for your facility. Review and click **Next**. A printable version of this information is available by clicking the "**Printable Summary in PDF Format**" link.



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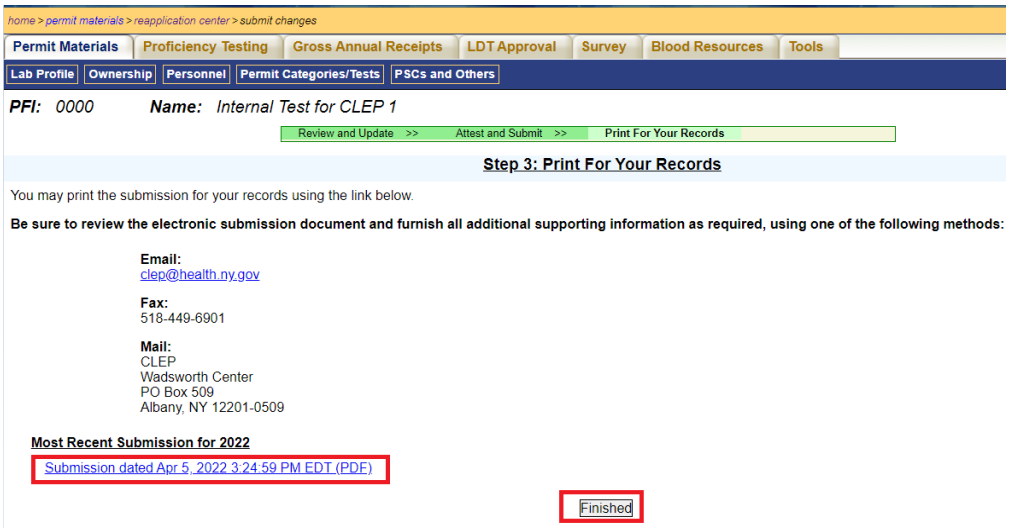
Please read the **Step 2: Attest and Submit** page in its entirety and click the checkbox to signify that you have read, and agree with, the attestation; then click **Next**.

The **Step 3: Print For Your Records** page allows access to the eCLEP summary in PDF format. ***NOTE: The eCLEP Summary is no longer required to be signed and returned to CLEP.*** Click on the **Submission dated [date, time] (PDF)** and print or save this document for your records, if desired. Then click **Finished**. You will be directed to the main Read-Only mode page.

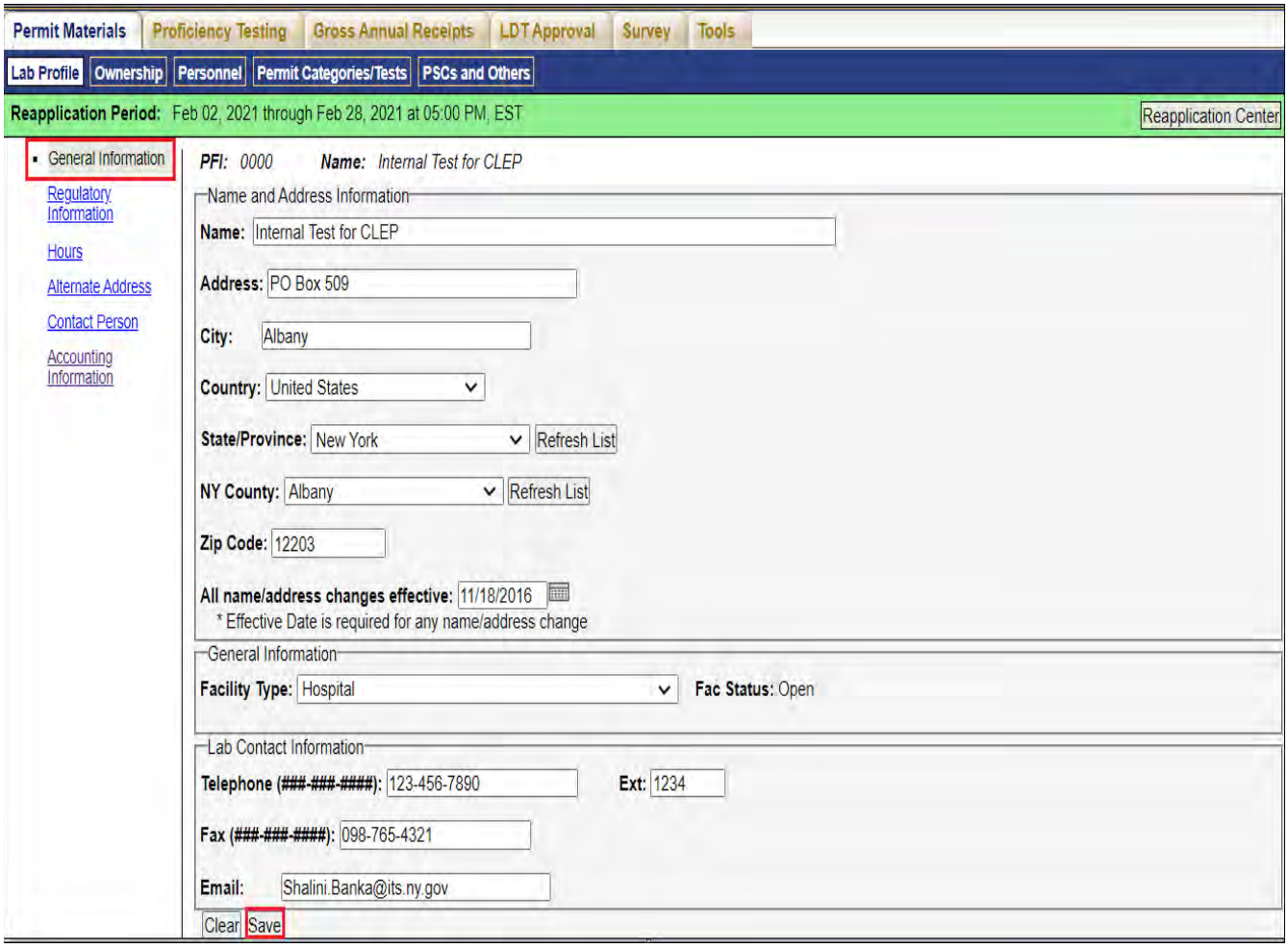


Navigating in the Permit Materials Module

Lab Profile

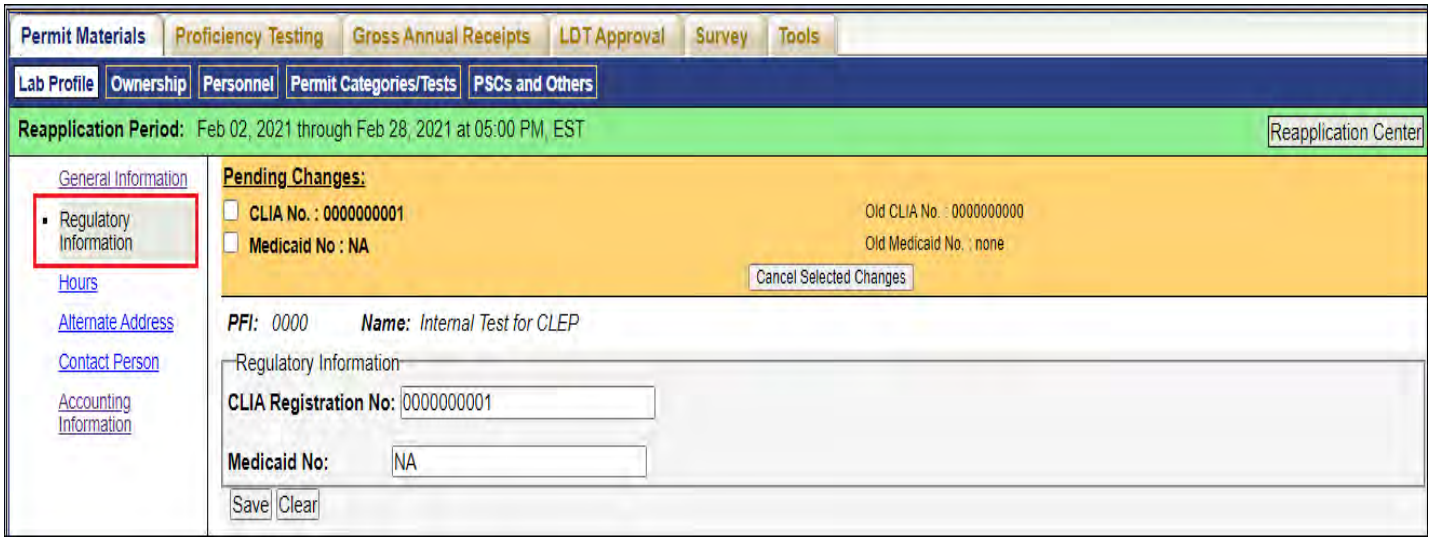
General Information

The **General Information** webpage allows you to make changes to the laboratory name and address, facility type and lab contact information. Note an effective date for any laboratory name and address changes is required. Enter the required information and click **Save**.



Regulatory Information

The **Regulatory Information** webpage allows you to revise the CLIA registration and Medicaid number for the laboratory. Enter the required information and click **Save**. Laboratories in New York should not revise the CLIA number without first contacting CLEPCERT@health.ny.gov.



Hours

The **Hours** section allows you to change laboratory testing hours. Enter the required information and click **Save**.

Note: The Clinical Laboratory Evaluation Program may seek clarification of information entered in the "Hours Note" field before accepting the proposed change.

NEW: **Hours are now collected in military (24-hour) format.**

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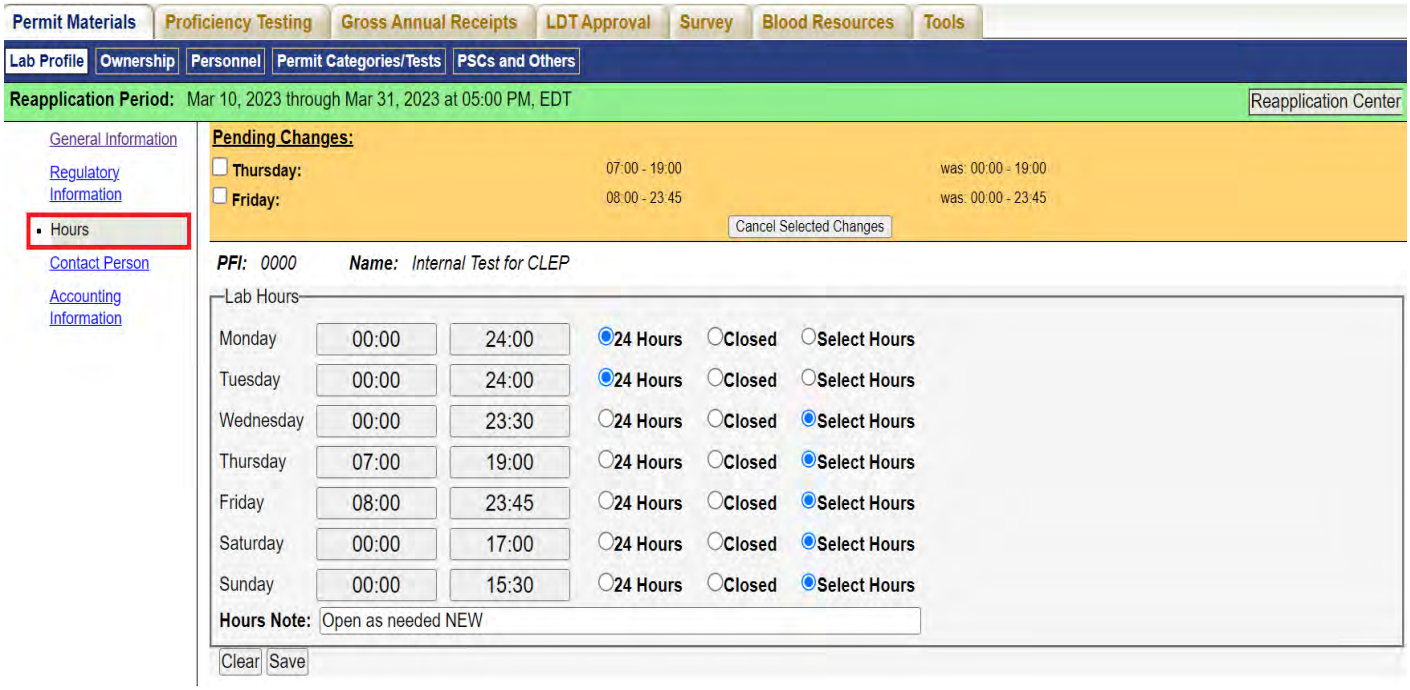
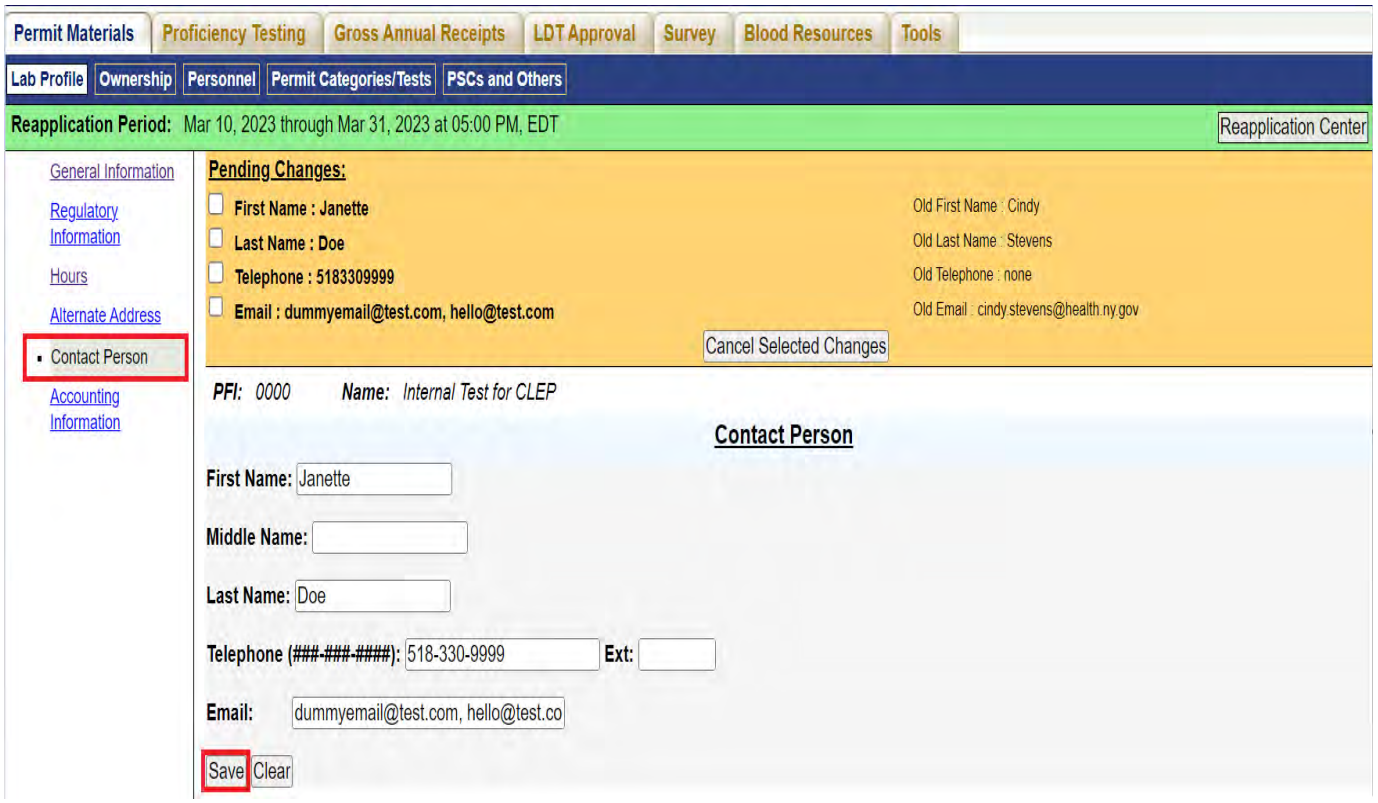


Contact Person

The **Contact Person** section allows you to change/update the contact person for the laboratory and their contact information (e-mail and phone number).

- The laboratory contact person is the individual who is designated by the laboratory director and owner(s) to communicate with the Department on matters relating to the clinical laboratory permit.
- You are required to verify/update the **Contact Person** in Reapplication mode.

USER TIP: More than one email address may be entered in the Contact Person Email field by separating each address with a comma.

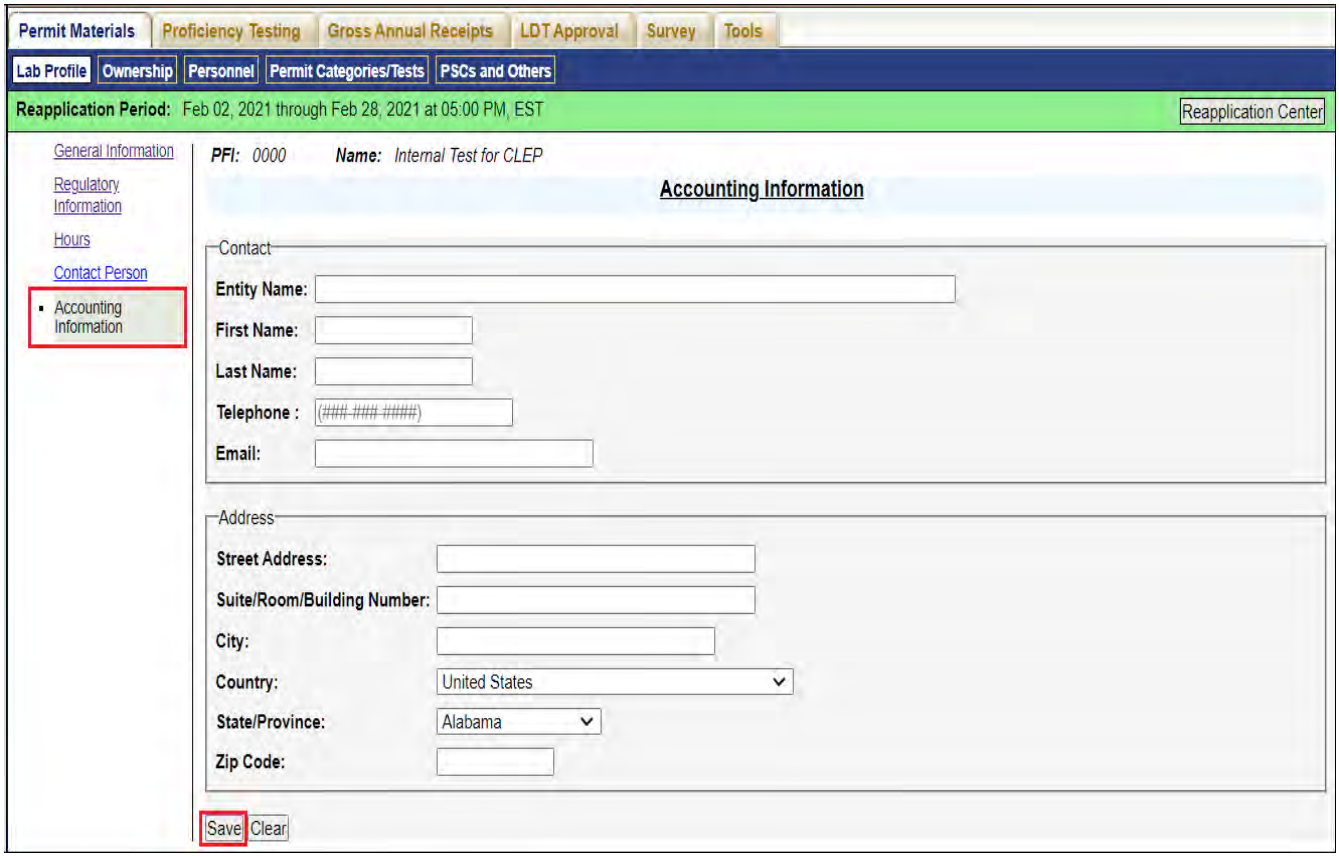


Accounting Information

The **Accounting Information** section allows you to add/update the accountant information for the laboratory and their contact information (e-mail, phone number and address). Enter the required information and click **Save**.

****NOTE: This section is optional. Data entered here will be used for emailing the permit and reference fees invoices. If no data is entered here, the invoice will be emailed to the laboratory director.**

As of permit year 2020-2021, invoices are emailed to the laboratory and are not mailed in hard copy.



Ownership

The Ownership section is divided into three subsections, **Owner**, **Declaration, and Upload**.

Laboratories will be required to upload a list of direct and indirect owners using the Upload Feature as part of the permit reapplication.

- **Direct ownership** means an individual or entity with an ownership interest or controlling interest in the applying facility.

- **Indirect ownership** means an individual or entity with an ownership interest, controlling interest, or corporate membership, in an entity with direct or indirect ownership in the applying clinical facility. Indirect owners who hold a ten (10) percent or greater ownership interest, controlling interest, or corporate membership, are required to be disclosed by the applying clinical facility

Examples of ownership structures:

Example 1 (Business Corporation): ABC Lab is owned by ABC Lab, Inc. ABC Lab Inc. has two major stockholders, Mr. Smith and Mr. Hernandez. ABC Lab, Inc. is the direct owner. Mr. Smith and Mr. Hernandez are indirect owners.

Example 2 (Business Corporation): ABC Lab, Inc. dba ABC Lab is owned by ABC Lab, Inc. ABC Lab, Inc has two primary investors; Umbrella Corp, Inc. and Ms. Smirnov. ABC Lab, Inc., is the direct owner. Umbrella Corp, Inc. and Ms. Smirnov are indirect owners.

Example 3 (Partnership): Acme Lab is owned by Zhang Brothers, LLP. The partners of Zhang Brothers, LLP are Zhang Industries and Mr. Lee. Zhang Industries is owned by A. Zhang and B. Zhang. Zhang Brothers, LLP is the direct owner. Zhang Industries, Mr. Lee, A. Zhang, and B. Zhang are all indirect owners.

Example 4 (Not-for-Profit Corporation): Healthy Hospital Laboratory is owned by Healthy Hospital, Inc., a not-for-profit corporation. Healthy Hospital, Inc. has two corporate members, Biggie Health Systems, Inc. and Bigger Health Systems, Inc. Biggie Health Systems, Inc. and Bigger Health Systems, Inc. are considered indirect owners in Healthy Hospital Laboratory.

Example 5: (Professional Corporation): Neighborhood Physicians, PLLC operates a clinical laboratory. Neighborhood Physicians, PLLC is owned by Hospital Physicians, PC and Dr. Patel. Hospital Physicians, PC and Dr. Patel are indirect owners.

- **Ownership Interest** means the possession of stock, equity in the capital, or any interest in revenue of an entity.
- **Controlling interest** means the ability to direct or control the operation or management of an entity. Members on the Board of Directors or Board of Trustees for not-for-profit corporations are considered to have controlling interests. Any individual or entity with a ten (10) percent or greater controlling interest is required to be disclosed by the applying clinical facility. Licensed physicians who are included on the Board of Directors/Board of Trustees for a not-for-profit corporation are required to disclose their authority to order laboratory tests if they have greater than 10% controlling interest in the applying clinical facility.
- **Corporate membership** means an individual or entity with a voting interest in a not-for-profit corporation that directly owns the applying facility. Corporate membership includes, but is not limited to, the right to vote in the election for directors of the clinical laboratory or on fundamental corporate transactions such as closing the business or amending the bylaws.
- **Management company** means any organization that operates and manages a clinical laboratory on behalf of the owner, with the owner retaining ultimate legal responsibility for the operation of the business.

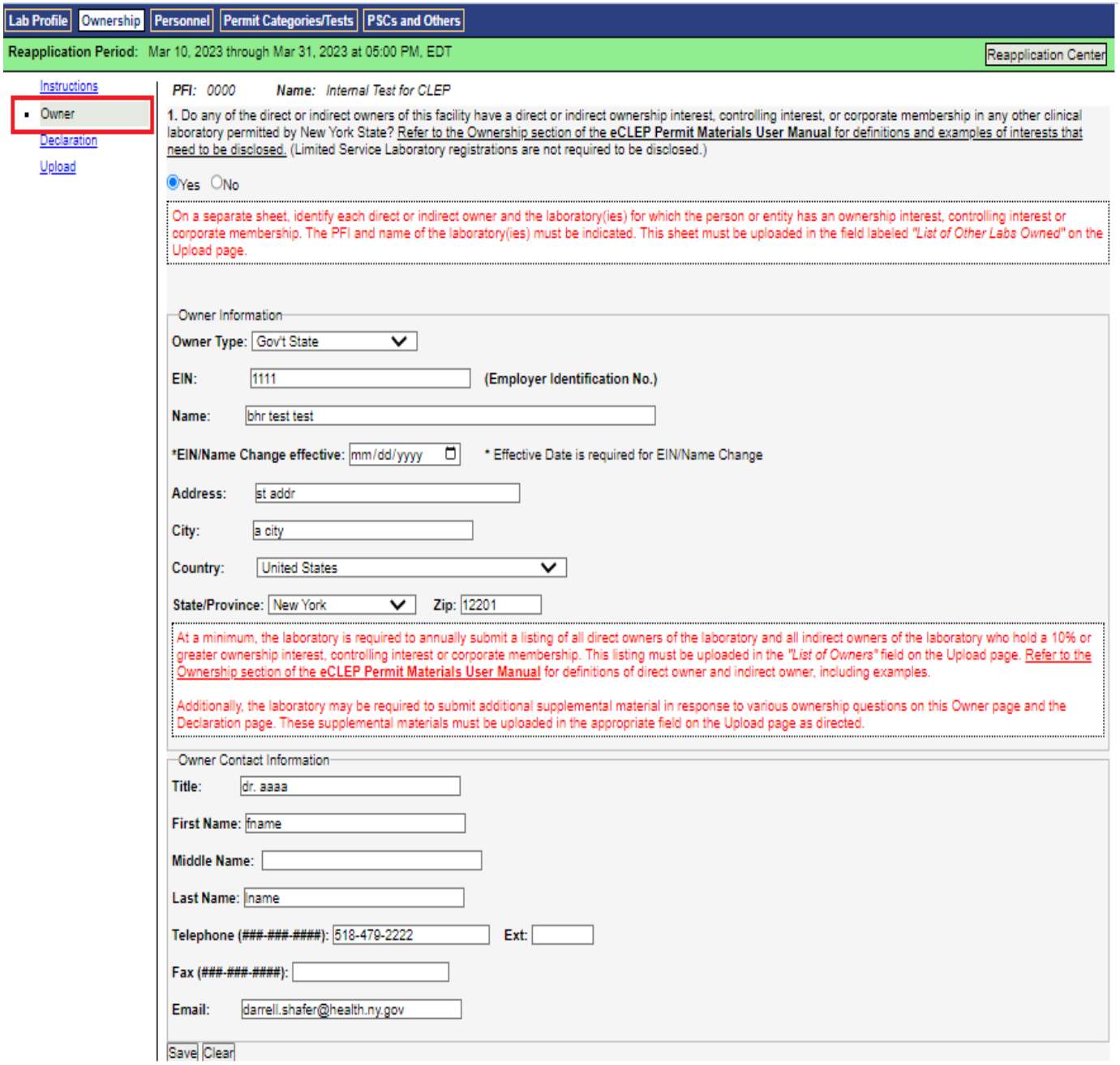
- During the **Reapplication** period, you will be required to enter any missing data and/or update information. **The reapplication cannot be submitted without providing this information.** You will receive error messages when you try to continue without addressing these fields. When this happens, please enter the missing data, select a dropdown option and/or click the radio button; then click **Save** again.

- During the **Open Mode**, update information as necessary to accurately reflect a laboratory change.

Owner

This section captures information such as the owner type, Federal Employer Identification Number (EIN, aka TIN), owner name, etc. If the response to question 1 is "Yes", you will be prompted to upload a list of all laboratories in which any of the direct or indirect owners have ownership, controlling interest, or corporate membership.

PLEASE NOTE: All laboratories that share a common Federal Employer Identification Number (EIN) are considered to be owned by the same entity and disclosure of the other laboratories owned by the direct owner is required. Note that to complete this section, the applying facility should consult their administration and/or legal department. It is not necessary to include Limited Service Laboratories in this list.



During Reapplication, all laboratories are required to upload a list of direct and indirect owners of the laboratory.

The list of direct owners must include (based on ownership type):

- **Individuals:** Names, addresses, percentage of ownership, and social security numbers of individual owners.
- **Partnership**: Names, addresses, percentage of ownership, and social security numbers of all partners.
- **Government**: The governmental entity and name of the representative official (i.e., Commissioner of Health, Chancellor, etc.) who can be contacted regarding ownership issues.
- **For-Profit Corporation**: Names, addresses, percentage of ownership, and social security numbers (or EIN) for corporate officers, and/or shareholders.
- **Not-for-Profit Corporation (NFPC)**: A list of the Board of Directors/Trustees/Governors of the NFPC.
- **Other**: Names, addresses, percentage of ownership and SSN or EIN, as appropriate.

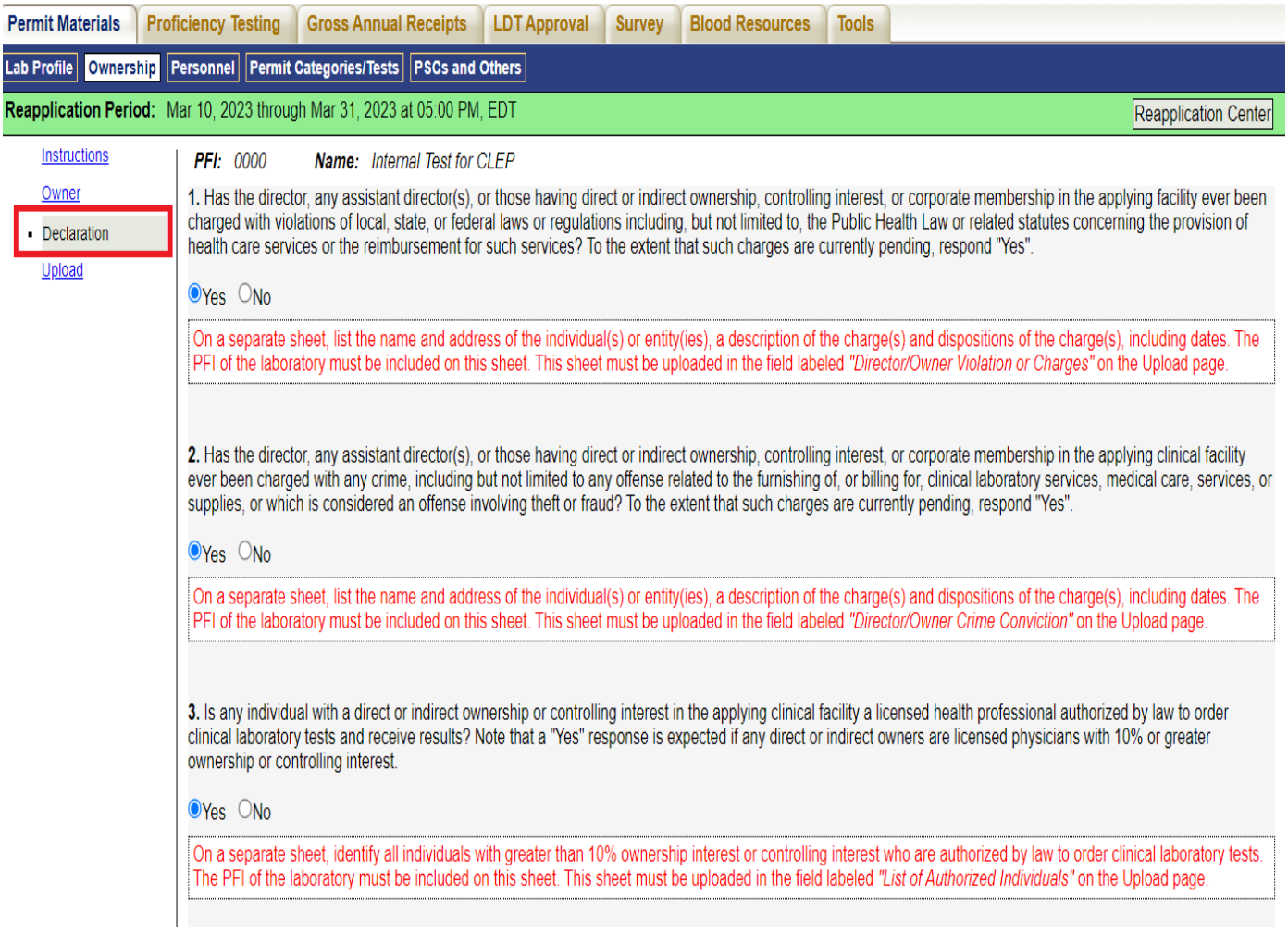
The list of indirect owners must include those individuals or entitites that 1) possess ten (10) percent or more of the voting shares of an entity that directly owns/operates a clinical laboratory; 2) maintain a controlling interest of ten (10) percent or more in an entity that directly owns/operates a clinical laboratory; or 3) maintain corporate membership in a not-for-profit corporation that directly owns/operates a clinical laboratory.

The list must include (based on ownership type):

- **Individuals:** Names, addresses, percentage of ownership, and social security numbers of individual owners
- **Partnership:** Names, addresses, percentage of ownership, and social security numbers the partners
- **For-Profit Corporation:** Names, addresses, percentage of ownership, and social security numbers (or EIN) for corporate officers, and/or shareholders
- **Not-for-Profit Corporation:** A list of the Board of Directors/Trustees/Governors of the NFPC.

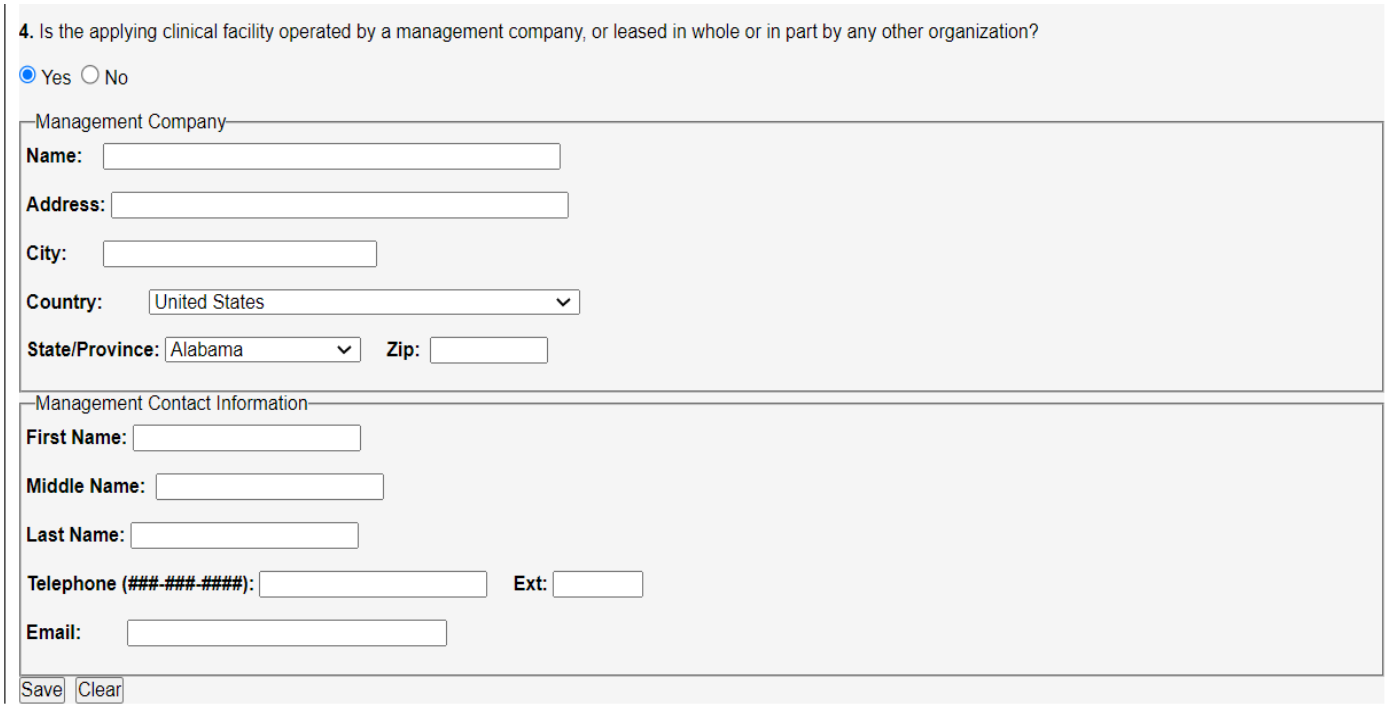
Declaration section

Respond to the questions presented in this section. For each “Yes” response, the laboratory will be prompted to upload supplemental documentation. These documents will be uploaded in the Upload screen described below.



eCLEP MANUAL

If a laboratory declares it has entered into a new management contract, a follow-up request to submit a copy of the contract to CLEP will be made, there is currently no upload feature for management contract submission.



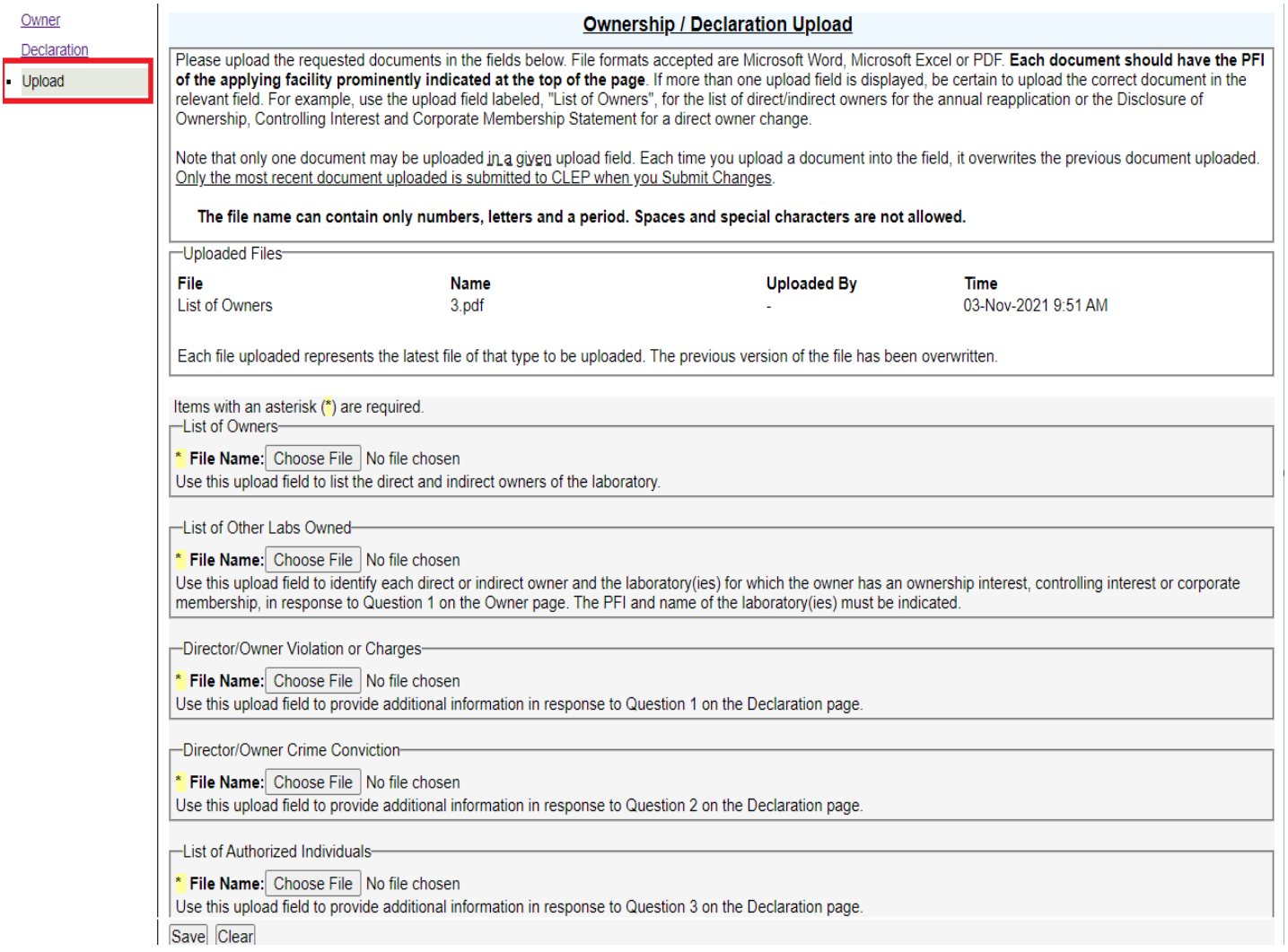
Upload section

Depending on the laboratory's responses to the questions on the Declaration page, users will see one or more fields requesting specific documents to be uploaded. **During Reapplication, all laboratories are required to upload a list of direct and indirect owners of the laboratory. Refer to page 24 for definitions of direct and indirect owners and page 27 for specific instruction on reporting the ownership.**

To upload a document, verify the document type you wish to upload matches the document type on the screen (List of Owners, List of Other Labs Owned, Director/Owner Violation or Charges, Director/Owner Crime Conviction, List of Authroized Individuals) then click **Browse** button to the right of the File Name space. Navigate to the electronic file on your computer, then click **Open** to upload.

If you accidently upload the wrong document, you may click on **Browse** button again and choose another document, the original uploaded document will be overwritten.

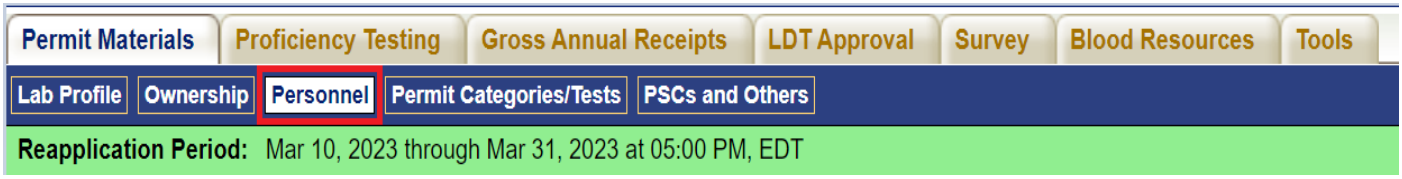
Once all documents have been uploaded, click **Save.**



Personnel

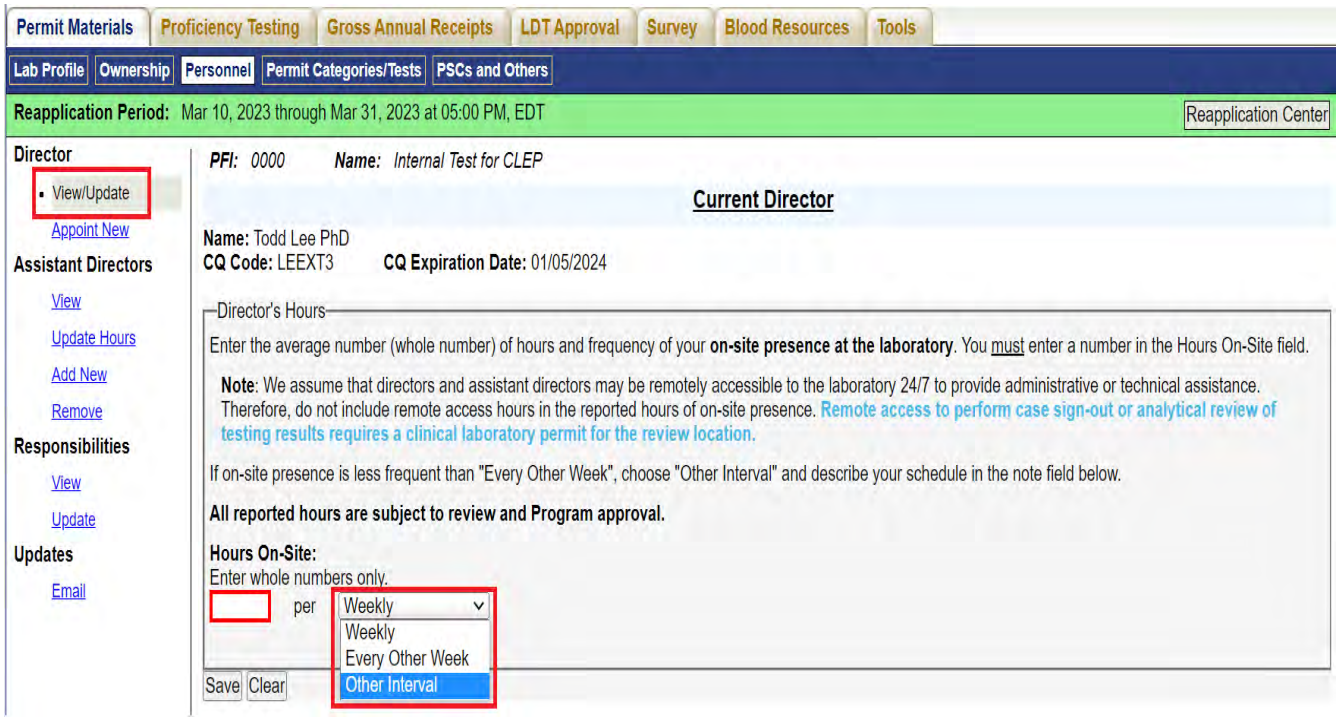
The **Personnel** section has many subsections, including Director, Assistant Director, and Responsibilities. Note that any yellow highlighted areas are required. You will need to know the Certificate of Qualification (**CQ**) code of any new directors or assistant directors. The CQ code (five letters followed by a number) can be found on the individual's certificate. If you are unable to locate this document for the individual, e-mail CLEP@health.ny.gov for help in looking up CQ codes.

- During the Reapplication mode, please review each subsection for accuracy.

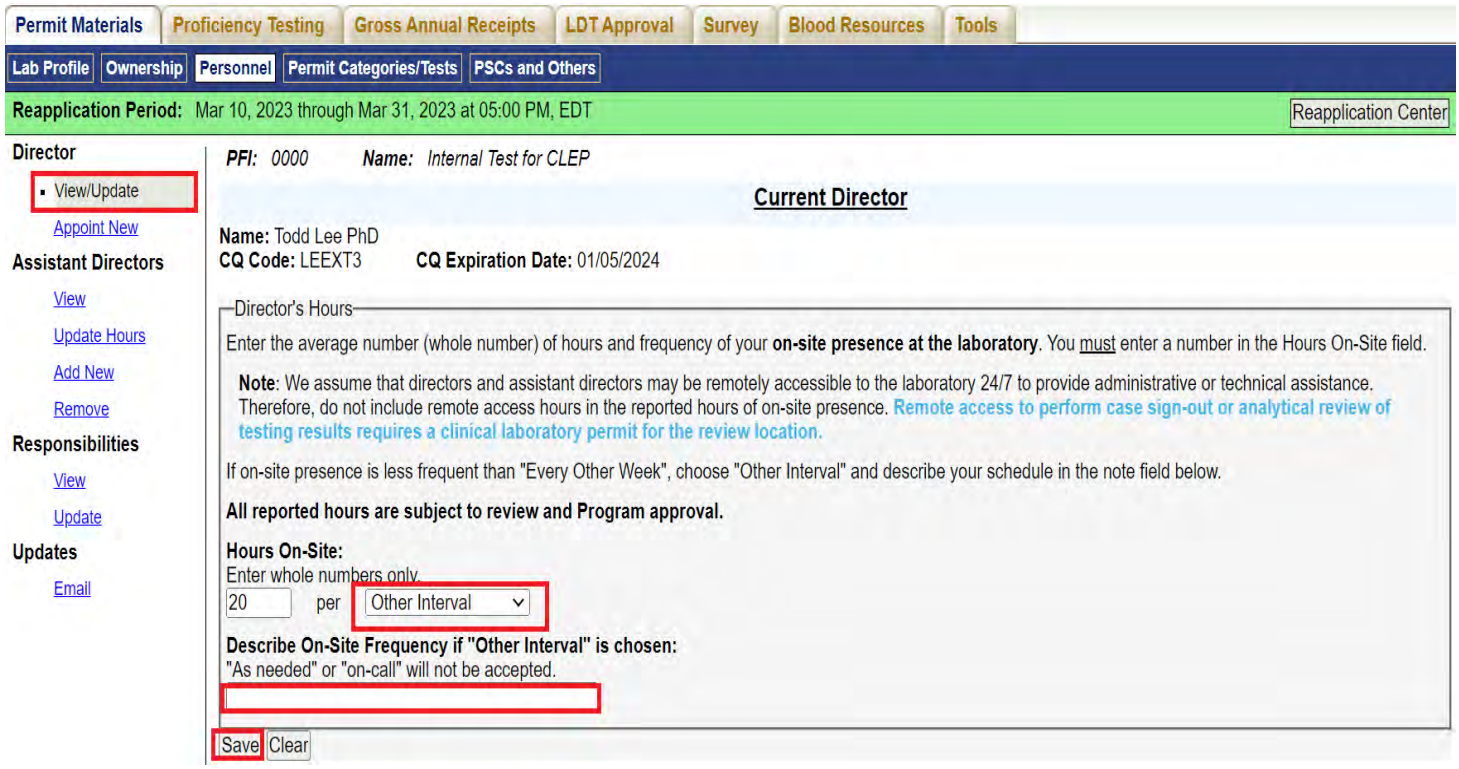


Director section

The **Director** section allows you to view and update current on-site hours for the Laboratory Director as well as appoint a new Laboratory Director. Update hours (whole numbers ONLY) and frequency as needed and click **Save**.



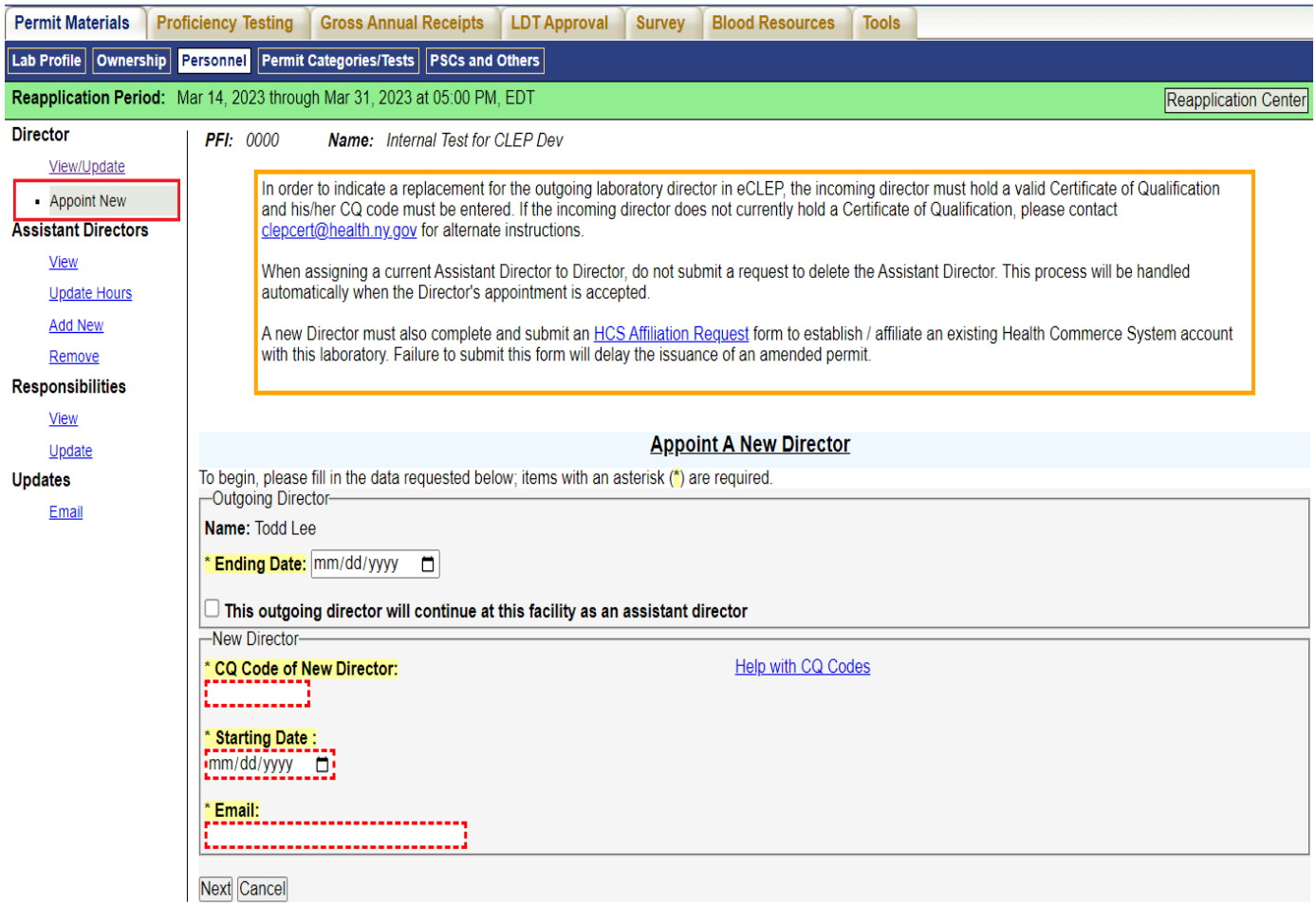
If the frequency "Other interval" is selected from the drop-down menu, then it is mandatory to provide the proposed frequency in the note field provided. Click **Save.**



ECLEP MANUAL

To appoint a new Director, enter the CQ Code of the new director, the effective dates of the change and the work email address at this facility. Click **Next**.

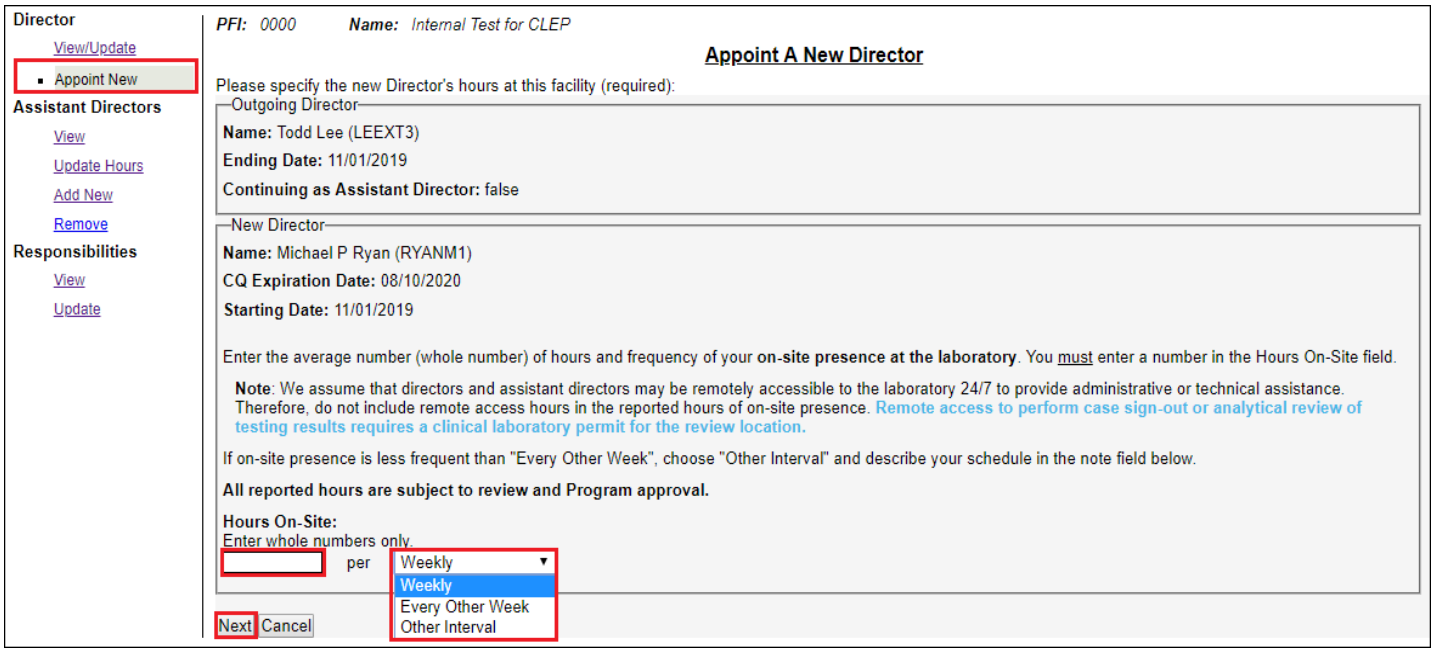
***Note**: In order to indicate a replacement for the outgoing laboratory director in eCLEP, the incoming director must hold a valid Certificate of Qualification and his/her CQ code must be entered. If the incoming director does not currently hold or has not applied for a Certificate of Qualification, please contact clepcert@health.ny.gov for alternate instructions.*



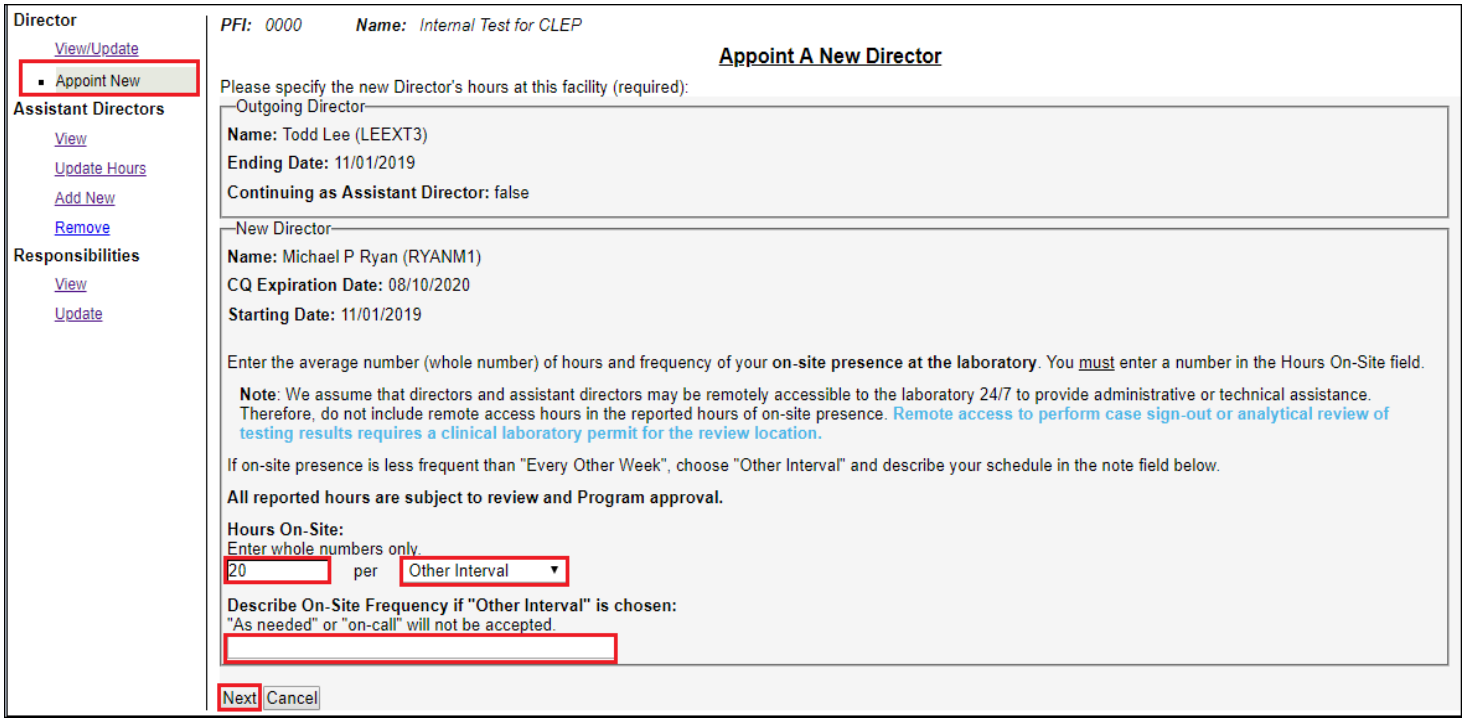
- Note, when a new Laboratory Director is appointed, s/he must also complete and submit an HCS Affiliation Request form available at **www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/health-commerce.**
- Note, a current Laboratory Director cannot be removed from the laboratory without identifying a replacement. **If the incoming director does not currently hold a Certificate of Qualification, please contact CLEP at clepcert@health.ny.gov for alternate instruction.**

Article 5 Title V of the New York State Public Health Law at Section 575 states that a permit shall become void by a change in the director, owner, or location. Therefore, timely transition to a new qualified director is essential. Please contact CLEP at clepcert@health.ny.gov for assistance.

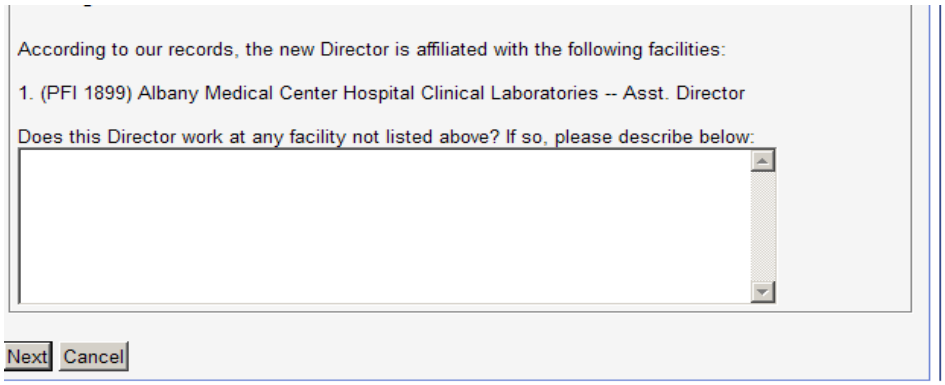
On the following screen, enter the new director's on-site hours (whole number ONLY) and select the frequency from the drop-down menu, click **Save**.



If the frequency "Other interval" is selected from the drop-down menu, then it is mandatory to provide the proposed frequency in the note field provided.



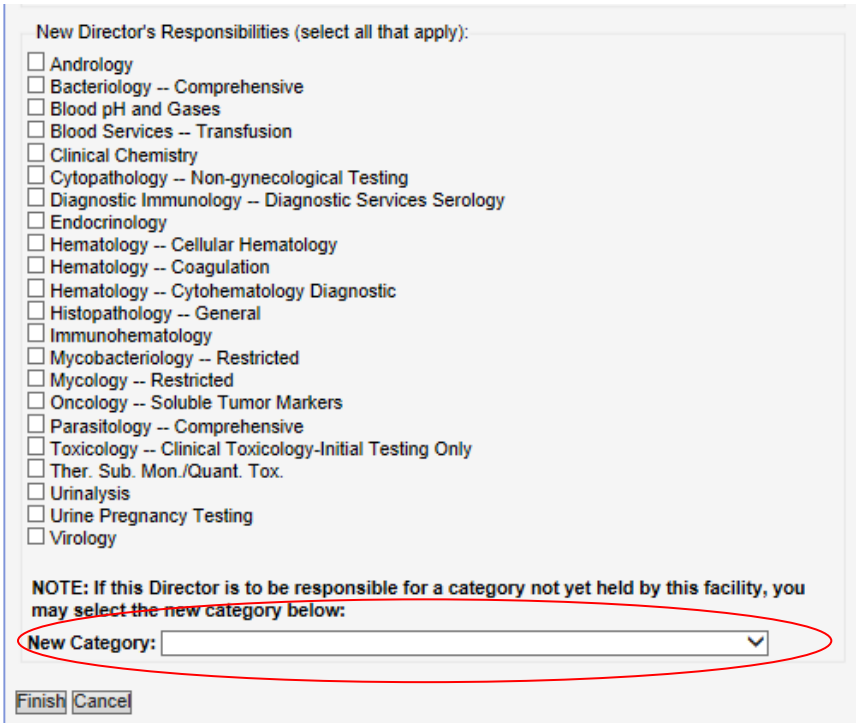
Review the additional places of employment for the new director; add additional facilities as needed; click N**ext**.



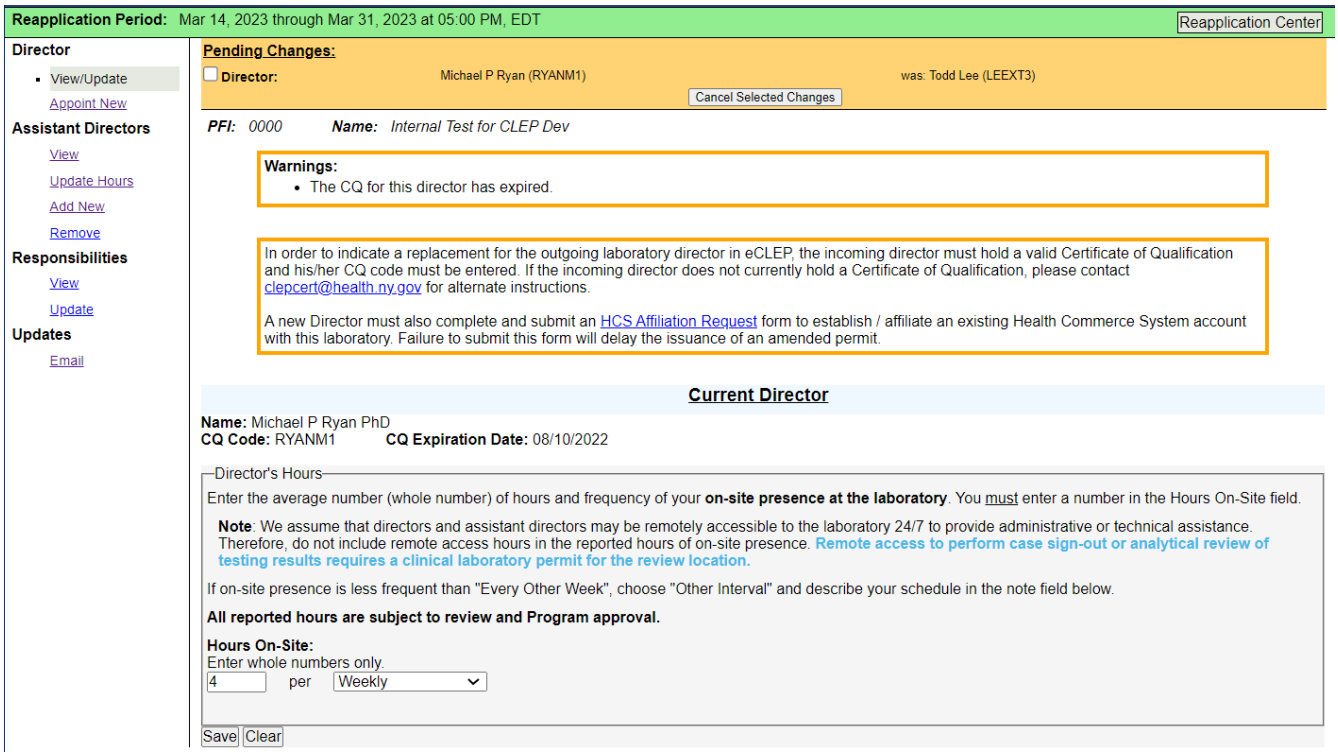
Indicate the permit categories in which the new director will have responsibilities, click **Finish**. The check box list includes all categories either held or in applied status for the laboratory.

Note: The new director must hold a Certificate of Qualification in the corresponding category to allow assignment of responsibility for a permit category. If the laboratory director does not hold the appropriate corresponding category on his/her Certification of Qualification, the request for assignment of responsibility for the permit category will be rejected. An individual may not serve as laboratory director unless s/he is assigned responsibility for at least one permit category.

This page also allows the laboratory to request one additional category by choosing a category from the New Category dropdown below the check box list, then click **Finish**.

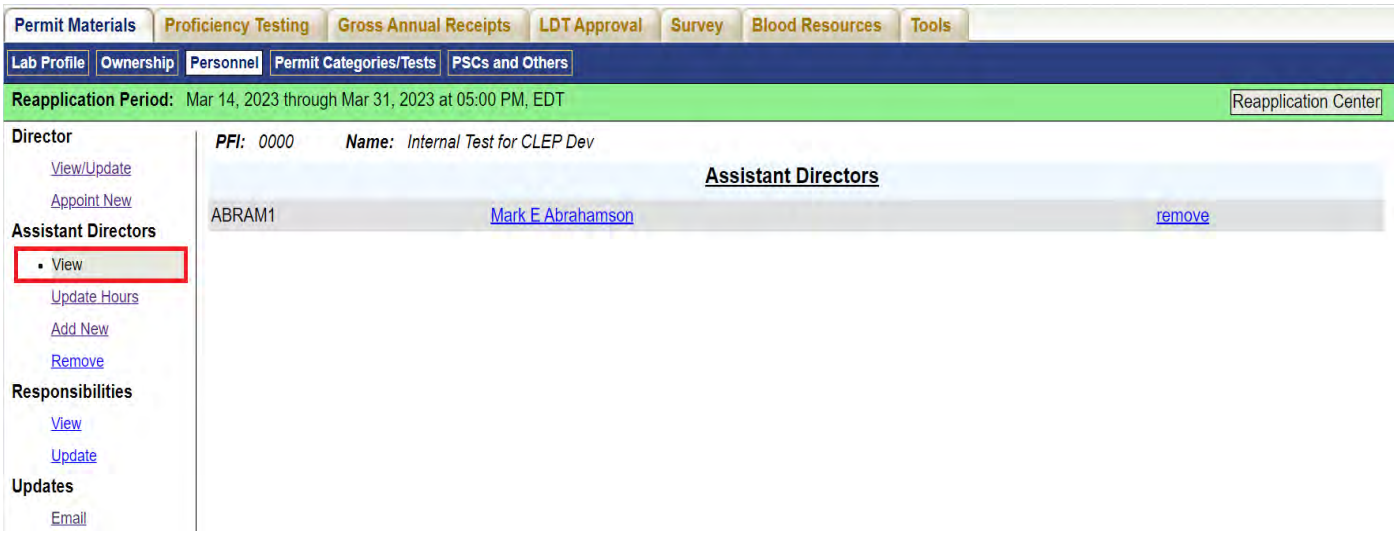


The next page will display the new director change. Review the information for accuracy and click **Save**.

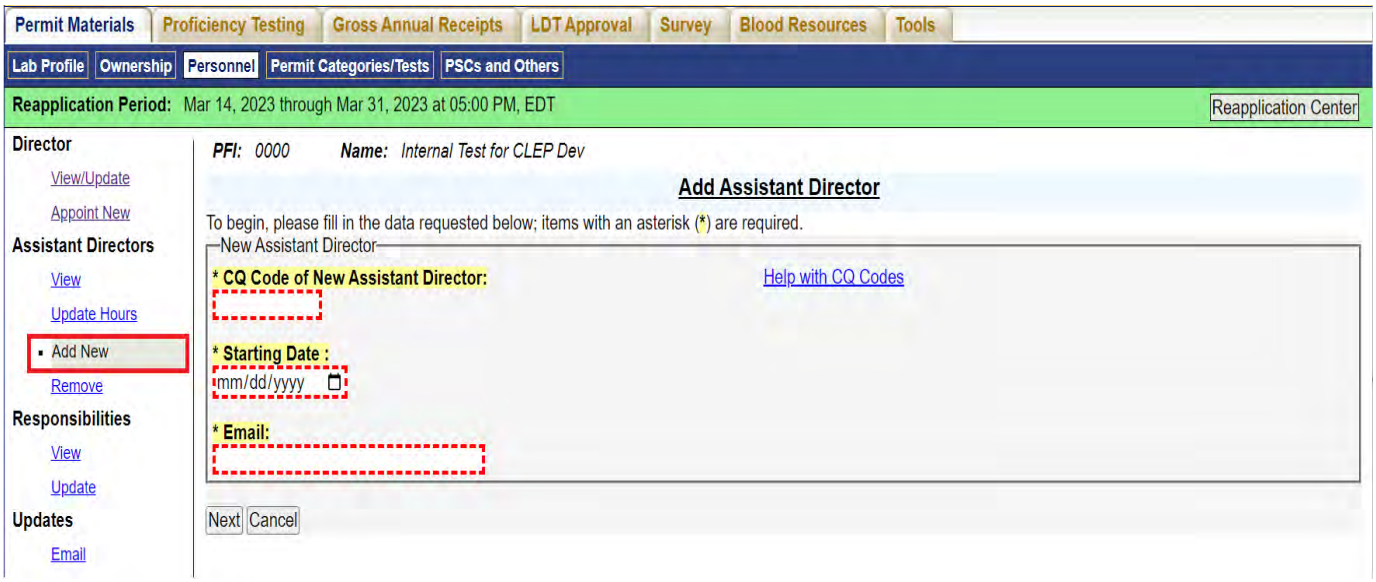


Assistant Director section

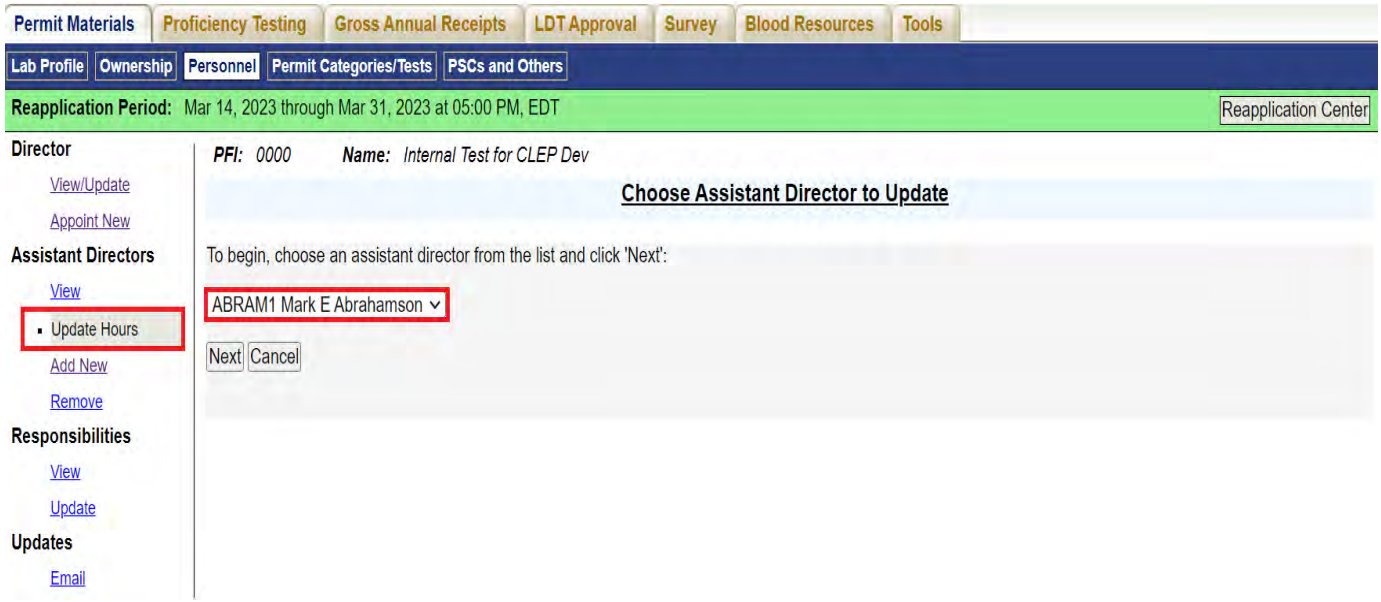
The **Assistant Director** section allows you to view the current assistant directors, update assistant director on-site hours, add a new assistant director(s), and remove an assistant director(s).



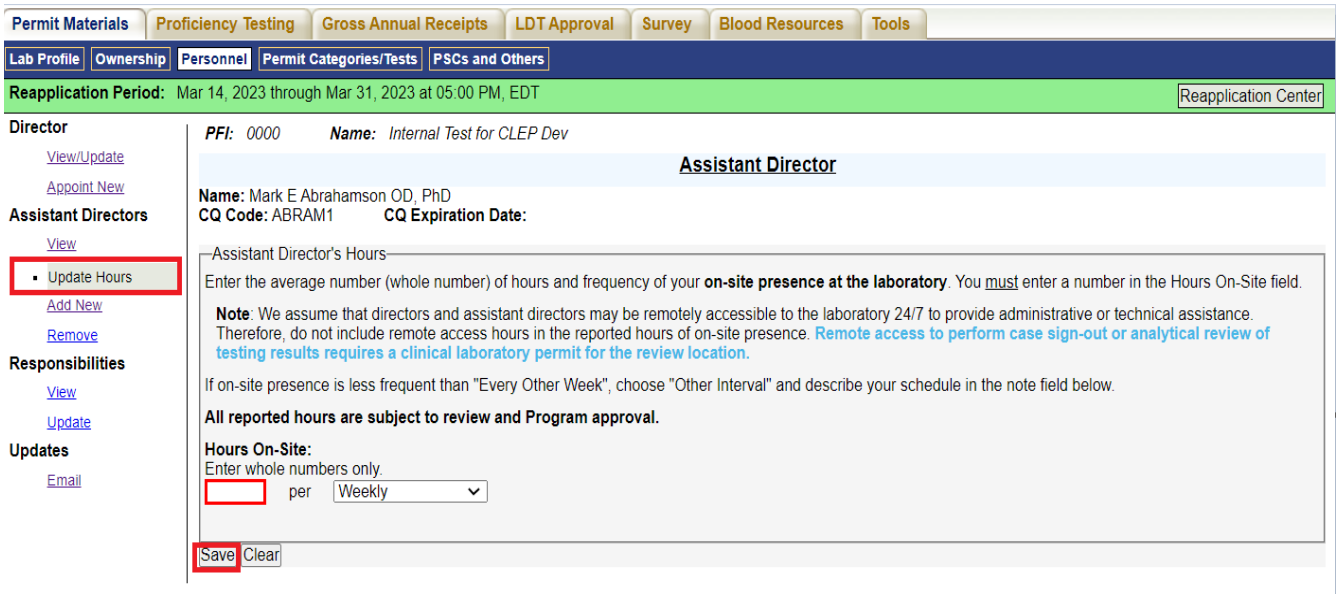
To add an Assistant Director, please follow the steps as presented above for appointing a new Laboratory Director.



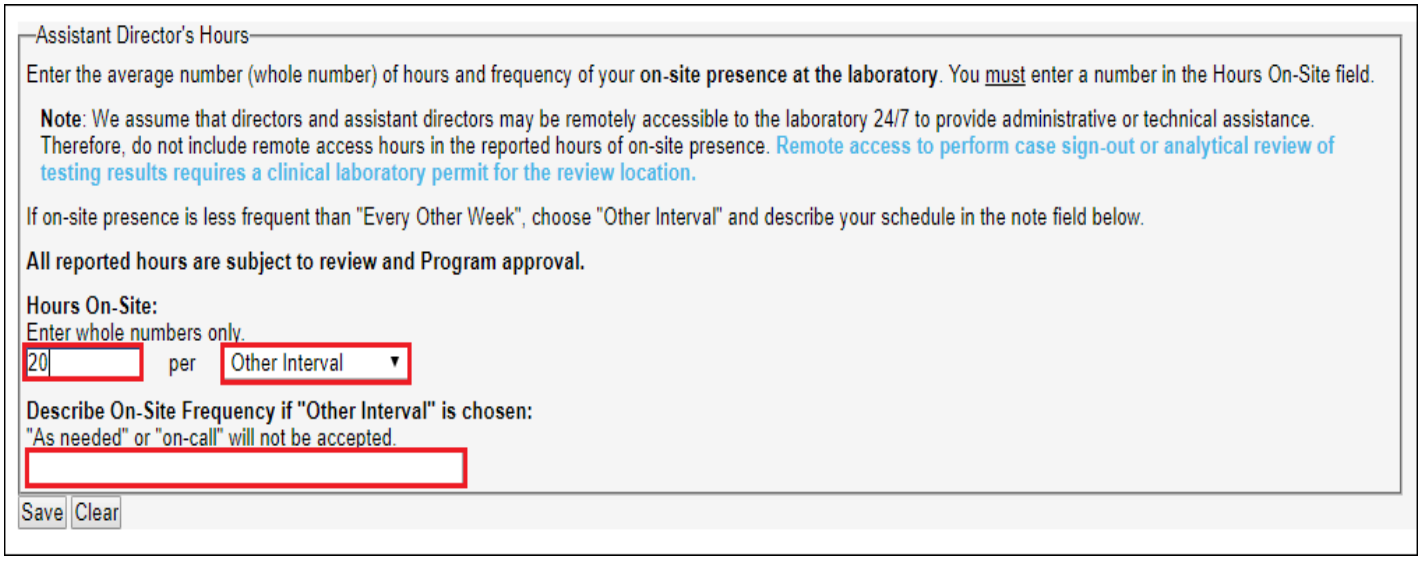
- **To update the on-site hours for an Assistant Director**, either click on the individual's name in the **View** page (see above) or choose the individual from the drop-down list presented on the **Update Hours** page, click **Next**.



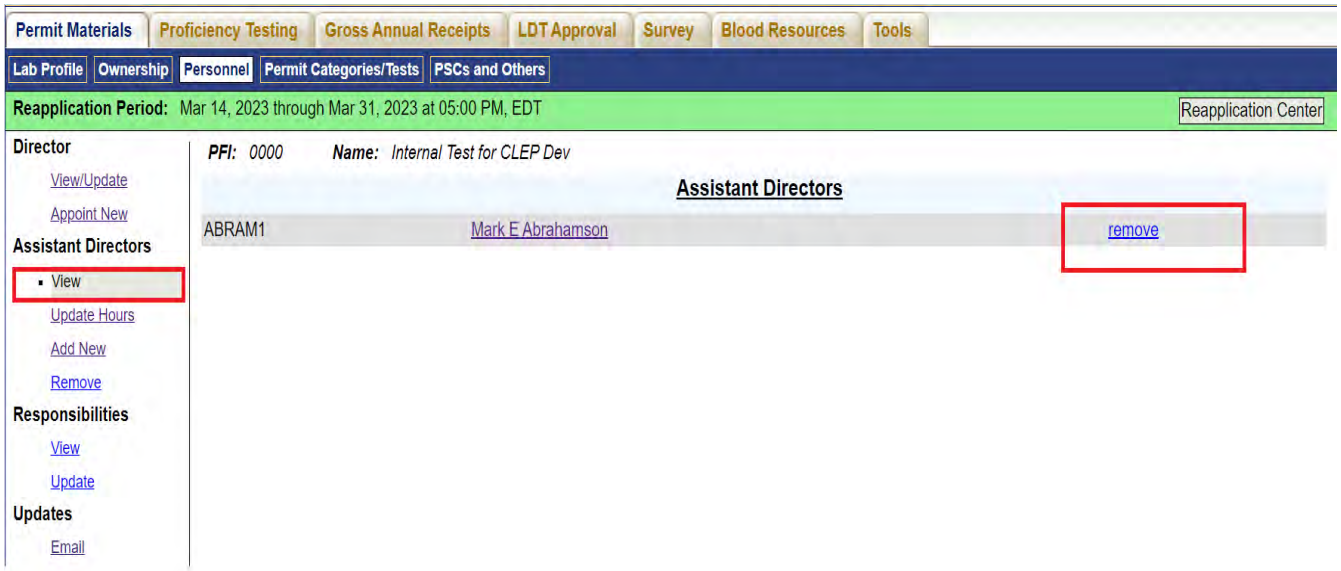
- On the next screen, update the hours as needed, click **Save. Note:** The Clinical Laboratory Evaluation Program may seek clarification of the Assistant Director's work schedule before accepting the proposed change.



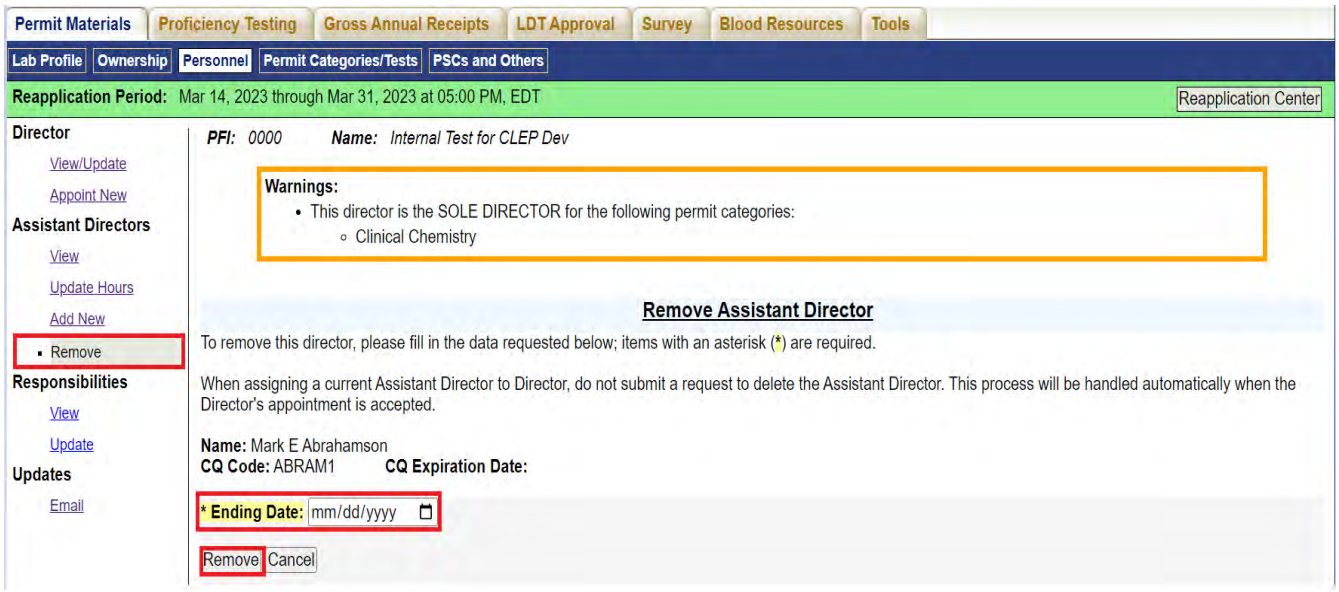
- If the frequency "Other interval" is selected from the drop-down menu, then it is mandatory to provide the proposed frequency in the note field provided.



- **To remove an Assistant Director,** either click the remove link next to the individual's name on the **View** page; or choose the individual from the list presented on the **Remove** page, click **Next**.



- On the following page, enter the effective date of the Assistant Director's departure, click **Remove**.



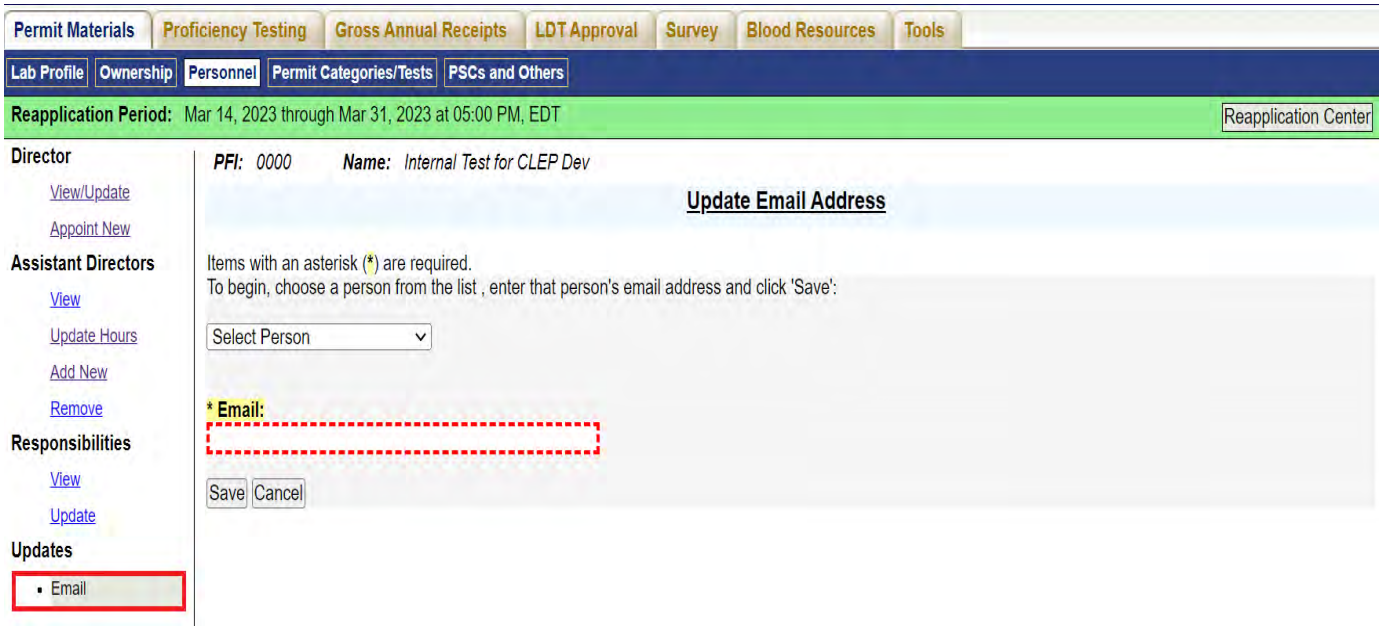
Note: If the departing assistant director is the sole individual responsible for a permit category(ies), the Clinical Laboratory Evaluation Program will notify the director that the laboratory is in jeopardy

of losing an approved (or pending) permit category unless a timely arrangement is made for assigning a qualified person (current or new) to be responsible for the permit category.

Article 5 Title V of the New York State Public Health Law at Section 575 states that a permit shall become void by a change in the director, owner, or location. Therefore, timely transition to a new qualified director is essential. Please contact CLEP at clepcert@health.ny.gov for assistance.

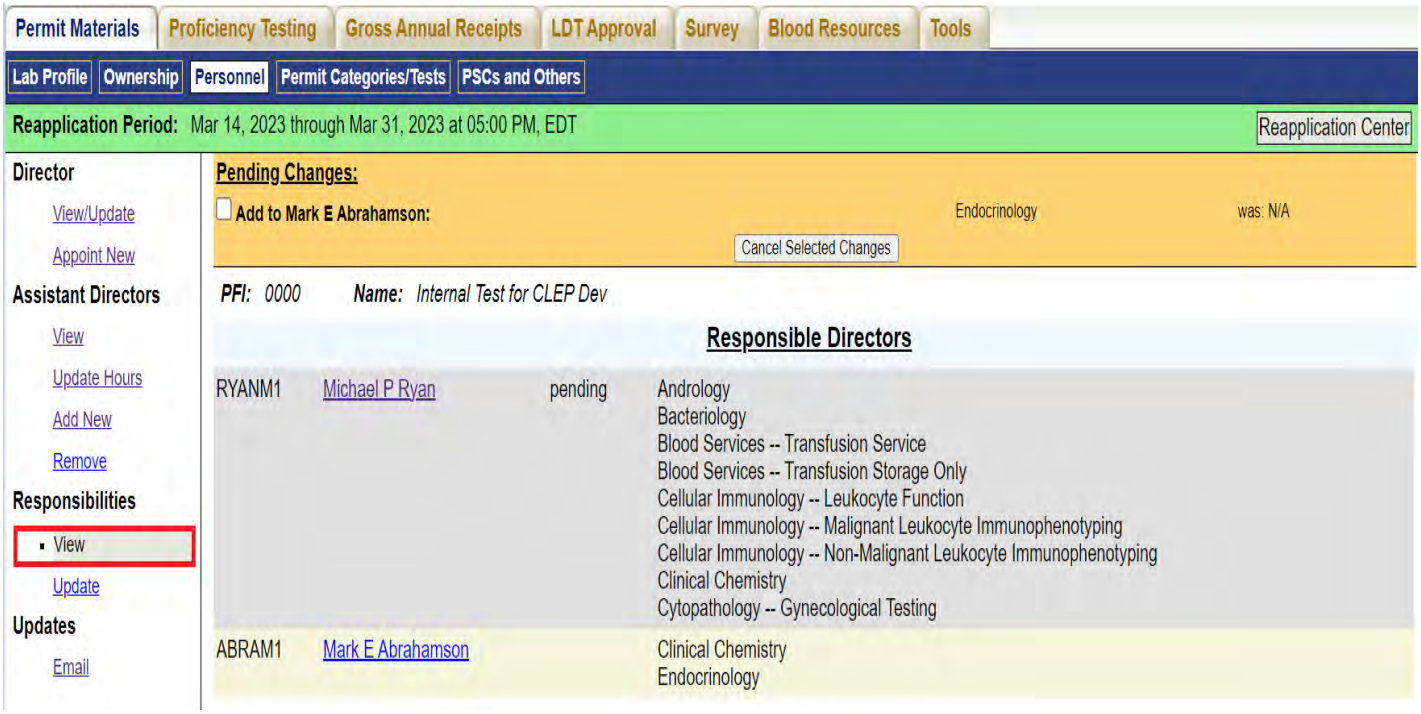
NEW

- **To update a personnel's email address**, on the **Email** webpage choose the individual from the drop-down list presented. Update the email address. Click **Save.**

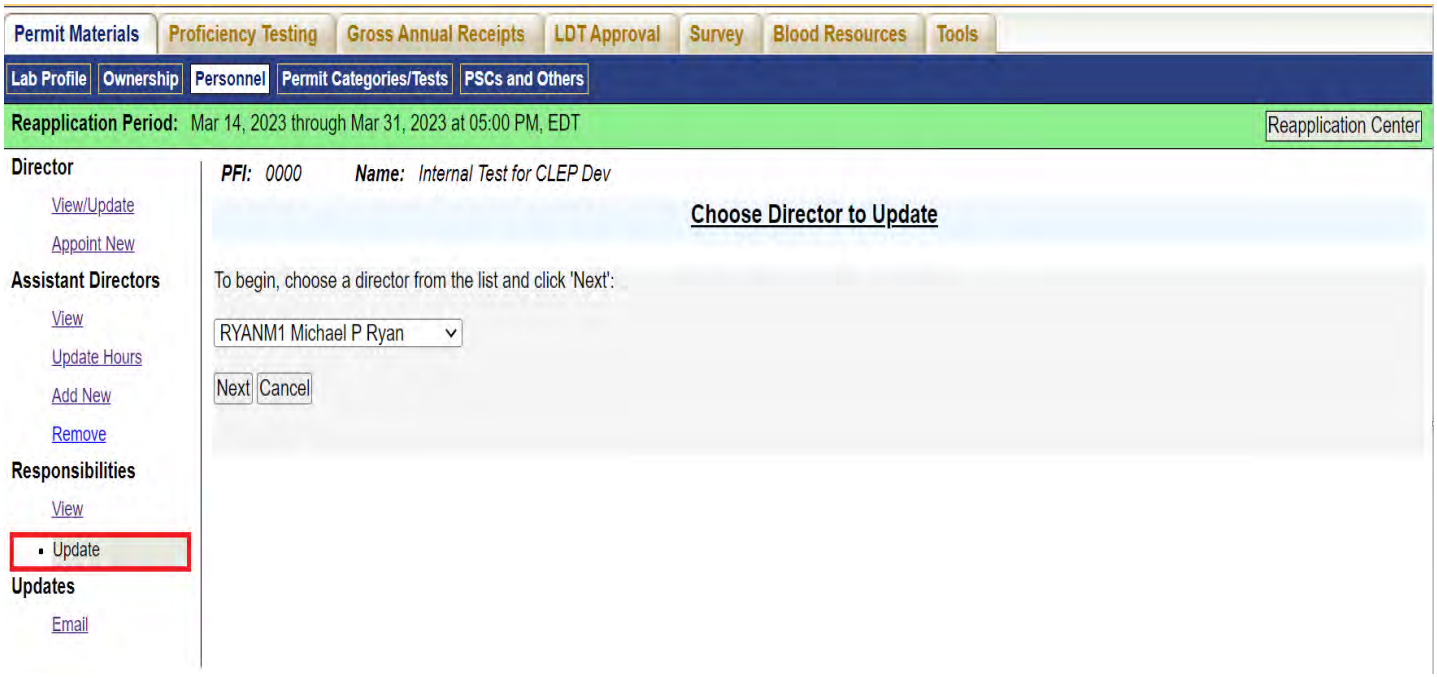


Responsibilities Section

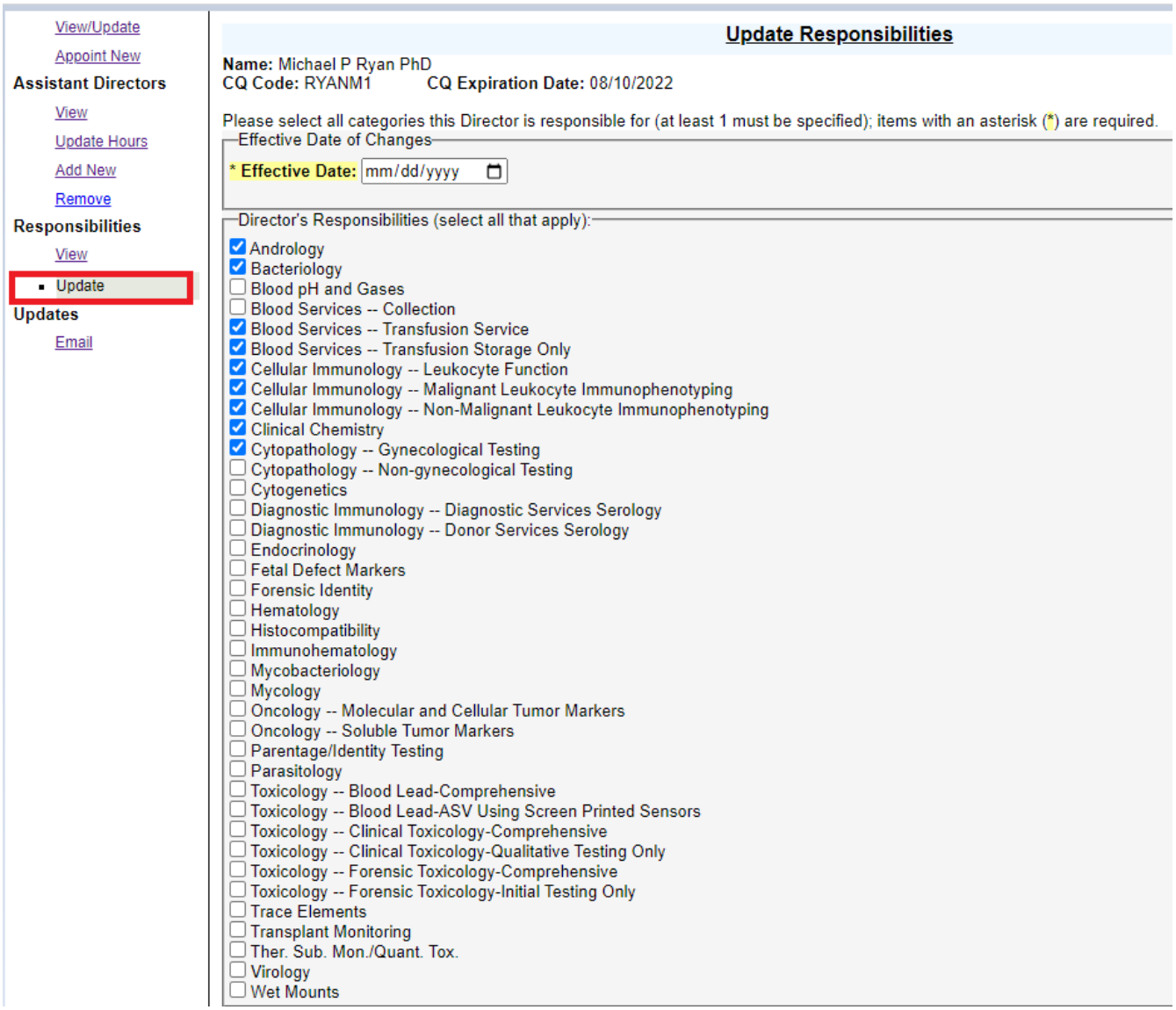
This section allows the laboratory to view all the permit categories and the corresponding CQ holders with responsibility. On the "**View**" page, clicking on a Director's name will allow you to edit the responsibilities for that individual.



From the **Update** page, choose a Director from the dropdown to make edits to responsibilities.



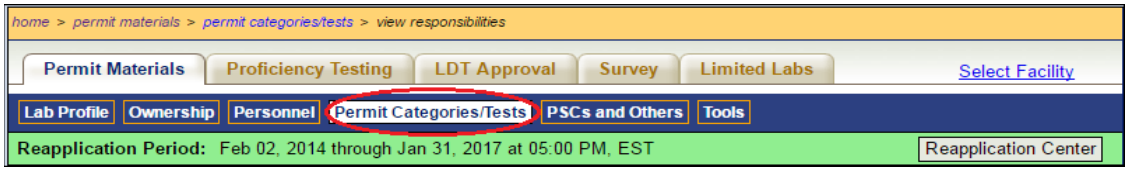
Existing permit category responsibilities are indicated by a check mark. Additional permit categories can be requested by adding a check mark next to the desired category and clicking 'Save'.



Permit Categories/Tests

The **Permit Categories/Tests** sections allows you to:

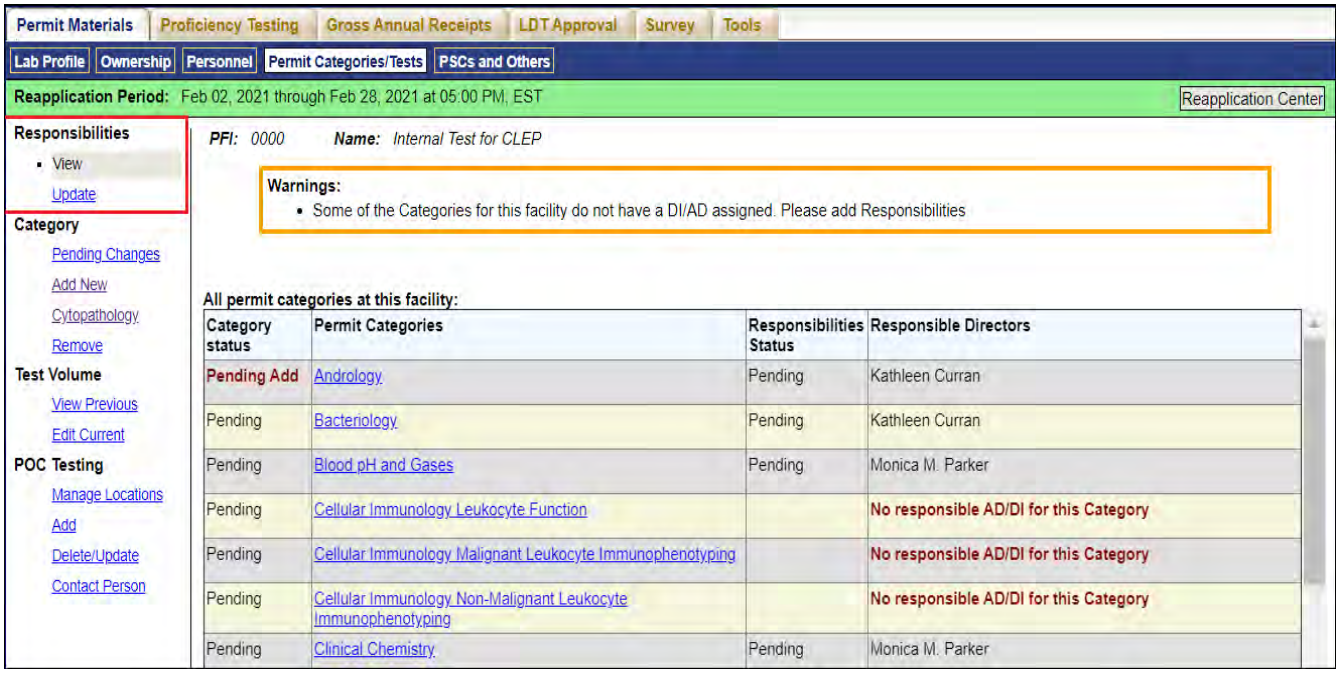
- add permit categories to the laboratory permit;
- change permit category responsibilities for the laboratory director and/or assistant director(s);
- remove permit categories from the laboratory permit;
- enter test volumes (required for laboratories located in NYS during permit reapplication).

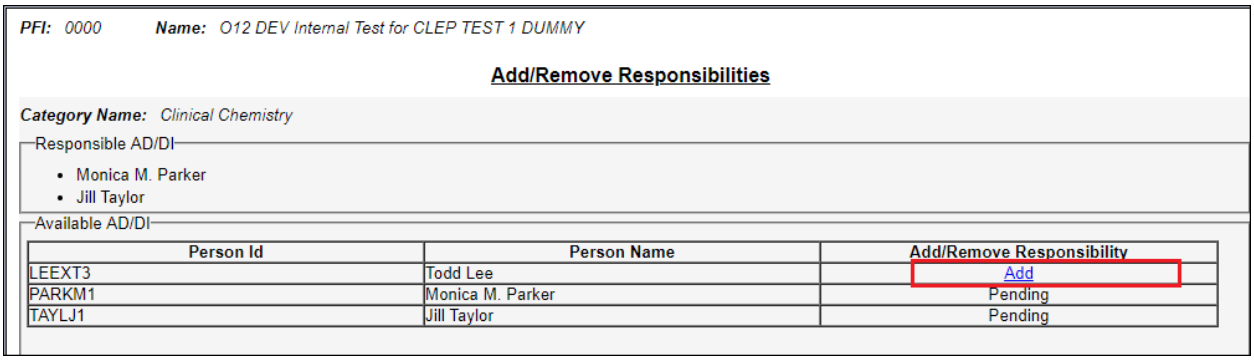


Responsibilities section

Under the **Responsibilities** section, you may view the laboratory's current permit categories, the status of each category, and the laboratory director (DI) /assistant director (AD) responsible for each permit category.

- Click on the permit category name to view the current DI/ AD responsible for the category and to add or remove individuals as responsible.

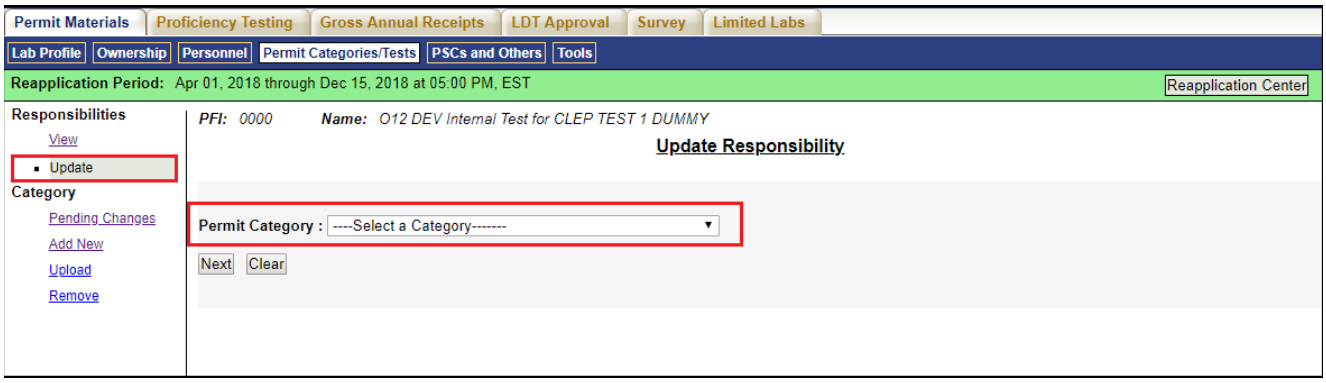




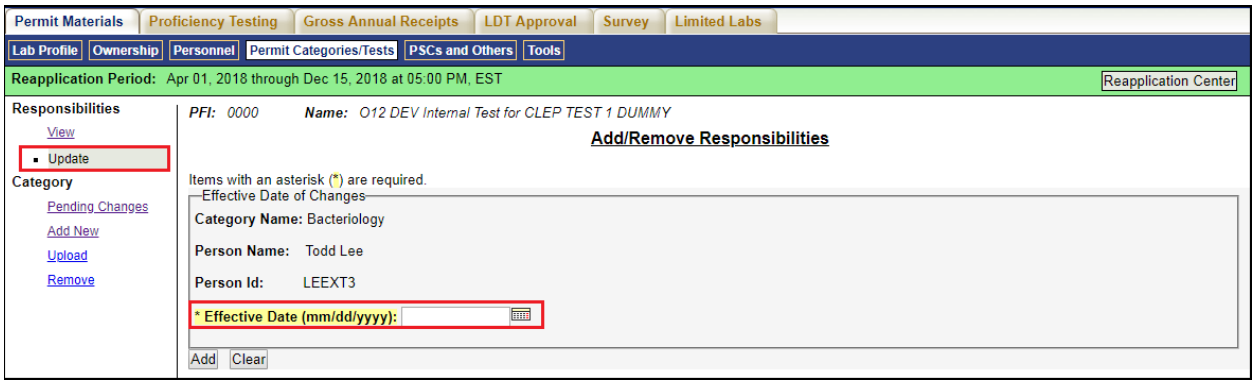
("Person Id" is the Certificate of Qualification code)

Alternatively, choose the category to update from the Responsibilities Update page, click **Next**. This dropdown menu will include all categories that the laboratory has applied for (pending) and those already held (approved). This will take you to the same page as above.

Note: Personnel changes still pending review by the Department will not appear as available for responsibility assignment (e.g., changes entered but not yet submitted in eCLEP). Only Certificate of Qualification holders already associated with the laboratory will be listed. A new Assistant Director must be added through the Personnel section.



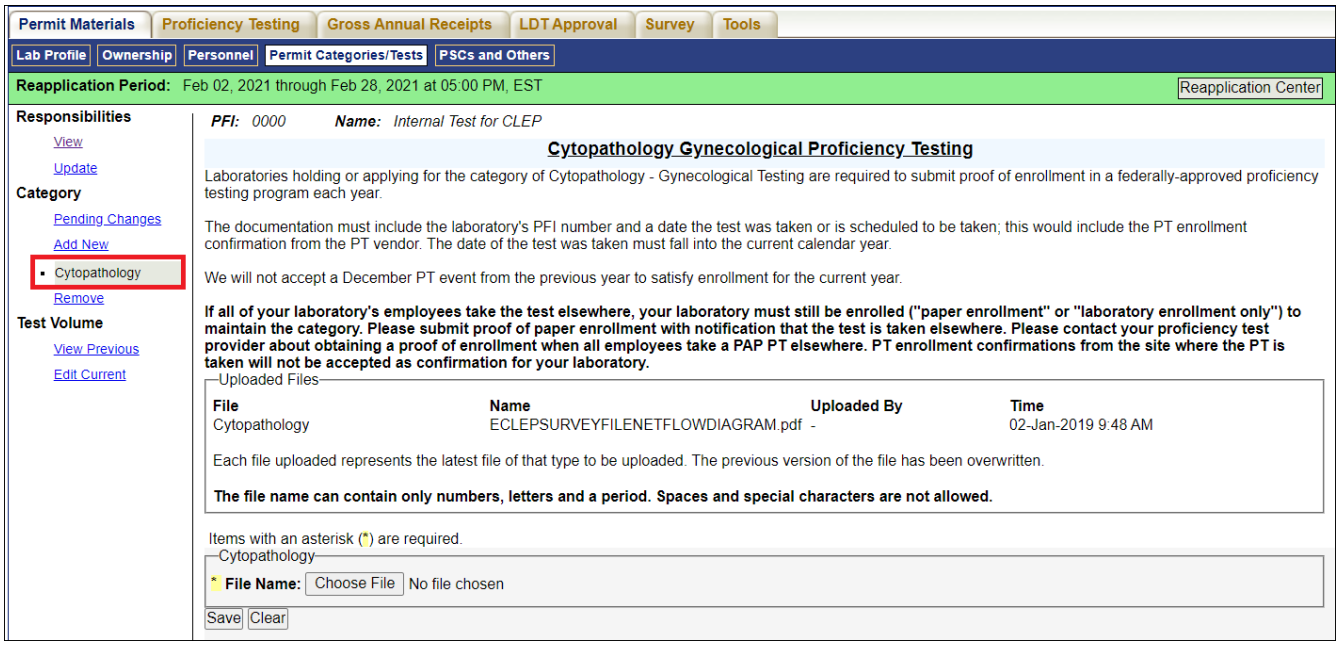
On the following page, indicate the effective date of the individual's new responsibility, click Add.



Category Upload – Cytopathology Proficiency Testing Enrollment

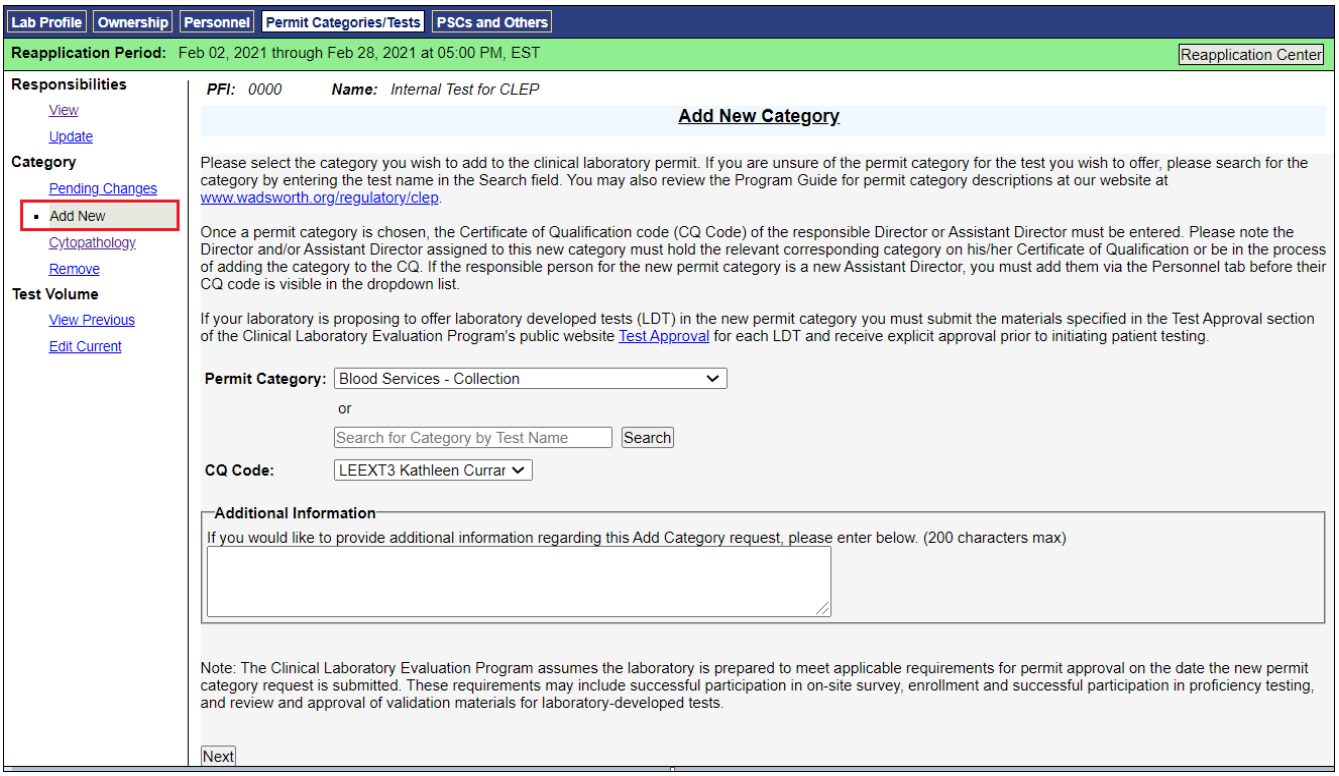
During permit reapplication, laboratories holding the category of **Cytopathology – Gynecological Testing** are required to upload proof of enrollment in a CMS-approved proficiency testing (PT) program. **Acceptable documentation is an enrollment confirmation from the PT program.** Purchase orders and order forms are not acceptable.

- The enrollment confirmation must reference the laboratory name and address.
- The PFI number of the laboratory must be handwritten on the paper if the PFI or CLIA number is not already included.
- If the laboratory personnel participate in PT at another site, the order confirmation for “paper enrollment” must be provided.



Add a Category

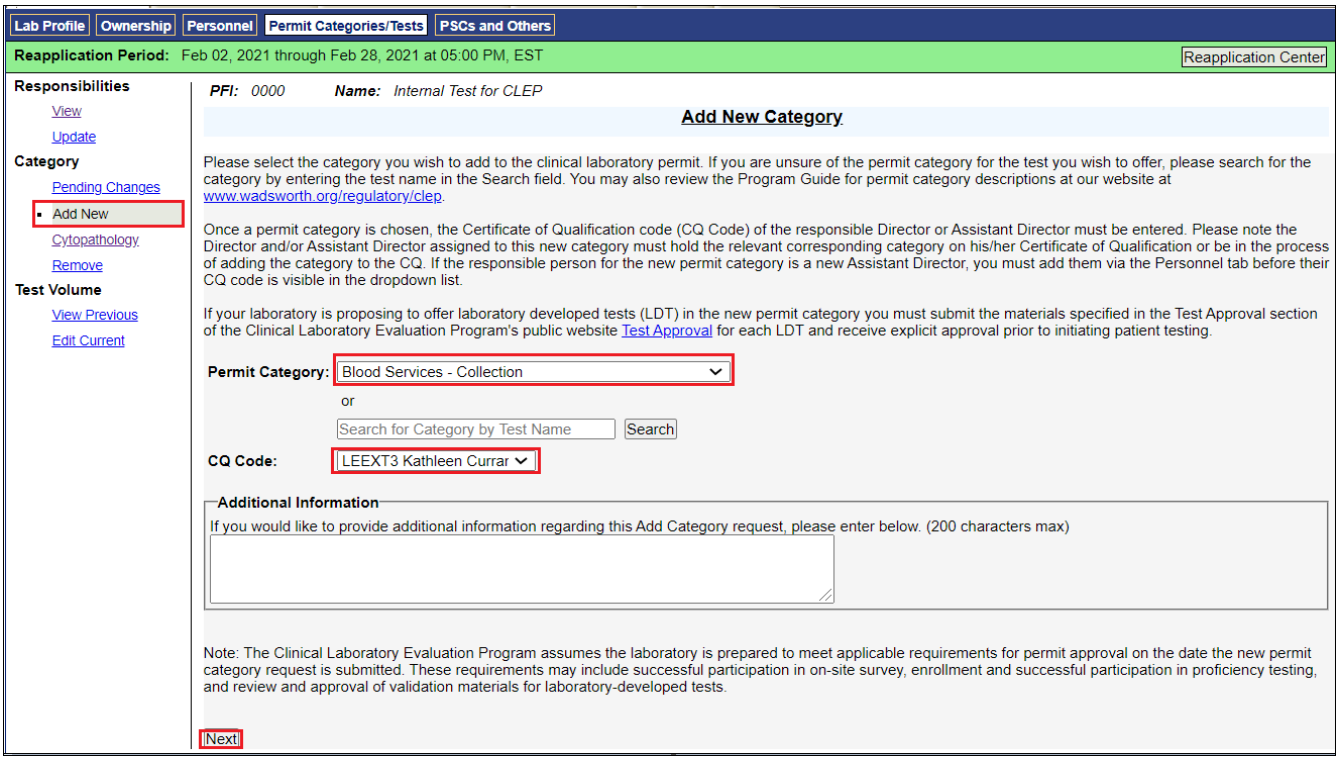
To request to add a permit category, click on the **Add New** hyperlink from the left panel under Category.



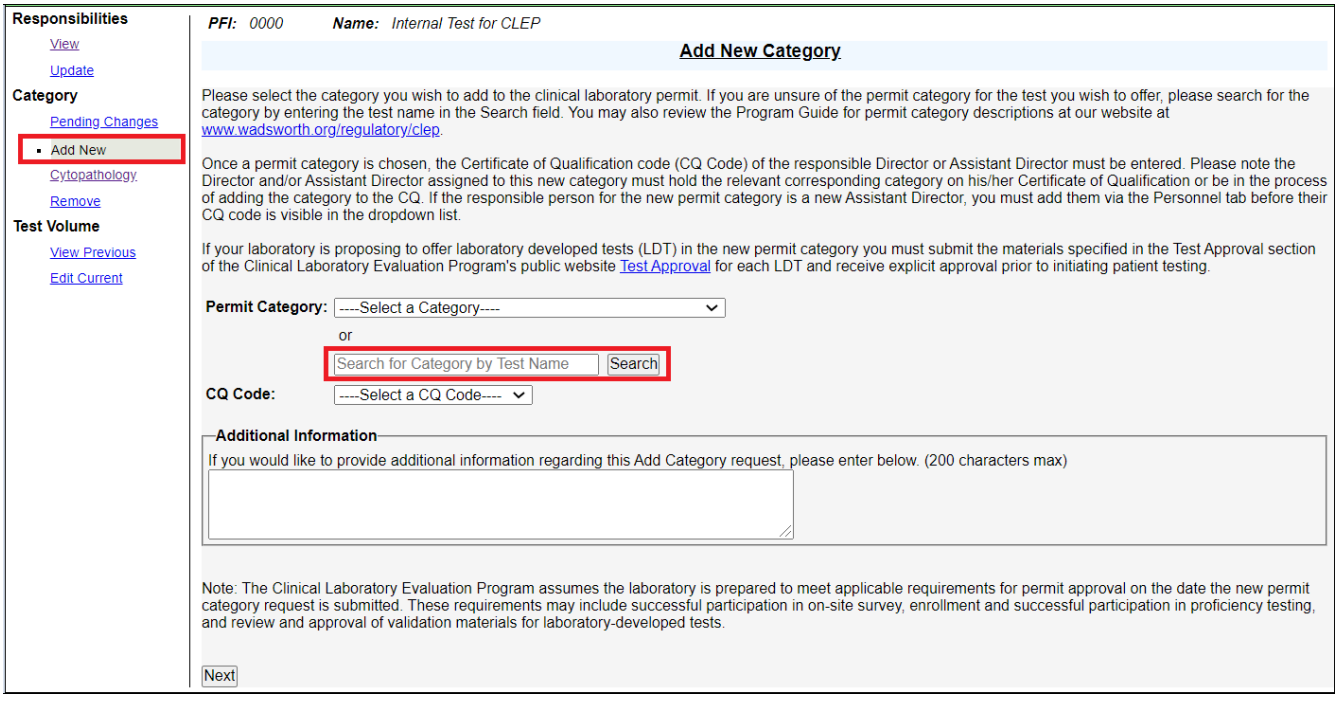
Choose the desired permit category from the dropdown menu and choose a responsible director or assistant director for the new category using the individual's CQ code. If you do not see the individual's CQ code in the list, you must add the individual under the Personnel tab before proceeding with the Add Category request. Please note that both **Permit Category** and **CQ Code** fields are mandatory.

Once the Permit Category and CQ code have been chosen, click the Next button. When requesting to add a category that includes analytes/test that are described in CLIA Subpart I (42 CFR 493 Subpart I), you will be required to indicate the CMS-approved proficiency test provider and product that will be used to satisfy proficiency testing requirements.

ECLEP MANUAL



If you are unsure of what category is required for the testing that will be offered by the laboratory, you can use the search engine to search for category by test name. Please make sure the browser you are using is not blocking pop-ups, otherwise your search result will not be displayed.



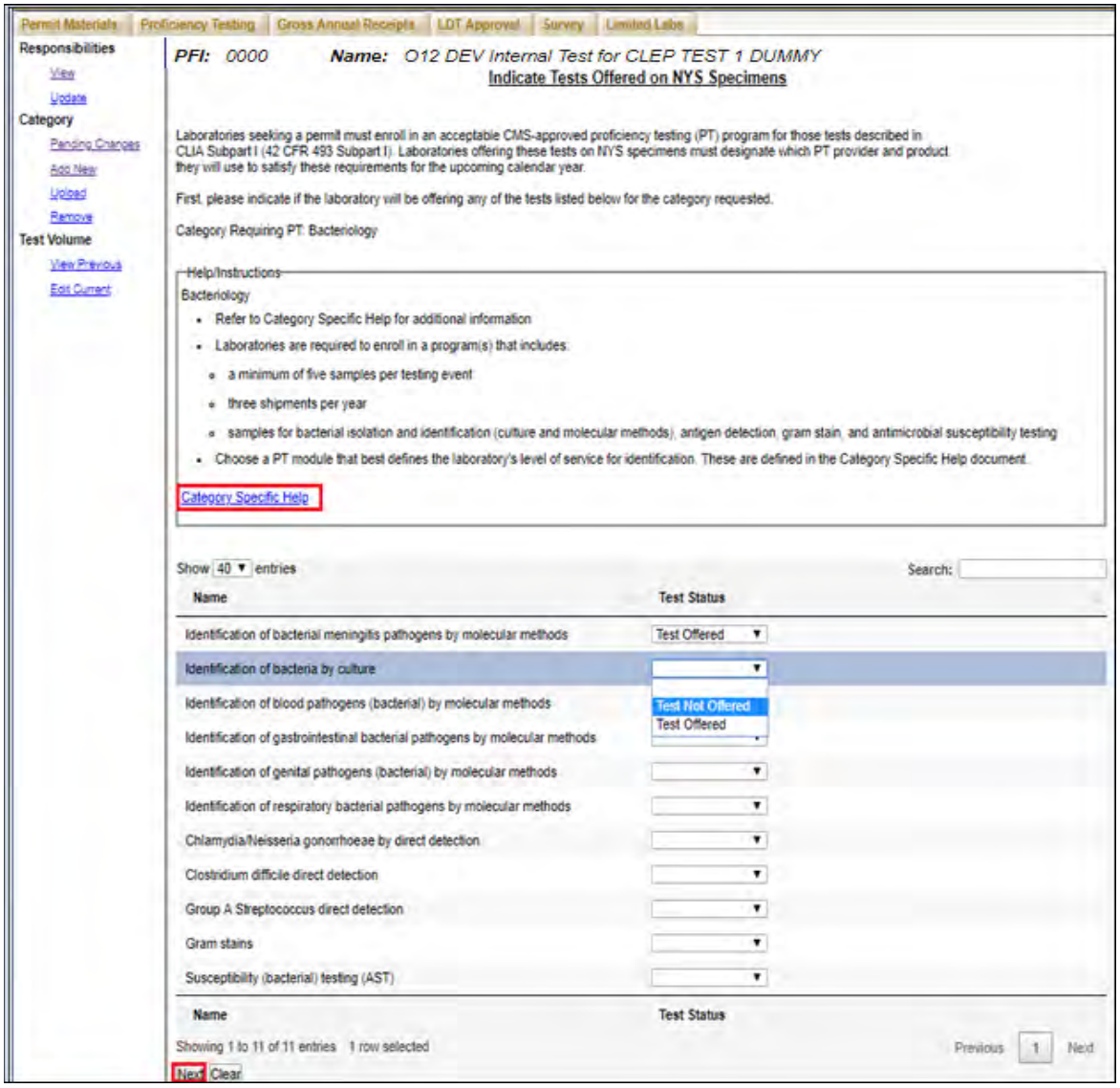
Indicate Tests Offered on NYS Specimens

This page provides a list of NYS-mandated PT analytes that are included under the new category. Please indicate whether you offer these tests or not by selecting an option from the drop-down menu.

More information on NYS-mandated PT Analytes can be found in the Proficiency Testing Guide available at https://www.wadsworth.org/regulatory/clep/pt.

The hyperlink **Category Specific Help** provides additional Proficiency Testing guidance by category.

All fields in this page are mandatory. Click Next button to proceed to the next page.



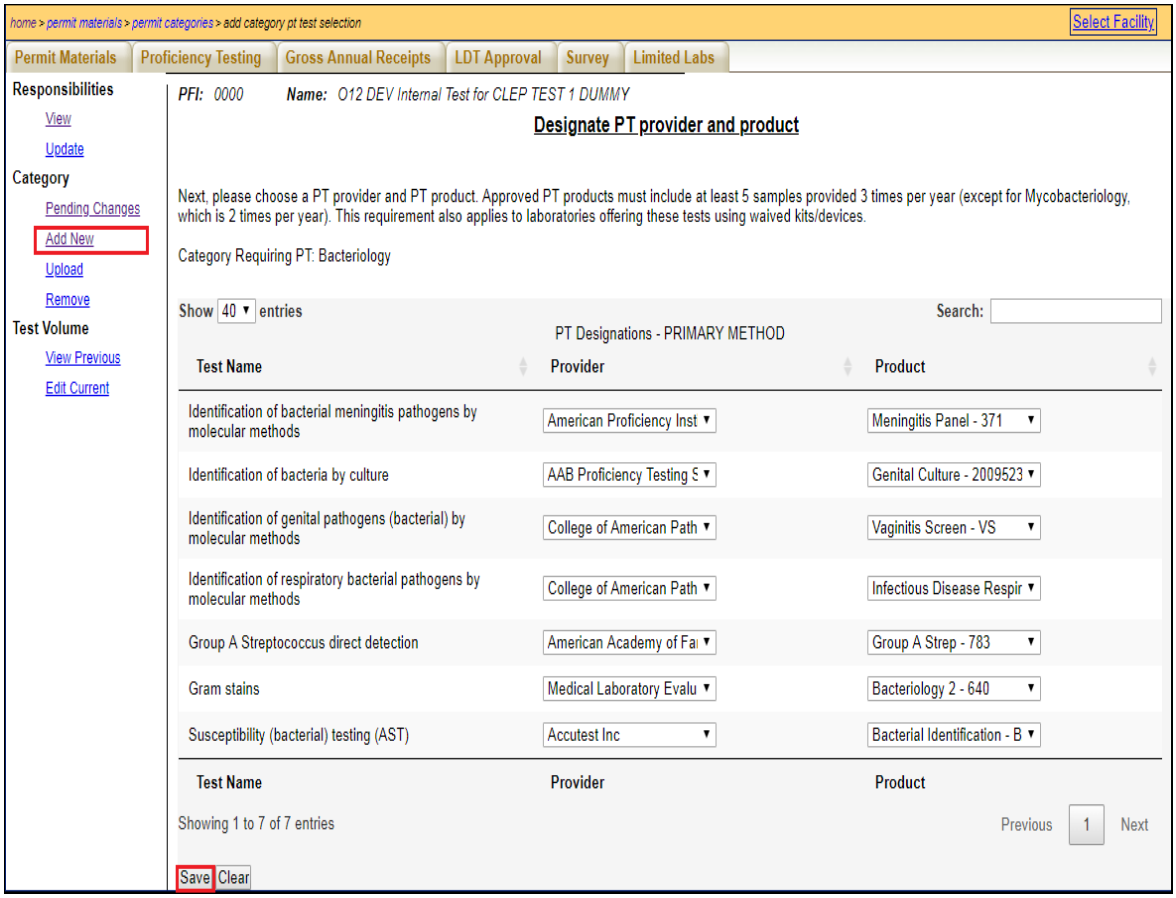
Designate PT Provider and Product

This page displays the tests that have been marked as “Test Offered” offered on the previous page.

Please provide the **PT Provider** and **Product** for each test and then click **Save** to proceed.

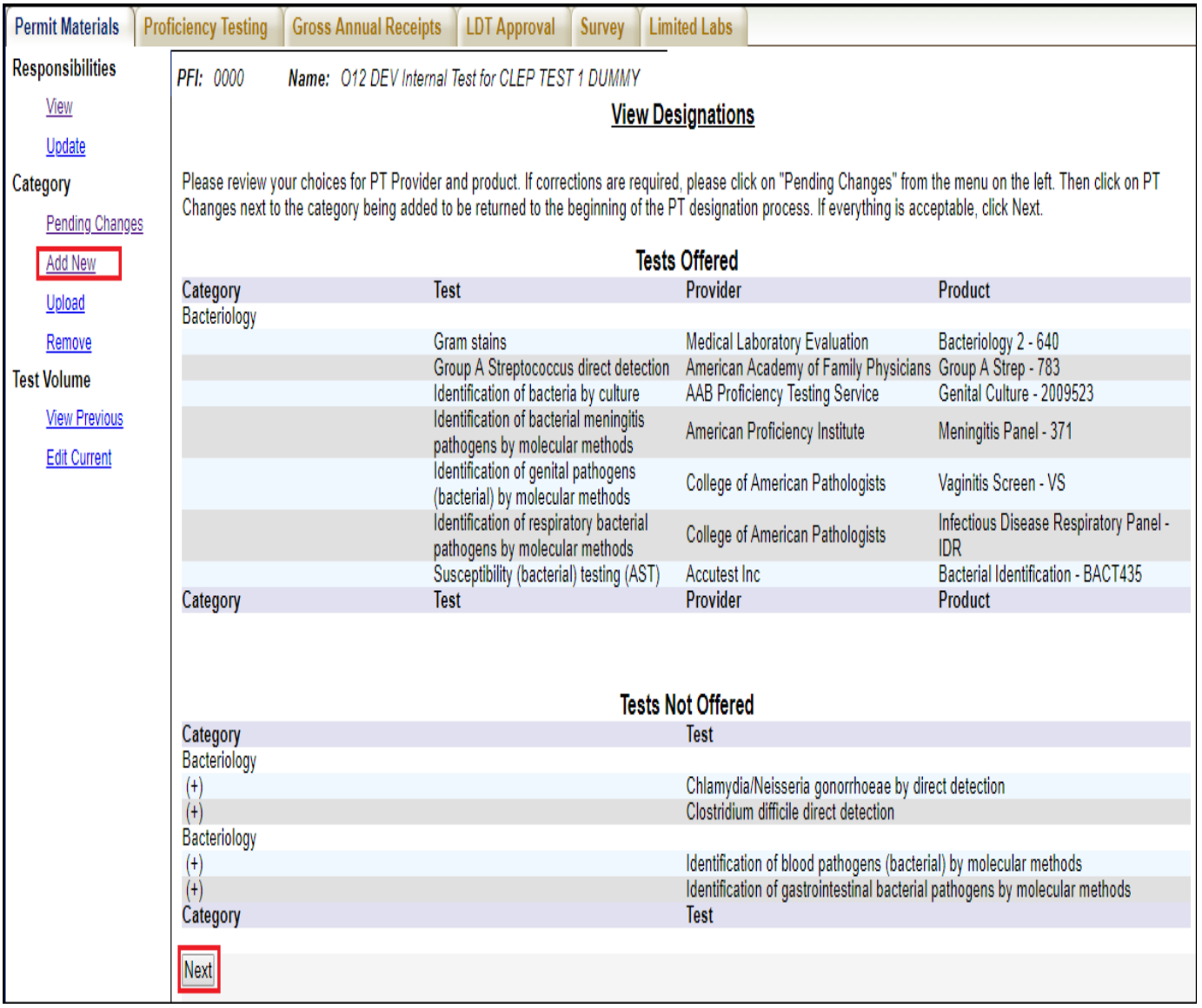
All fields in this form are mandatory.

USER TIP: If the PT Provider and Product you intend to purchase is not listed, then it has not been deemed acceptable to meet proficiency testing requirements. Contact PTAdmin@health.ny.gov for additional guidance.



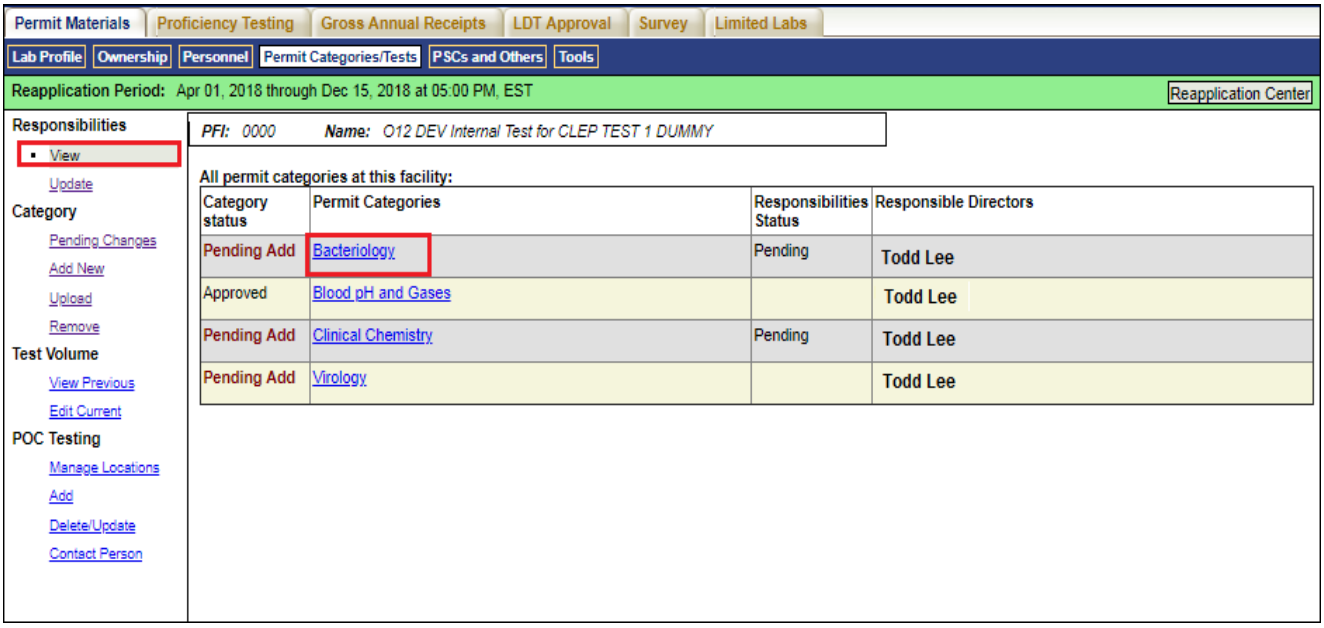
ECLEP MANUAL

View Designation page is a summary of the Proficiency Testing information that had been entered. Review and click on **Next** button to complete the process.

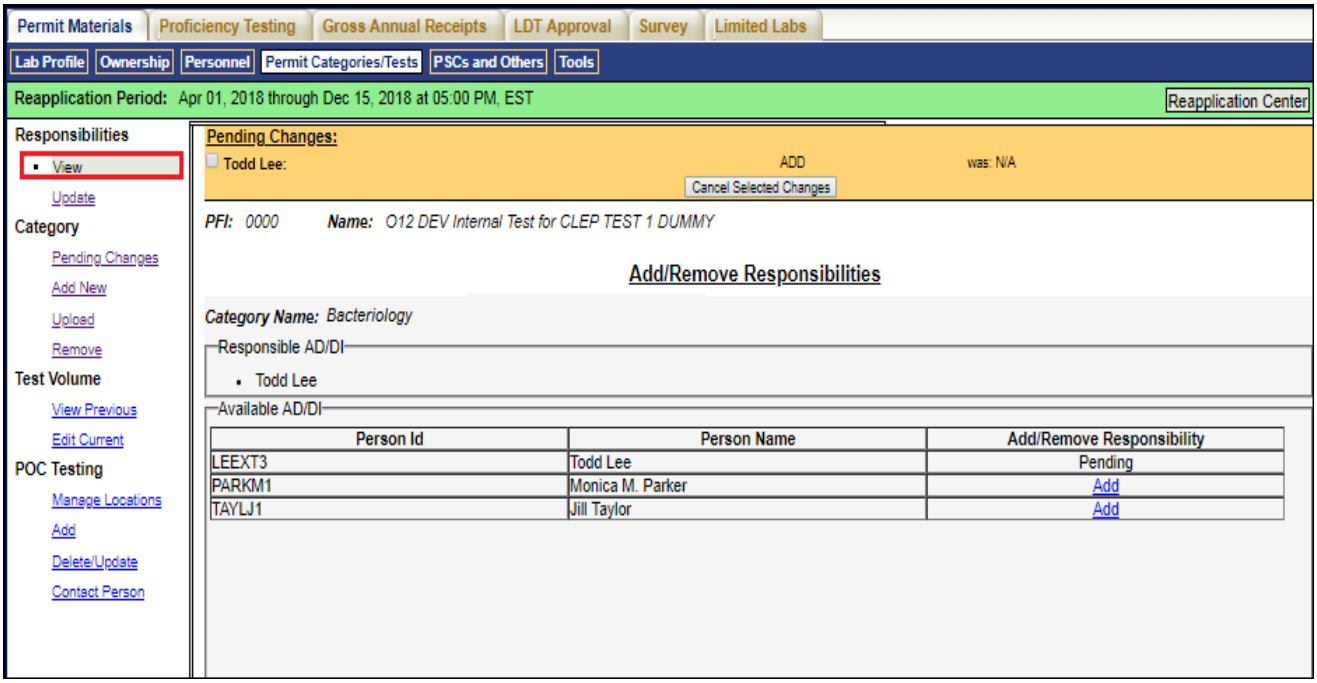


Adding More Than One CQ Holder to a New Category

To add multiple CQ holders to a new category, first add the new Category, then go to **View** under **Responsibilities** and select the newly added Category.



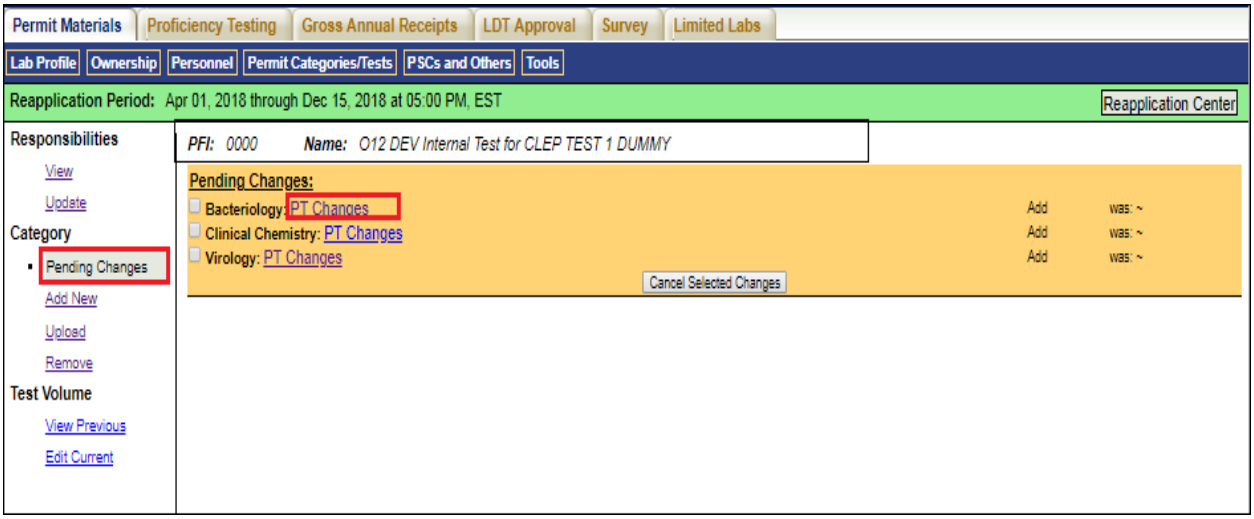
Then proceed to add additional CQ holders to the new Category:



Pending Changes page displays the list of all unsubmitted requests.

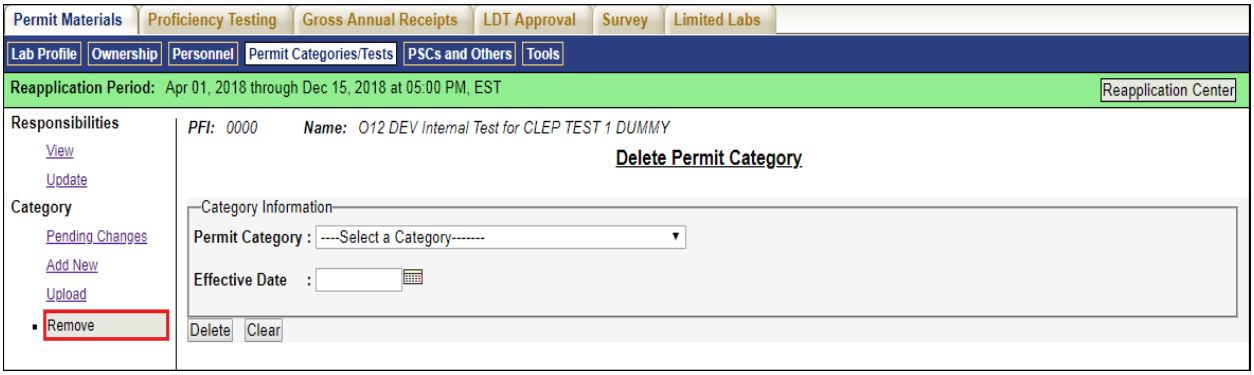
To cancel an Add Category request: select a change request by clicking the box to the left of the category name and press the **Cancel Selected Changes** button.

To modify the Add Category request: Click on the hyperlink **PT Changes**. This will allow user to modify ONLY the Proficiency Testing information entered.



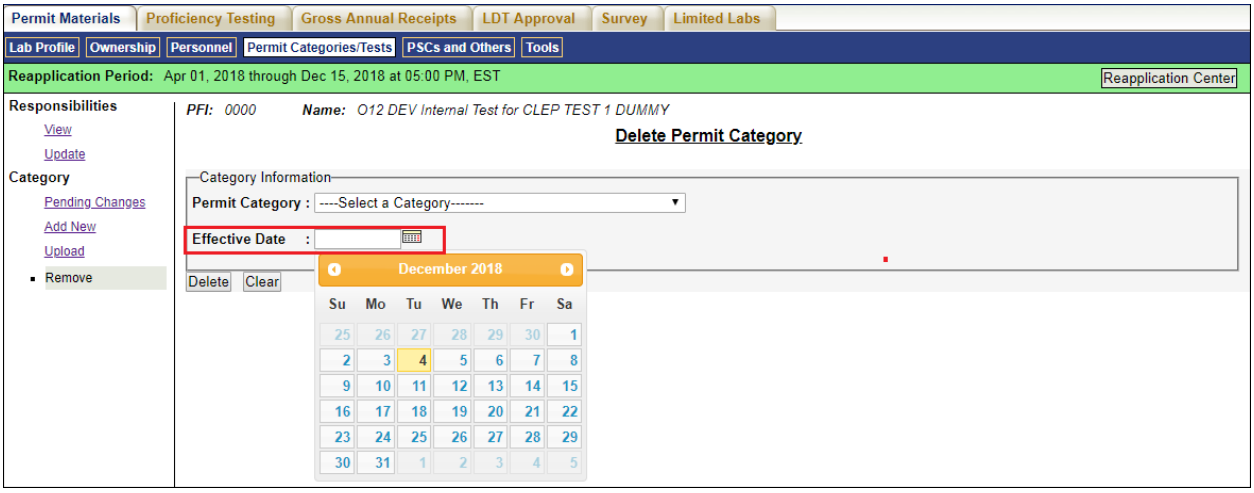
Remove a Category

Under the **Category** subsection, you may remove a permit category from the laboratory's permit. Select the category to remove from the dropdown list, click **Delete**.



Note: When a permit category is removed, the director's and/or assistant director(s) assigned responsibility for that permit category will also be removed.

On the following page, indicate the effective date of the permit category deletion, and then click **Delete**.

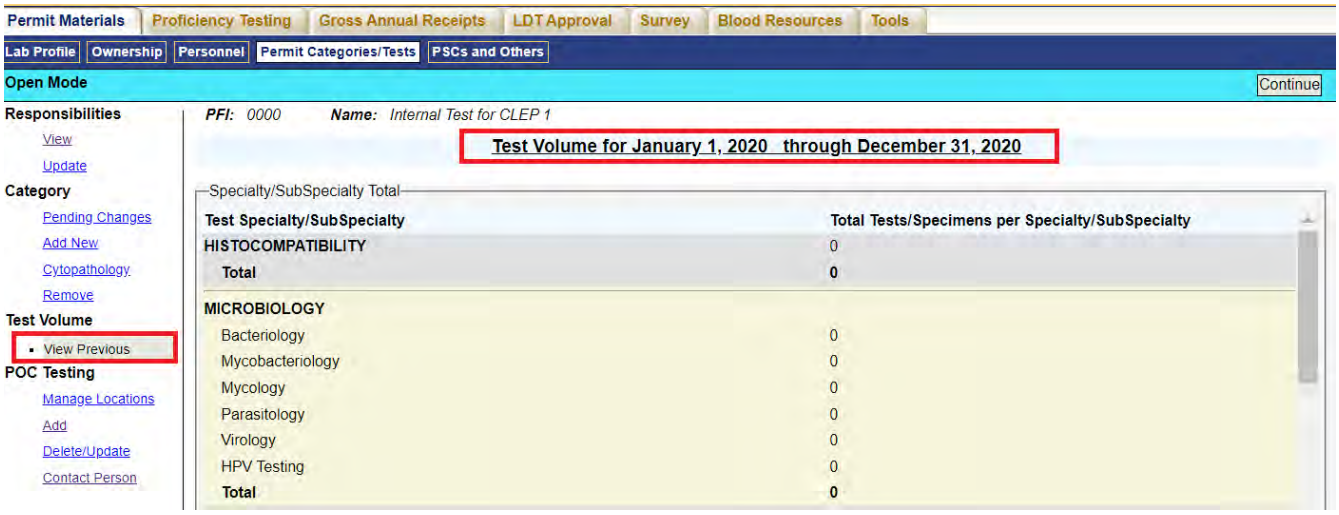


Test Volume

Note: this section is only visible to laboratories located in New York.

Laboratories located in New York are required to report **Test Volume** for each category of testing. The Test Volume section allows you to view the volumes of testing entered during the previous reapplication period and, in the Reapplication mode, enter the previous year's testing volumes for each permit category of testing. A Guidelines for Reporting Test Volume is available in the Tools Section of eCLEP. Please contact CLEP at CLEP@health.ny.gov for questions on reporting test volumes.

- In the Open mode, you can view the current information in the database.



- In Reapplication mode, the laboratory is required to report the testing volumes for the previous calendar year. Enter volumes for each permit category held on the laboratory permit. Use the scroll bar to view all categories.
    - If you indicate "No tests performed this year", you must provide a reason.

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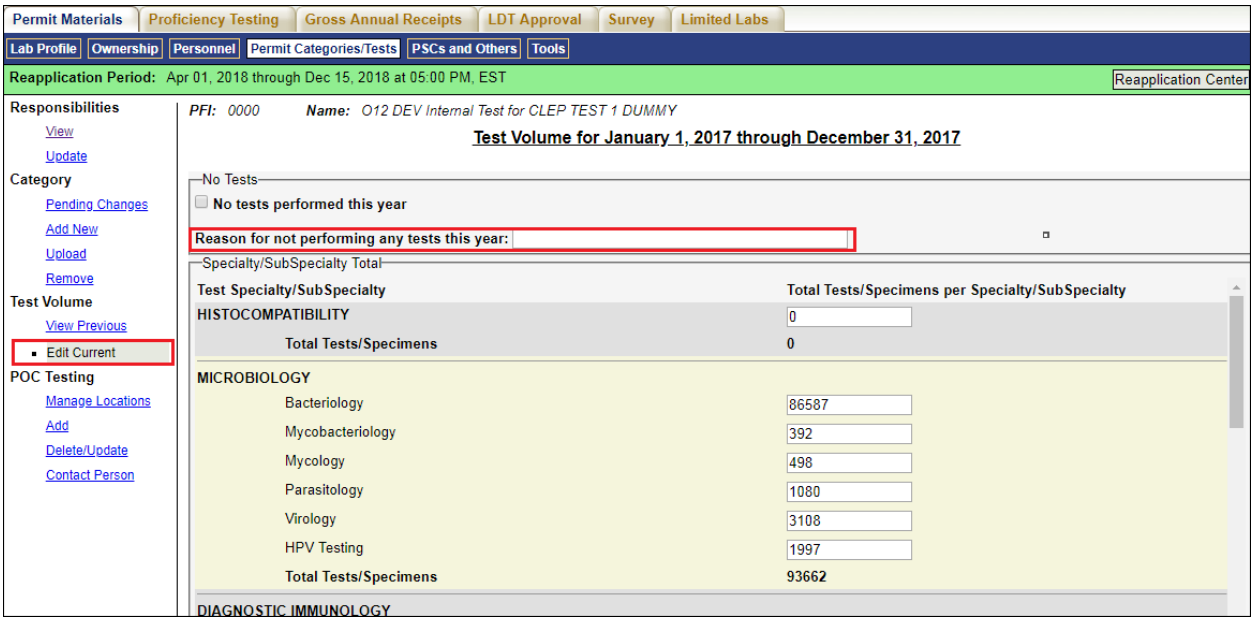
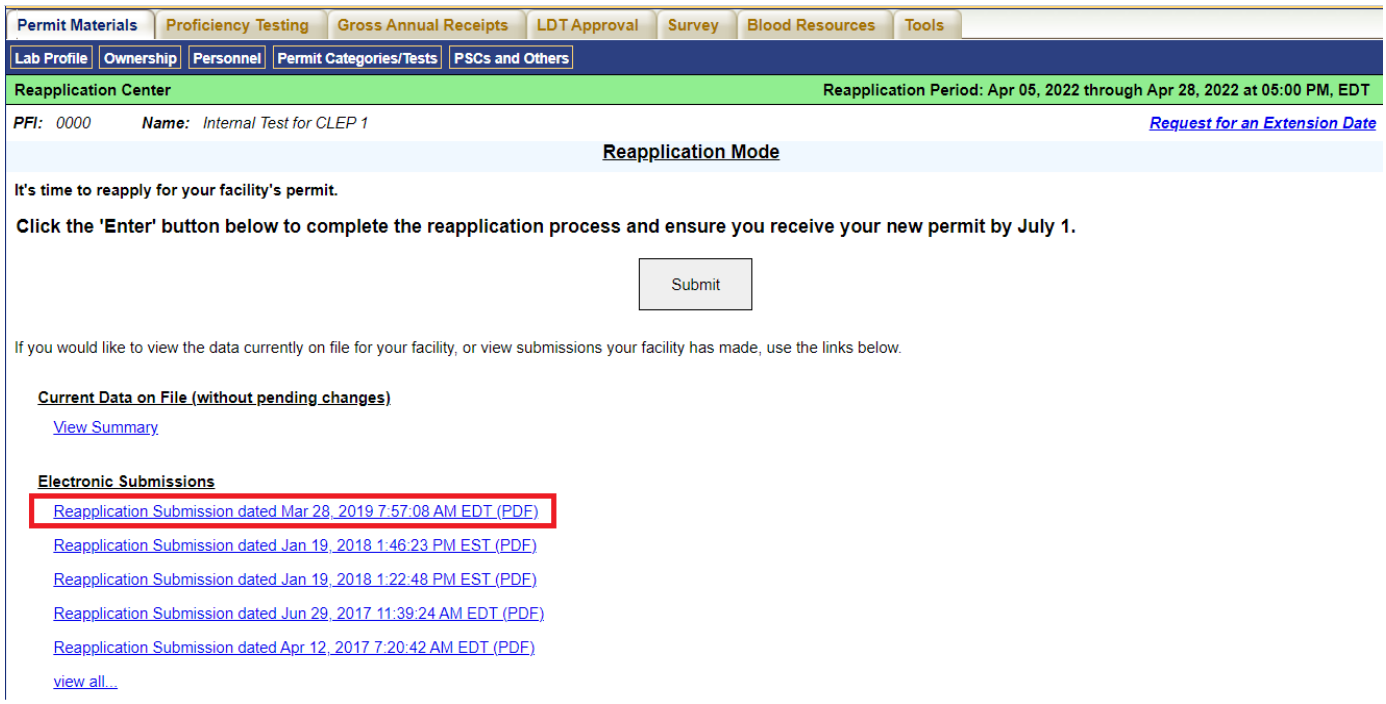


- To obtain a pdf version of the previous year's test volume, access the previous year's Reapplication Submission from the Reapplication Center page and print or save as needed.

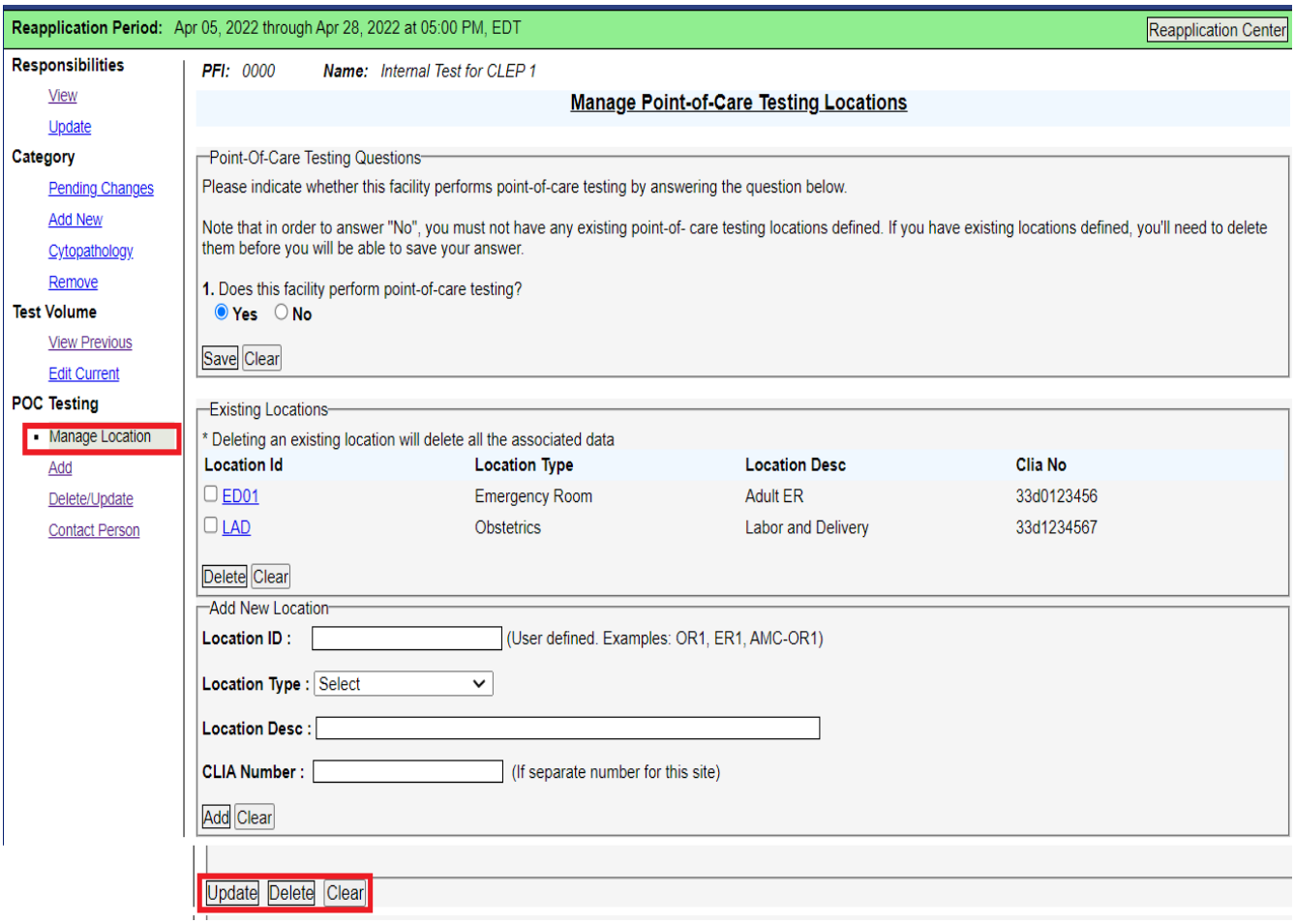


POC Testing

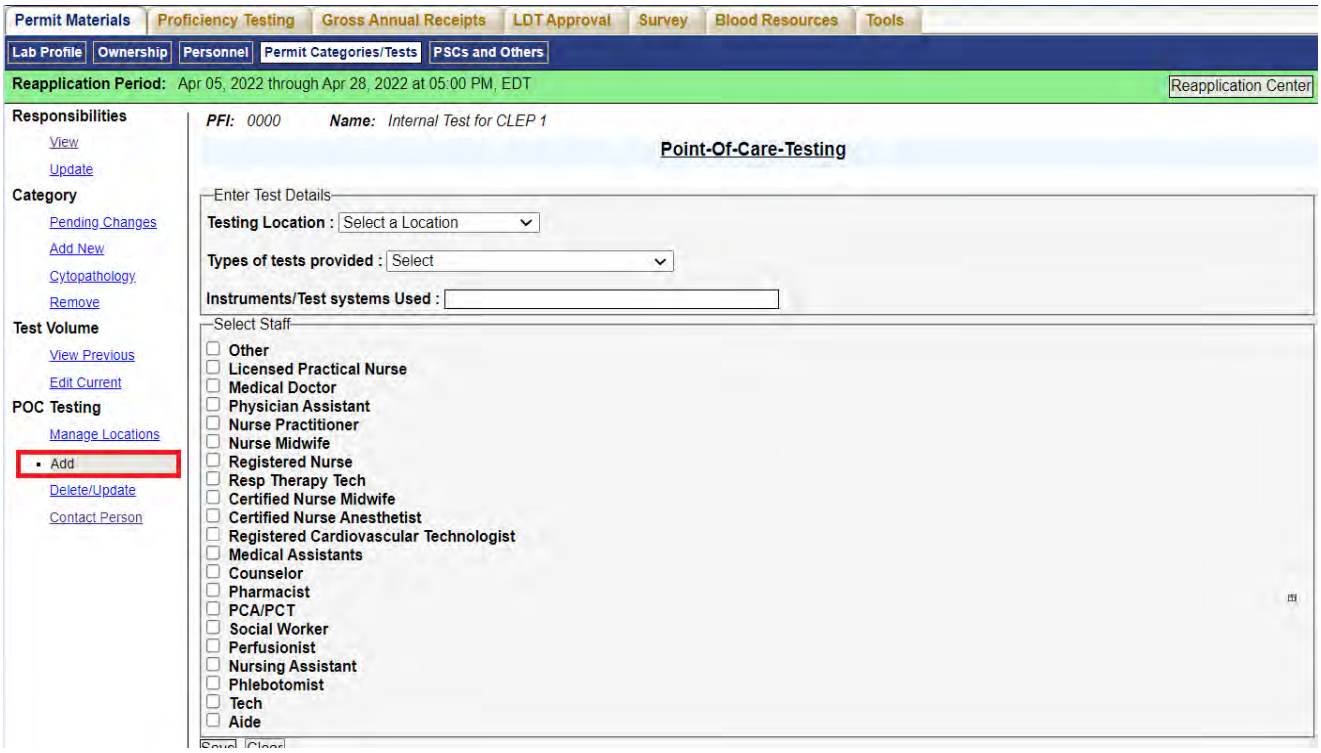
***This section is visible only to laboratories at hospitals, Article 28 facilities, correctional facilities, etc., located in New York*.**

The **Point-of-Care (POC) Testing** section allows you to manage locations and testing performed at the point of care, rather than the laboratory proper, at the facility.

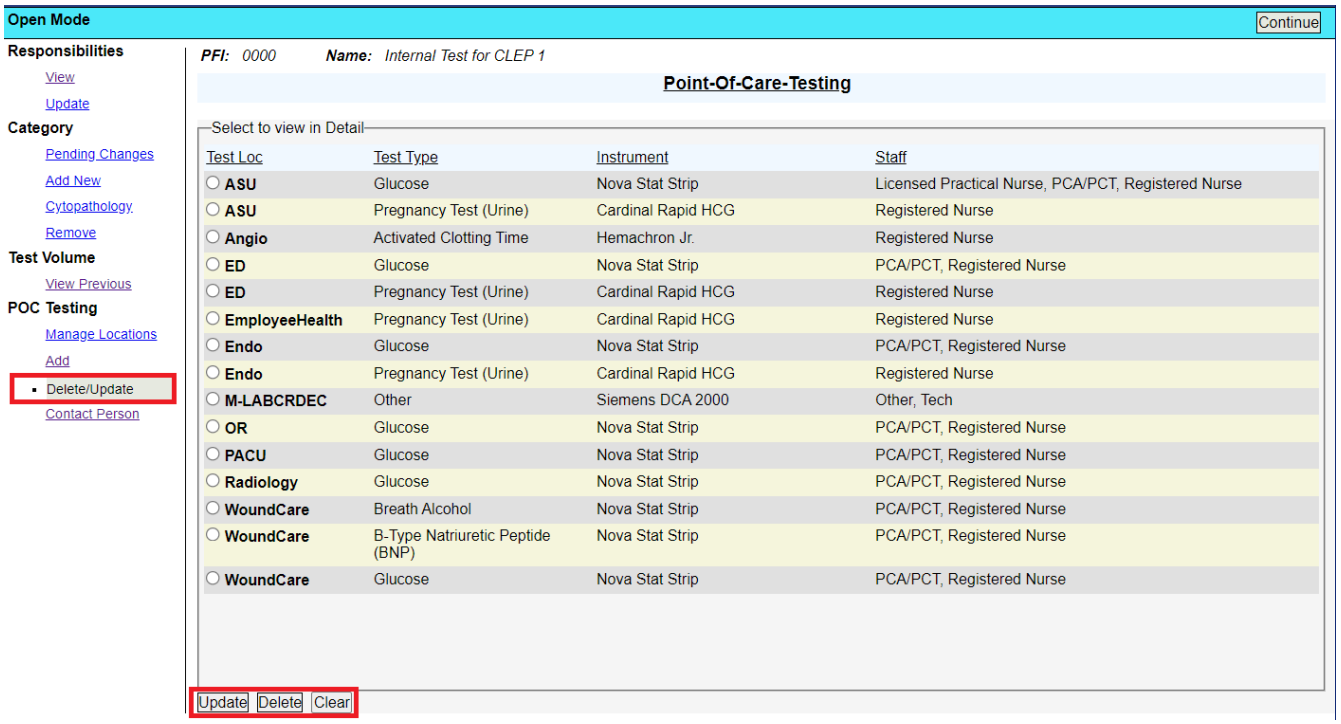
- Under **Manage Locations**, you may add or delete Point-of-Care Testing (POCT) locations.



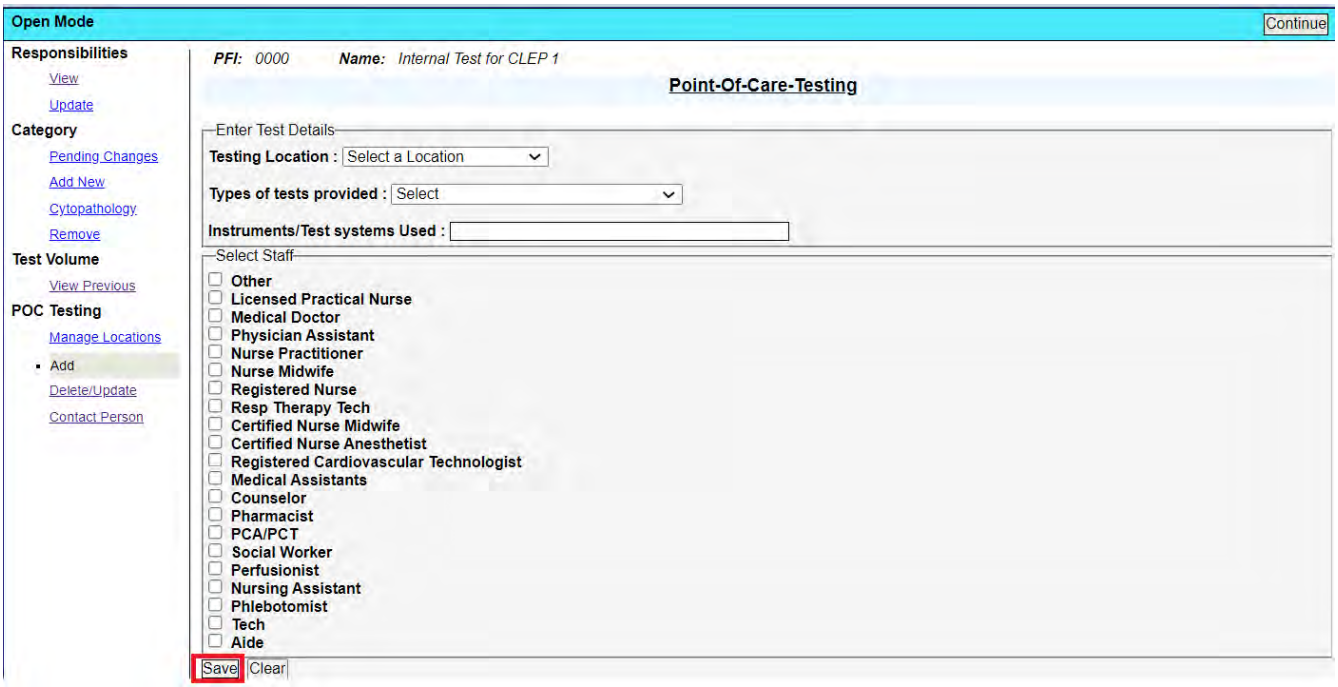
- The **Add** page allows you to add a test to a POCT location. Choose a POCT location from the dropdown list, choose the test being performed from the dropdown list, enter the instrument used and finally choose the staff performing the testing by selecting the check box next to the appropriate staff description. Click **Save**.



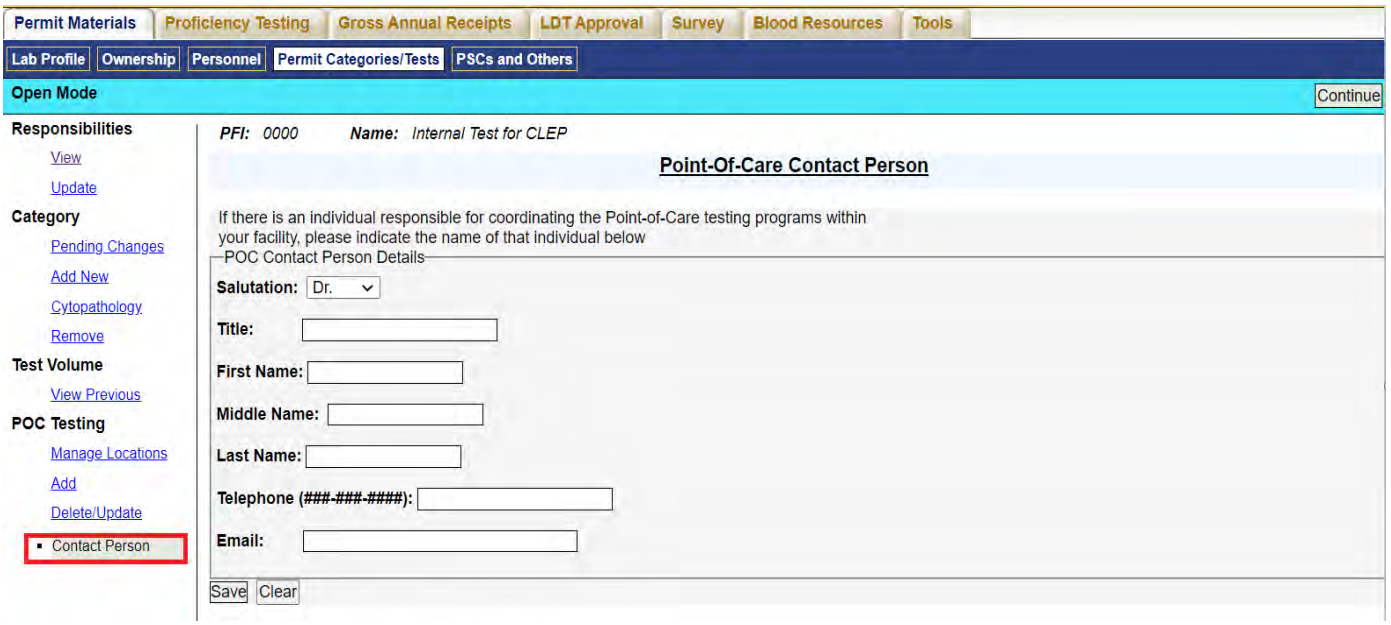
- The **Delete/Update** page allows you to update or delete a test from a POCT location.
  - Choose a test by clicking the appropriate radio button, then click **Update** or **Delete**, as appropriate.
  - Clicking **Delete** will automatically remove the test from the list.



- Clicking Update will bring you back to the Add page, where you can revise the appropriate information, click **Save**.



The **Point-Of-Care Contact Person** page allows you to indicate a POCT Coordinator for the laboratory. Enter the appropriate contact information and click **Save**.



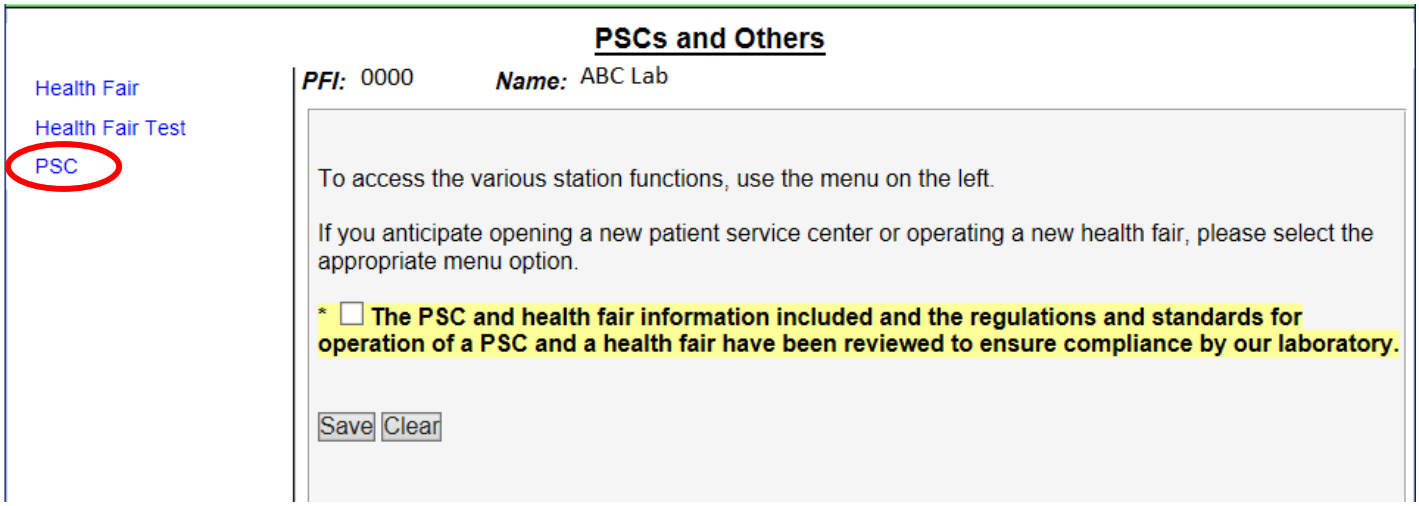
PSCs and Others

The PSCs and Others tab allows the laboratory to request approval to operate a patient service center (PSC) and/or health fair (HF). This area also allows you to update the PSC and HF information (location, phone number, etc.) and complete the annual reapplication process for both.

Note: This feature was introduced for the 2016 reapplication.

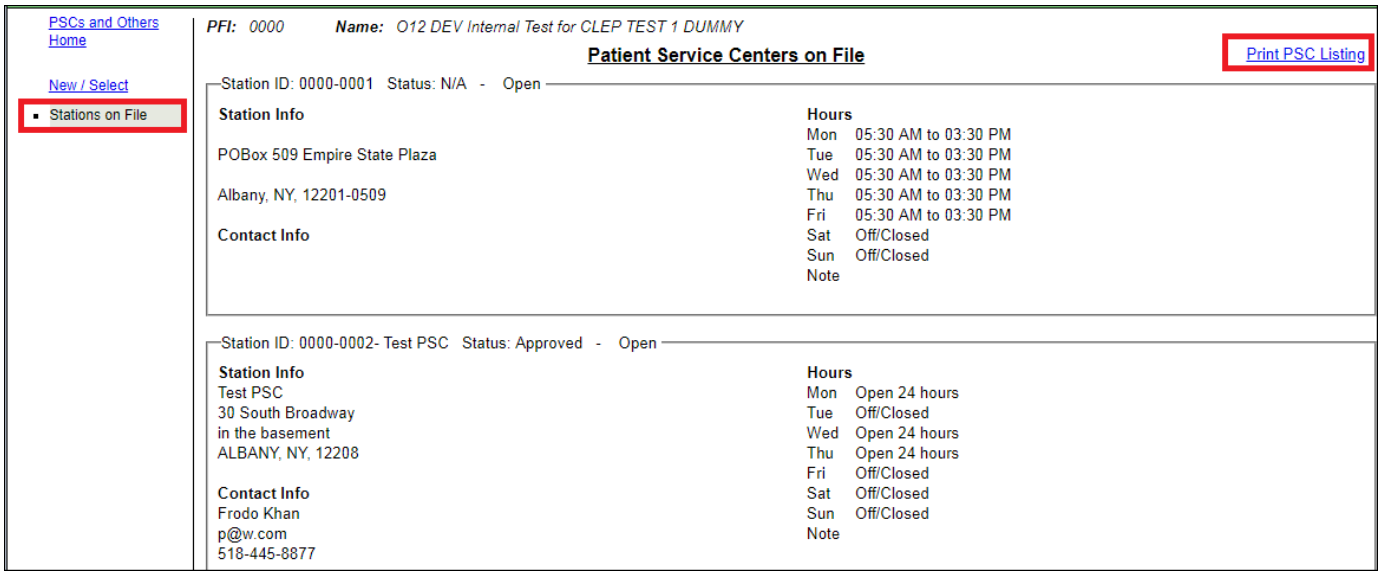
PSC Reapplication

During the reapplication period each Spring, laboratories currently operating an approved patient service center (PSC) should review the current data on file with the Department and update such information as appropriate. To review, click on the **PSC** link on the left of the screen.

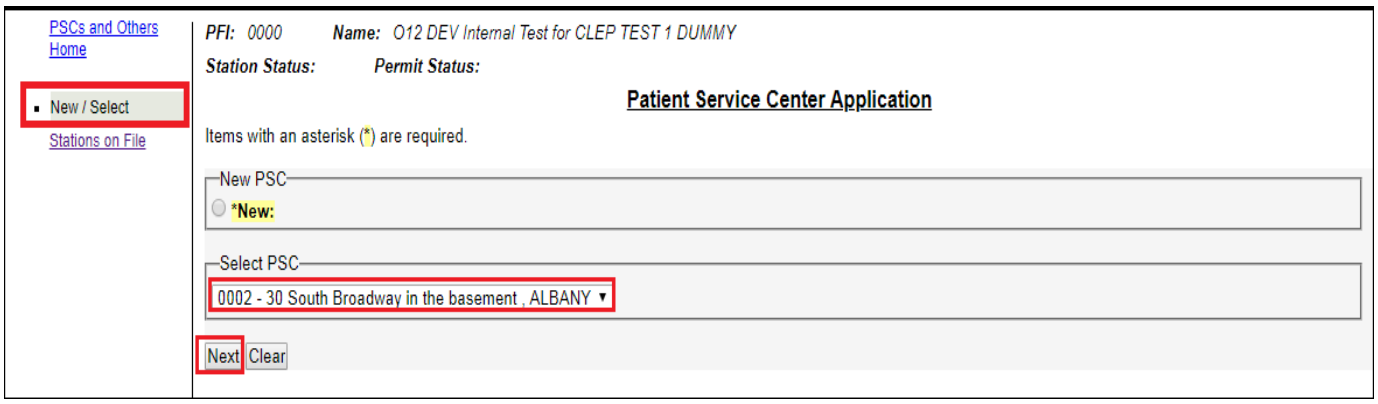


On the next screen, choose 'Stations on File' from the menu on the left to view all stations associated with the laboratory.

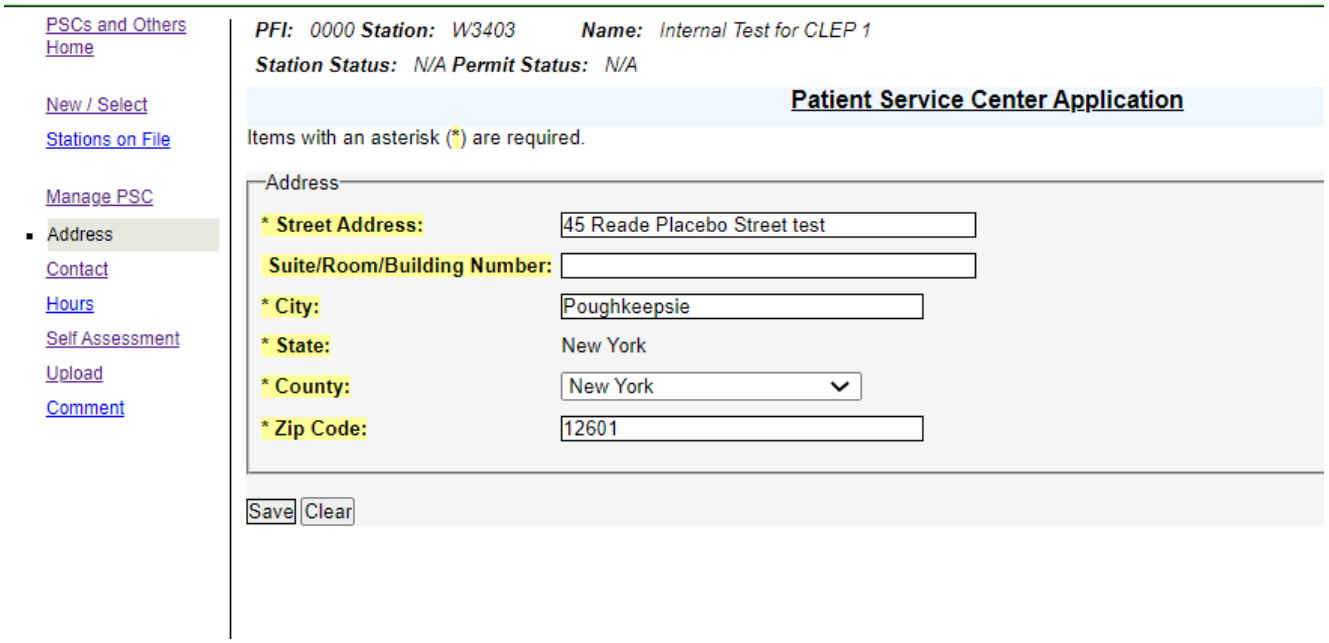
A list of all patient service centers is viewable and printable from a new screen under the PSC section. Click on the **Print PSC Listing** link to print or save the list.



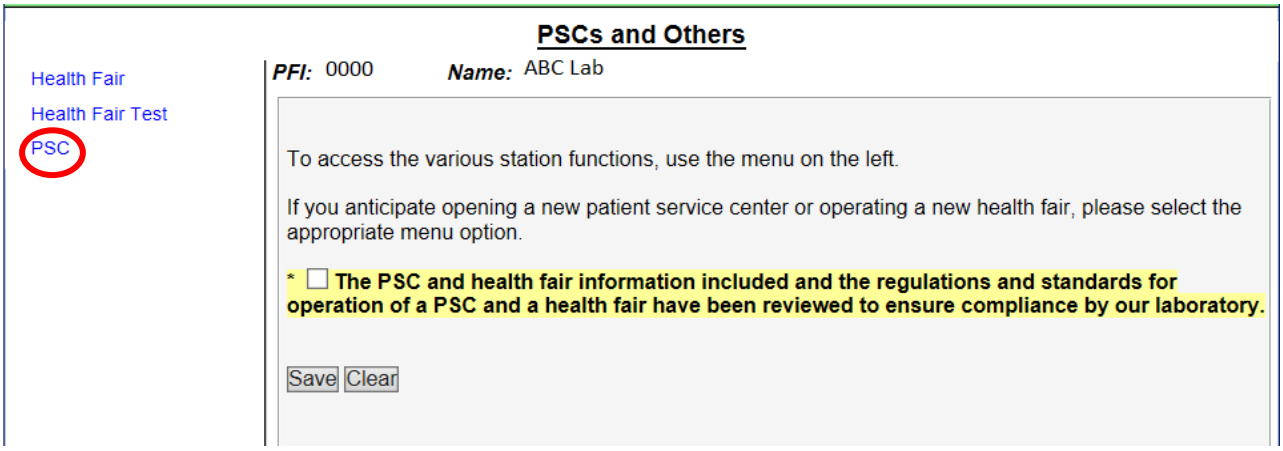
To make updates to an existing PSC, click on the 'New/Select' link from the PSC menu on the left. Then Choose the desired PSC from the dropdown box and click 'Next'.



If an existing PSC location has been selected, the menu of links on the left of the screen will now look different and the PSC address screen will be shown. Users can update the Address, Contact and Hours screens. Click **Save** after making changes. Address changes require an effective date.

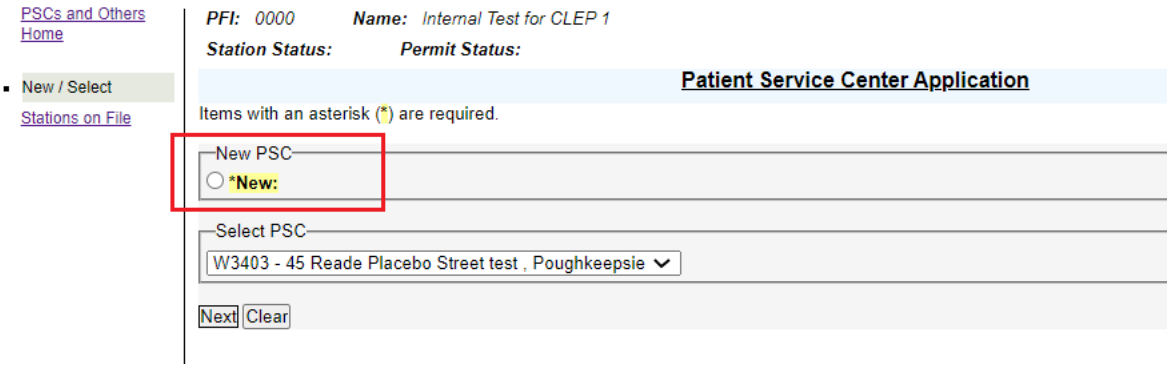


Also during the reapplication period each Spring, the laboratory will be requested to attest that the relevant NYS regulations and standards for the operation of a PSC and/or HF have been reviewed to ensure compliance by the laboratory. Click the check box next to the highlighted text to indicate this, then click **Save**.

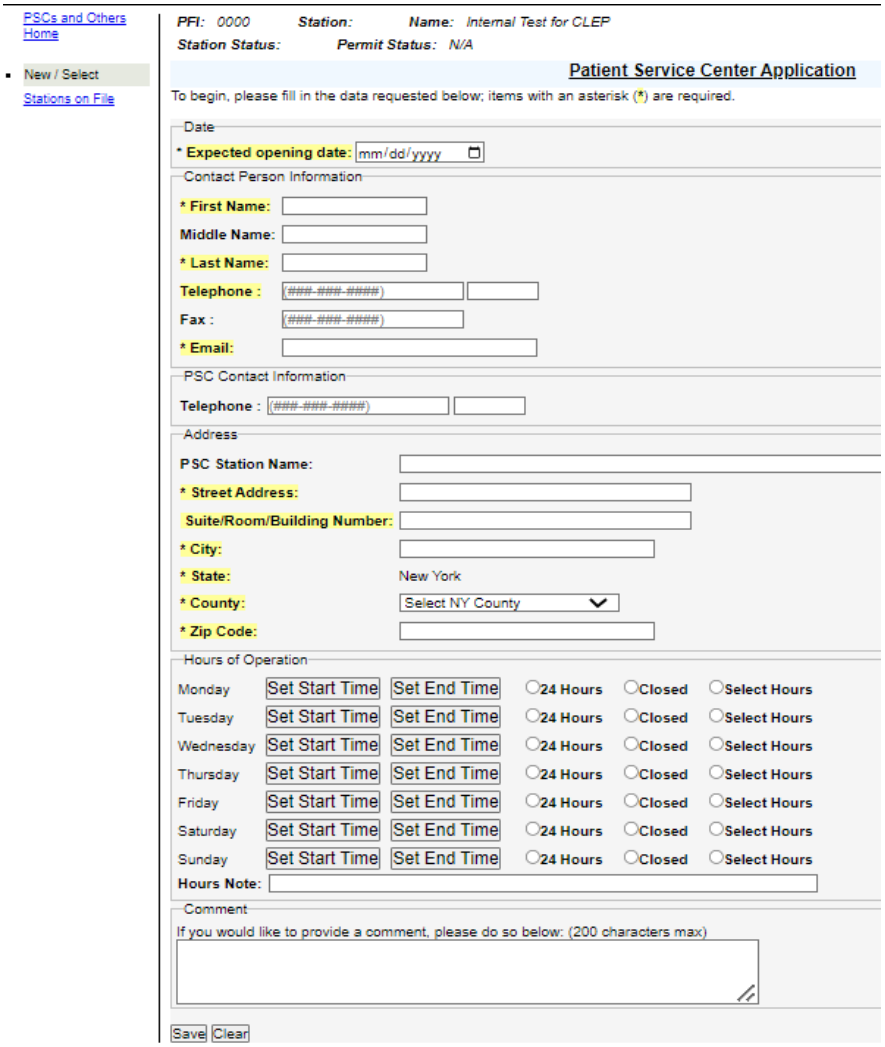


Request a New PSC

To request approval to operate a patient service center (PSC), click on the PSC link on the left of the screen. On the next screen, click on the New radio button, then click **Next**.

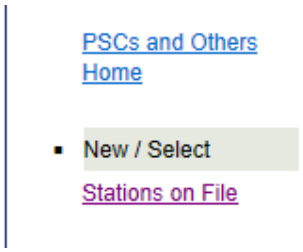


On the next screen, fill in the requested information and click **Save**. Please allow at least two weeks for processing; enter the expected opening date accordingly. Please be reminded that the PSC cannot operate without explicit approval from the Department.

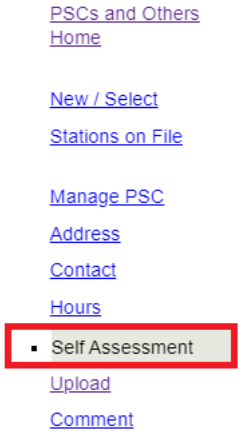


Once you click Save, the links on the left will change.

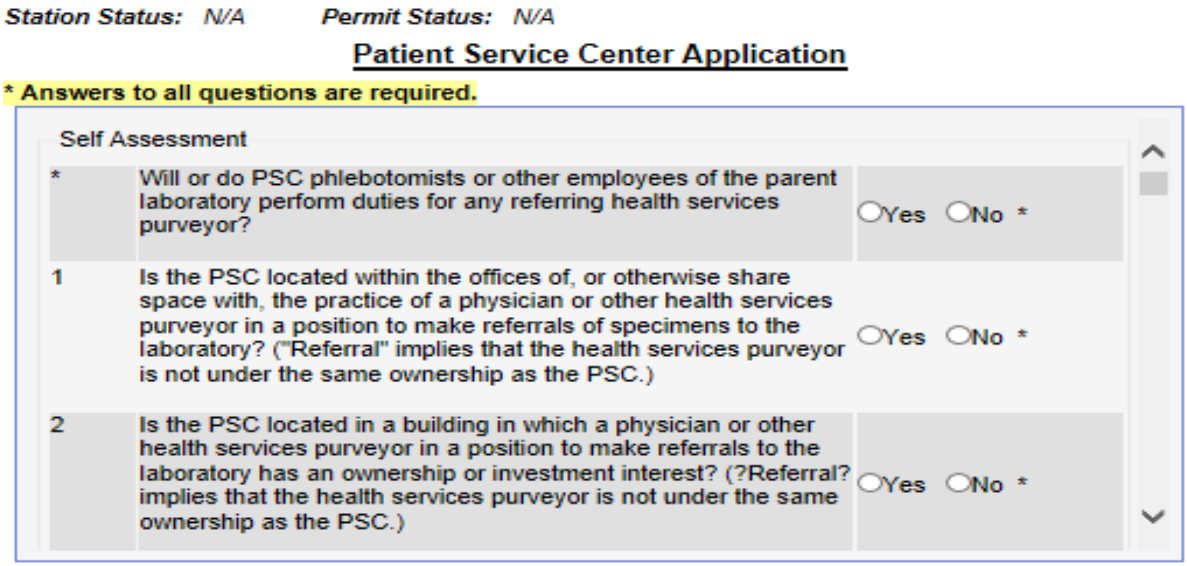
Initial view:



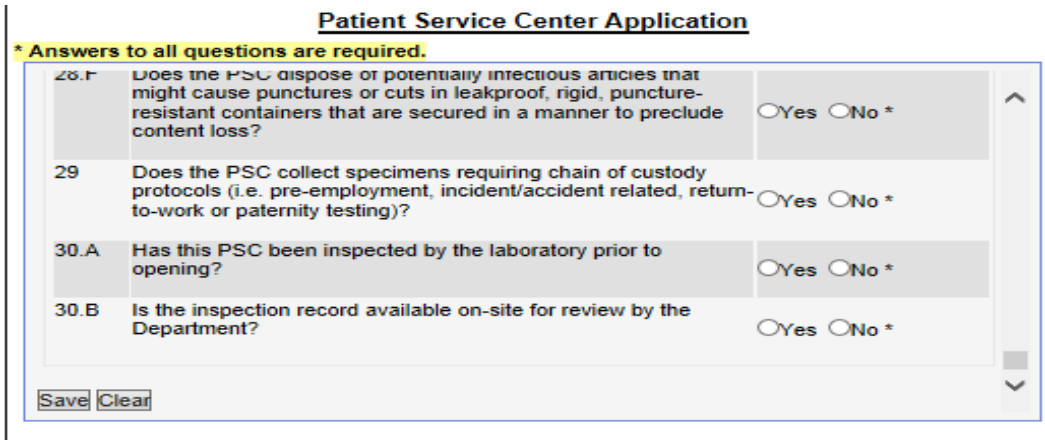
Current view:



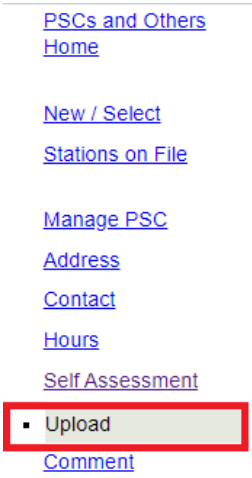
To complete the application process, a self assessment must be completed and requested documents (i.e., floor plan and lease) must be uploaded. Click on **Self Assessment**. Answer the questions provided.

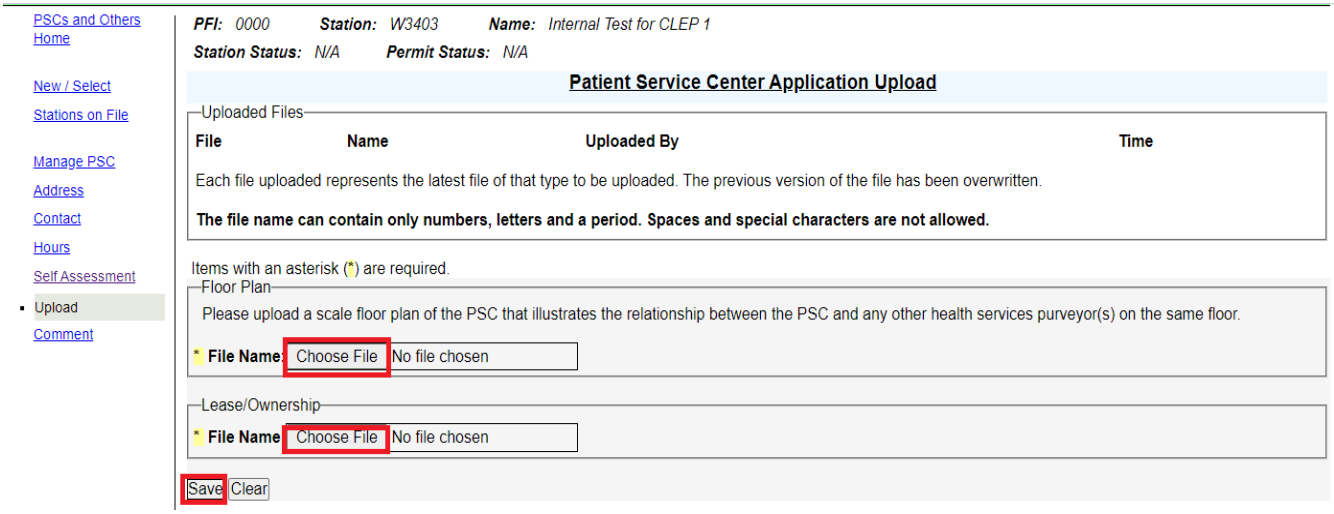


Once all questions have been answered, click **Save**.



After all the questions have been answered and the responses have been saved, click **Upload** on the left of the screen to upload a copy of the PSC floor plan and lease**.** Click on **Choose File** to navigate to the electronic file on your computer, then click **Open** to upload. Once both documents have been uploaded, click **Save.**

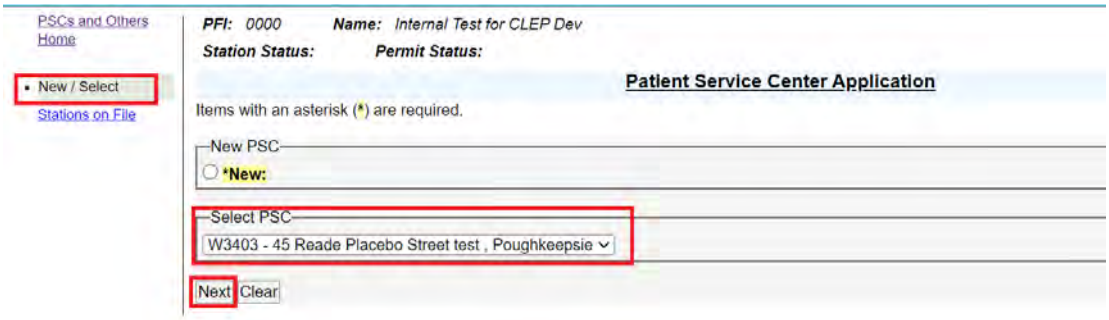




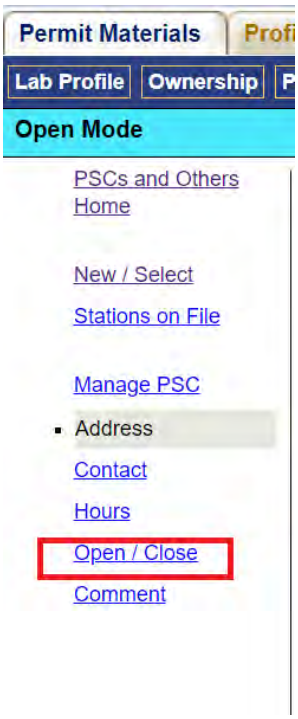
Temporary or Permanent Closure of a PSC

Navigate to the PSC webpage:

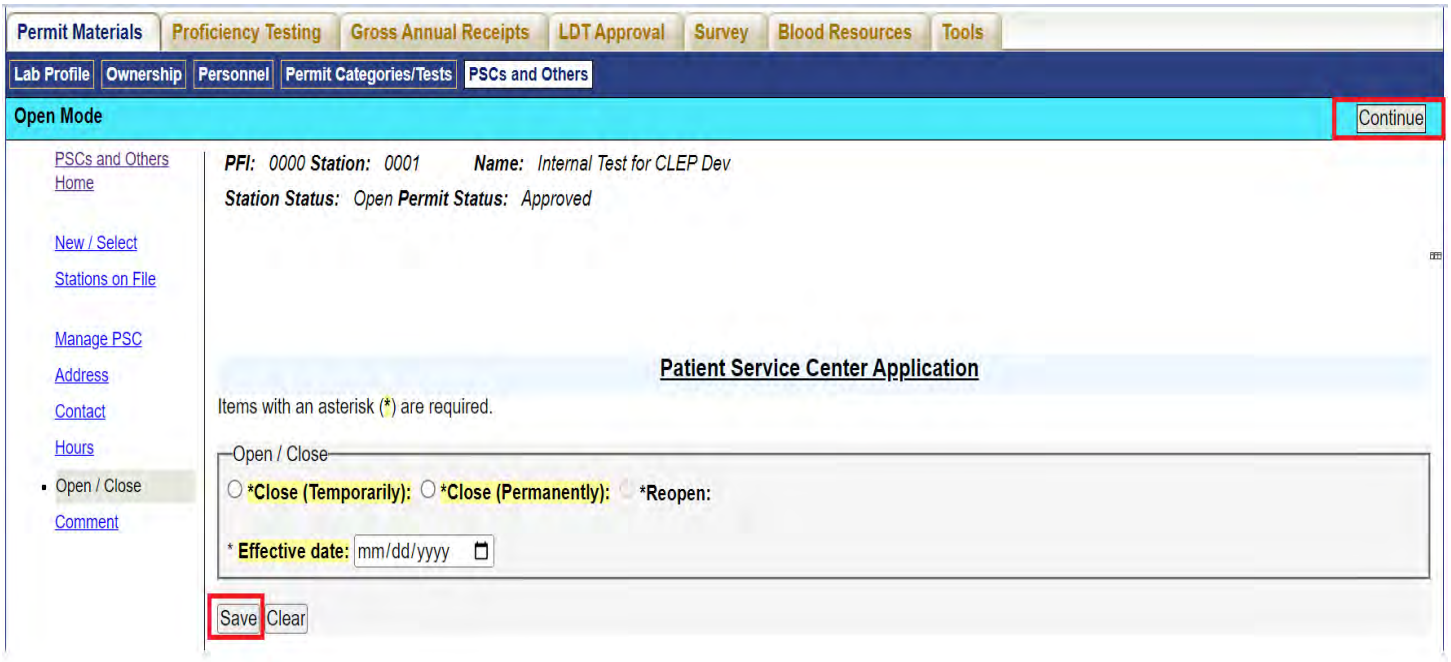
On the **New/Select** webpage, select the PSC station from the drop-down menu and click on **Next**:



Click on the Open/Close link on the left panel:

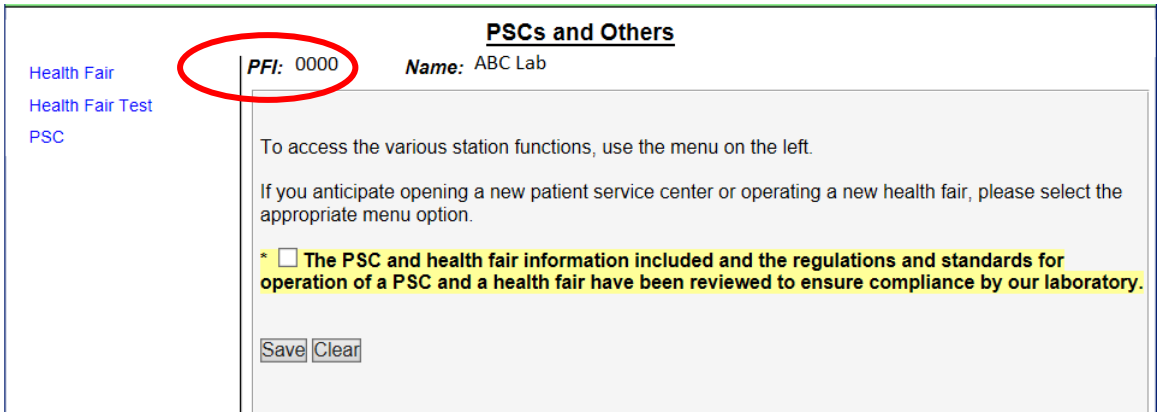


Select the appropriate radio button to either **Close (Temporarily)** or **Close (Permanently)** the station. Enter an effective date and then click on **Save**. Click on the **Continue** button (located to the top right corner of the teal bar) to continue with the submission process. Please note that you need attest and successfully complete the submission process.

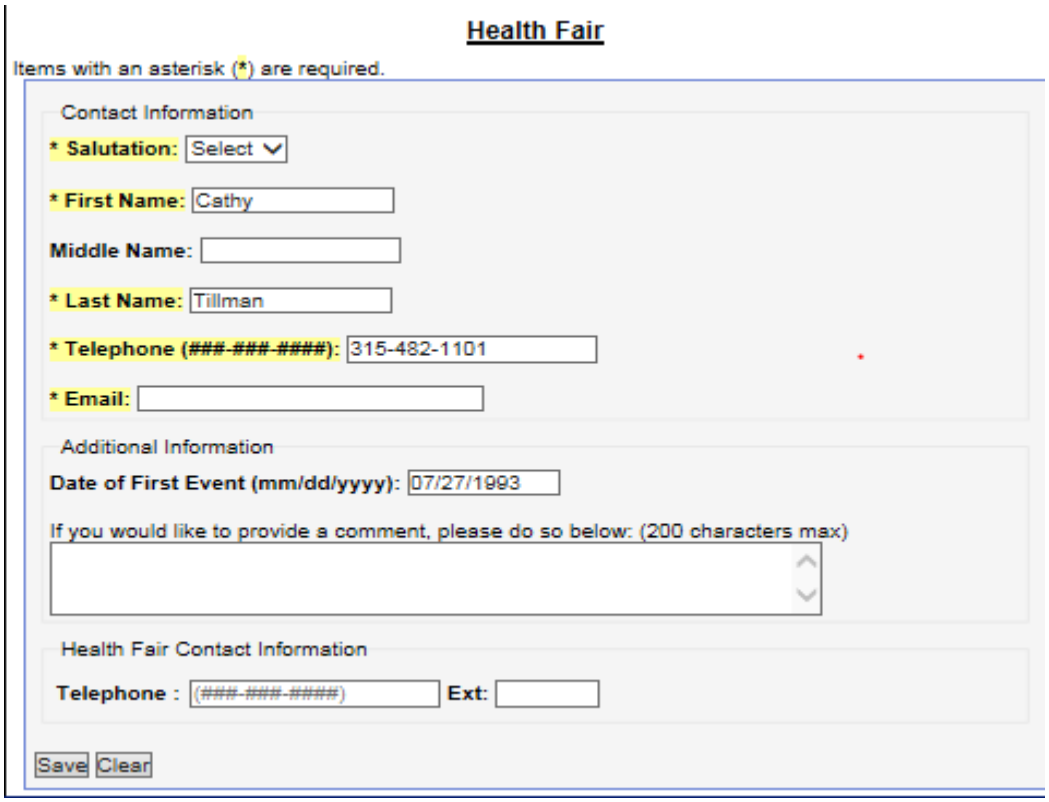


Health Fair Reapplication

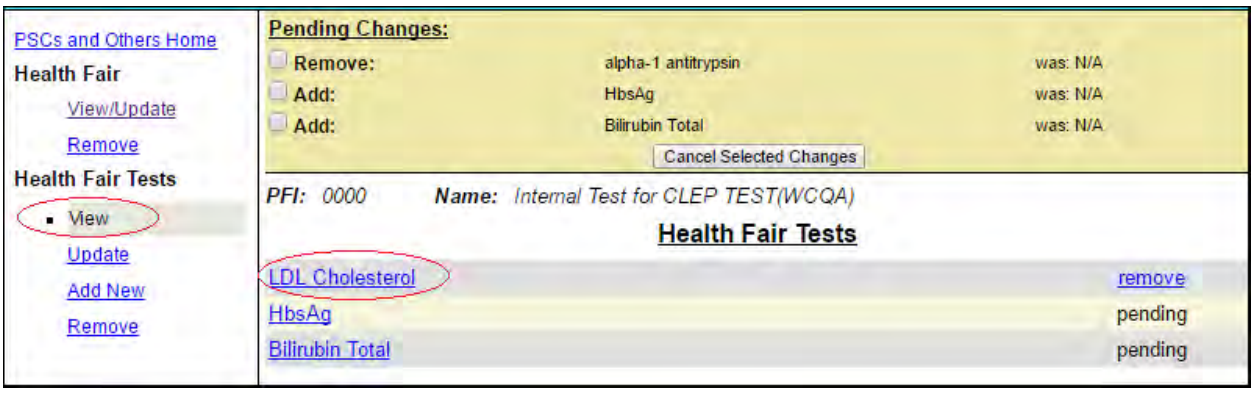
During the reapplication period each Spring, laboratories currently holding a health fair permit should review the current data on file with the Department and update such information as appropriate. To review, click on the **Health Fair** link on the left of the screen.



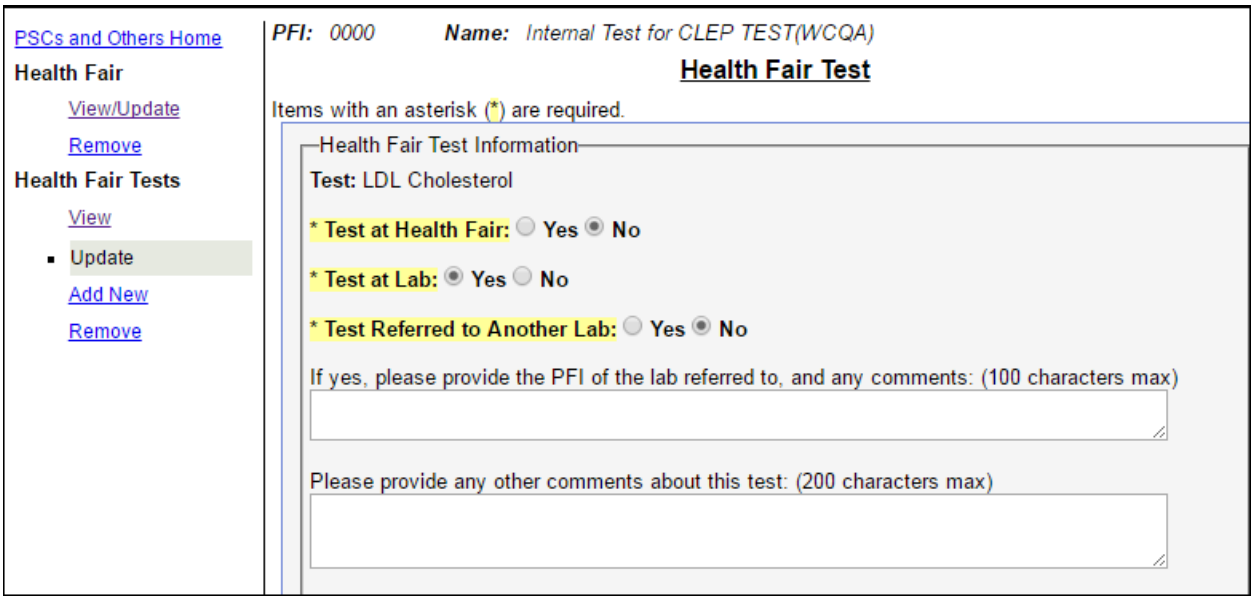
The Health Fair sreen will appear. Review and update information as required. If changes are made, click **Save**.



Using the links on the left of the screen, review the tests associated with the health fair. Click on a test name.

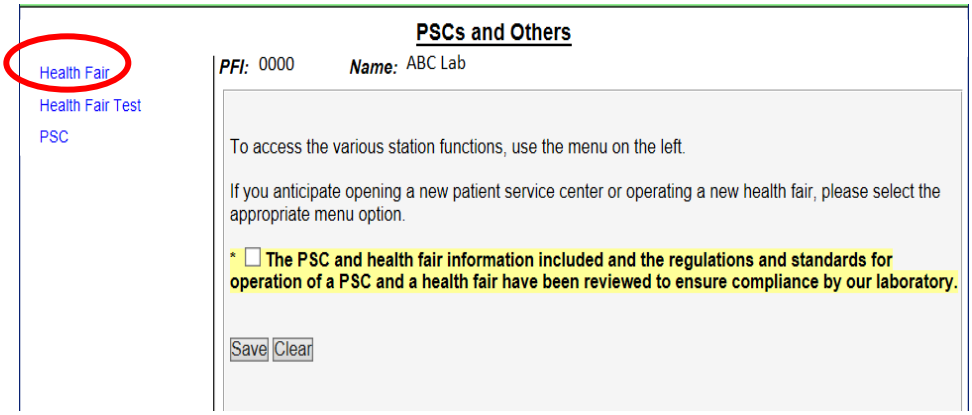


Review and update the test information as needed. If changes are made, click **Save**.

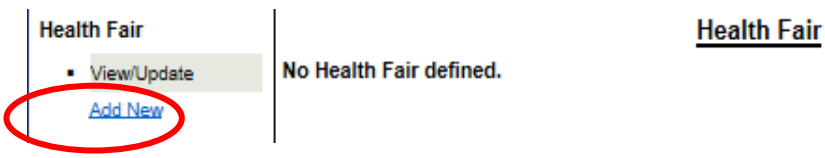


Request a Health Fair Permit

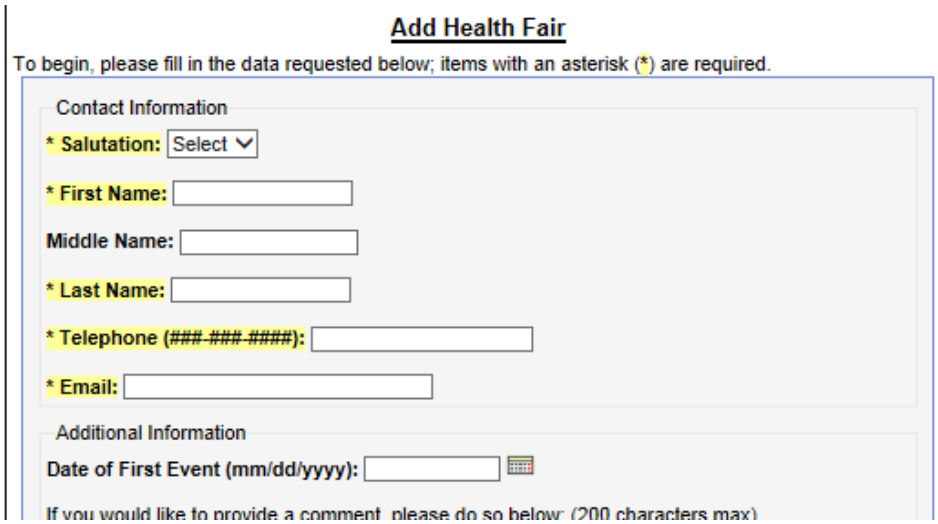
To request approval to operate health fairs, click on the **Health Fair** link on the left of the screen.



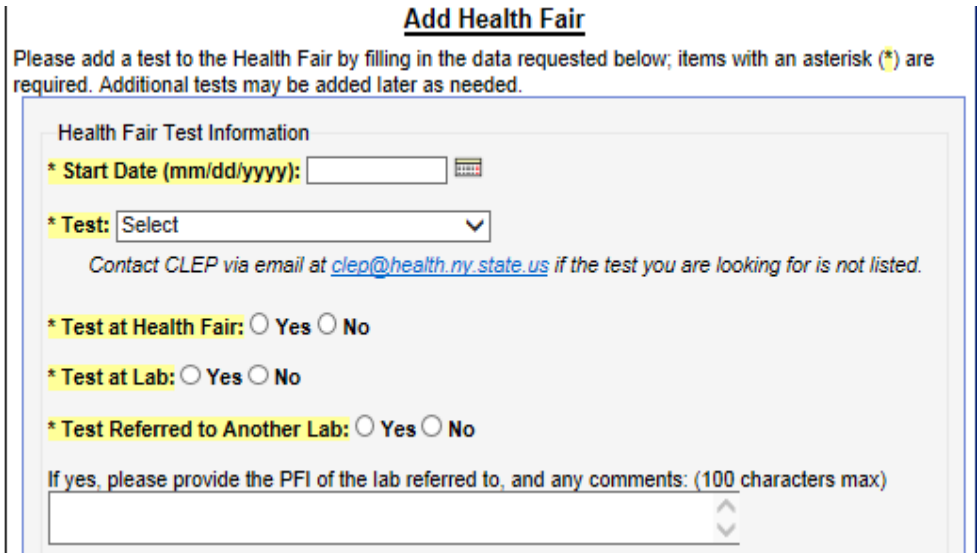
Click on **Add New** on the left of the screen.



Enter the requested information, click **Next**.



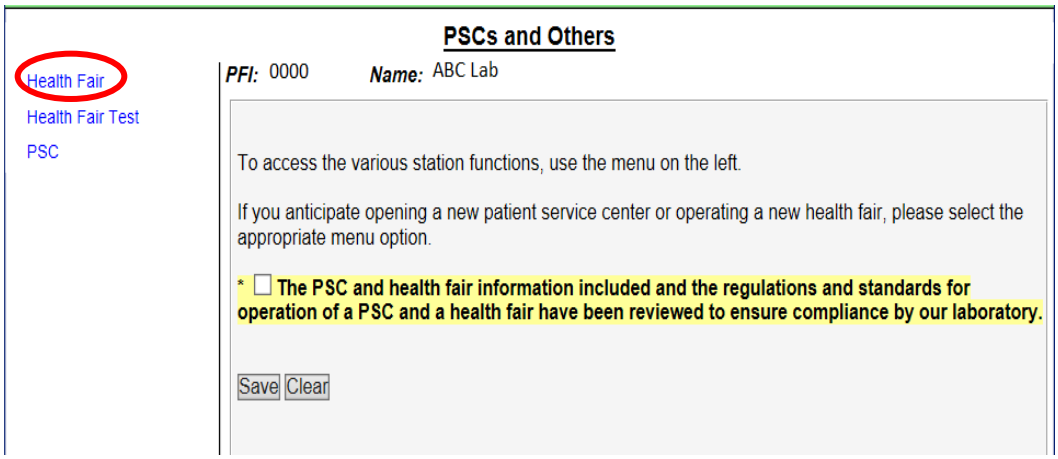
Enter the requested information about the tests to be associated with the health fair, click **Save**.



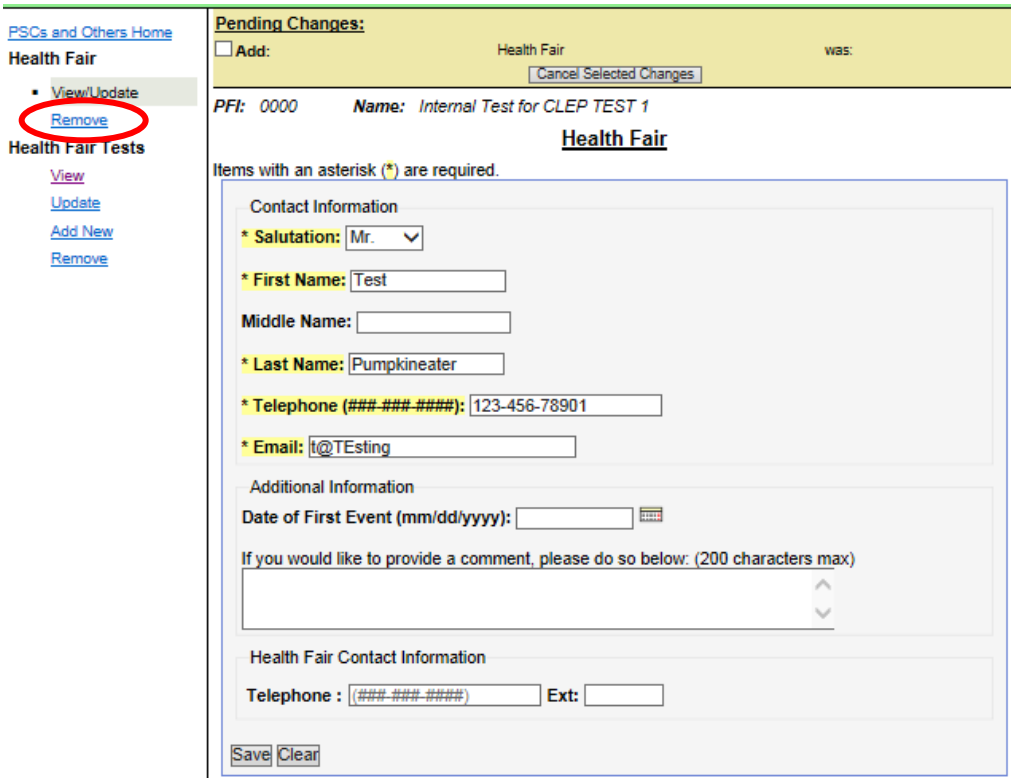
Add additional health fair tests by using the Add New link under Health Fair Tests on the left of the screen.

Remove a Health Fair Permit

To remove approval to operate health fairs, click on the **Health Fair** link on the left of the screen.

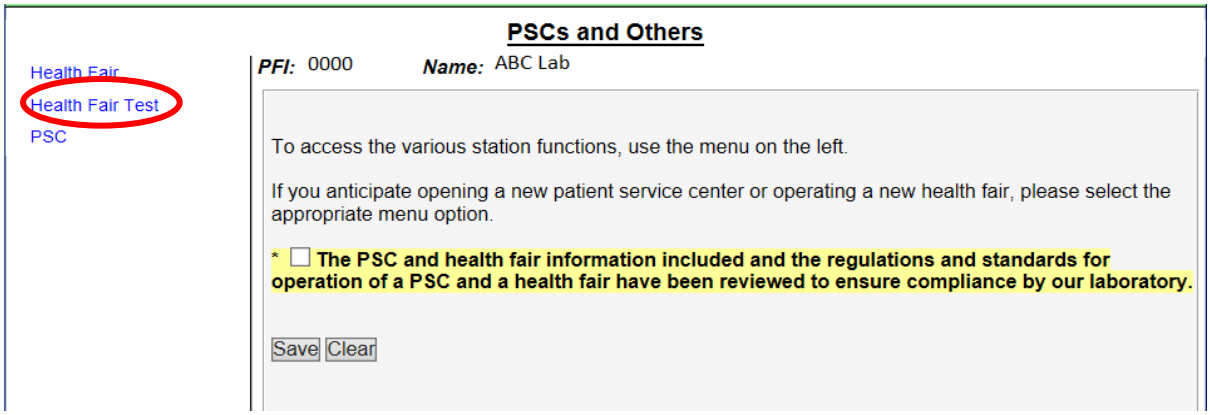


Click on **Remove** on the left side of the screen**.**

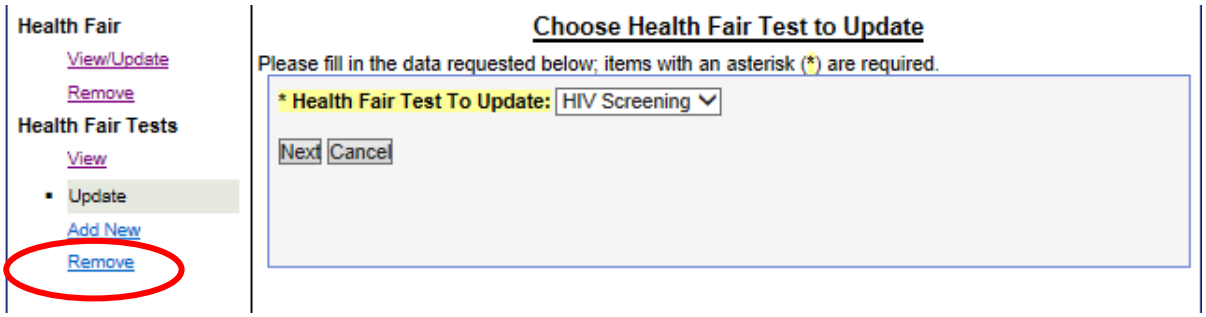


Remove a Health Fair Test

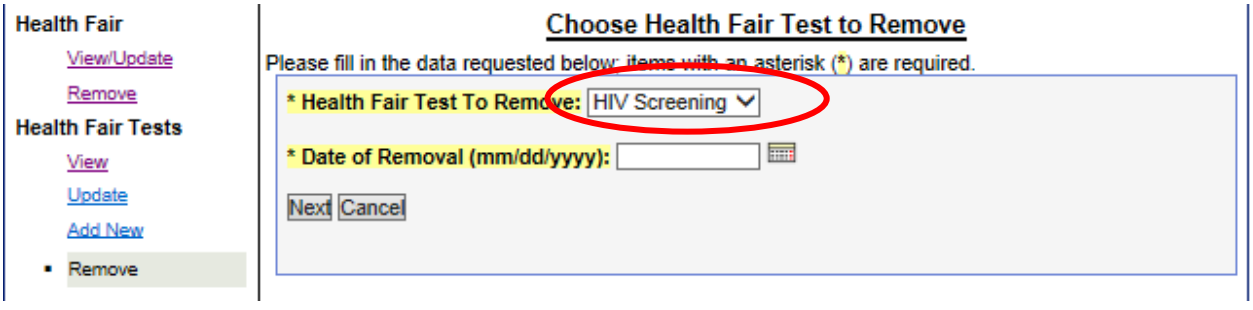
To remove a test from an approved Health Fair permit, click **Health Fair** of **Health Fair Test** from the left side of the screen.



Click **Remove** under Health Fair Tests on the left side of the screen.



Choose the test to remove form the dropdown menu and enter effective date of removal. Click **Next.**



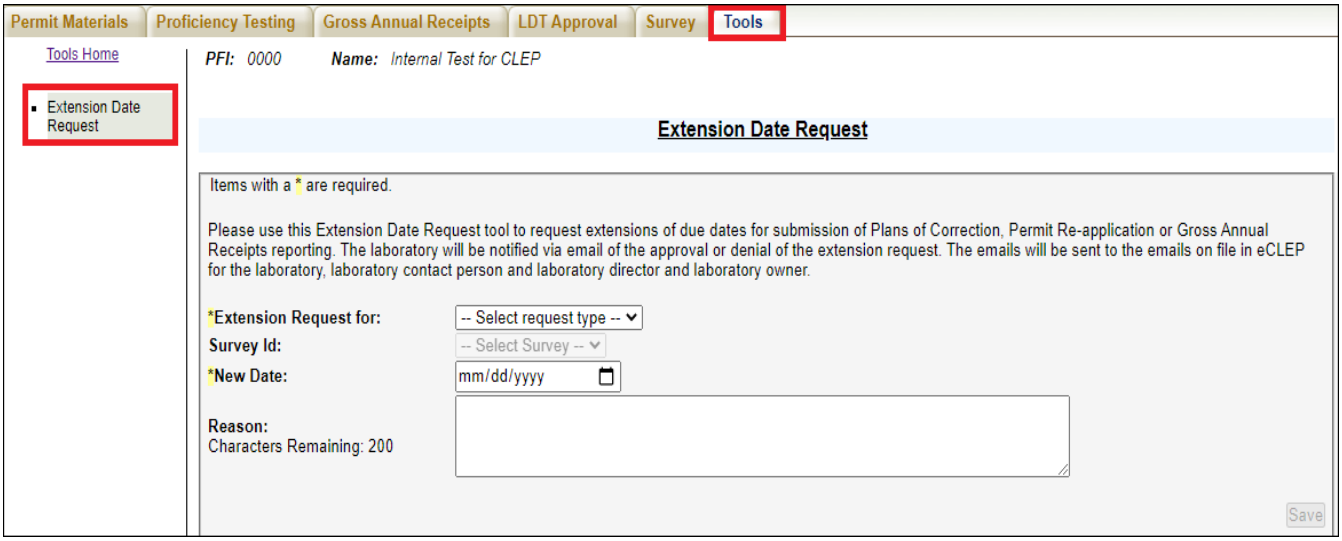
Tools

Request for an Extension Date

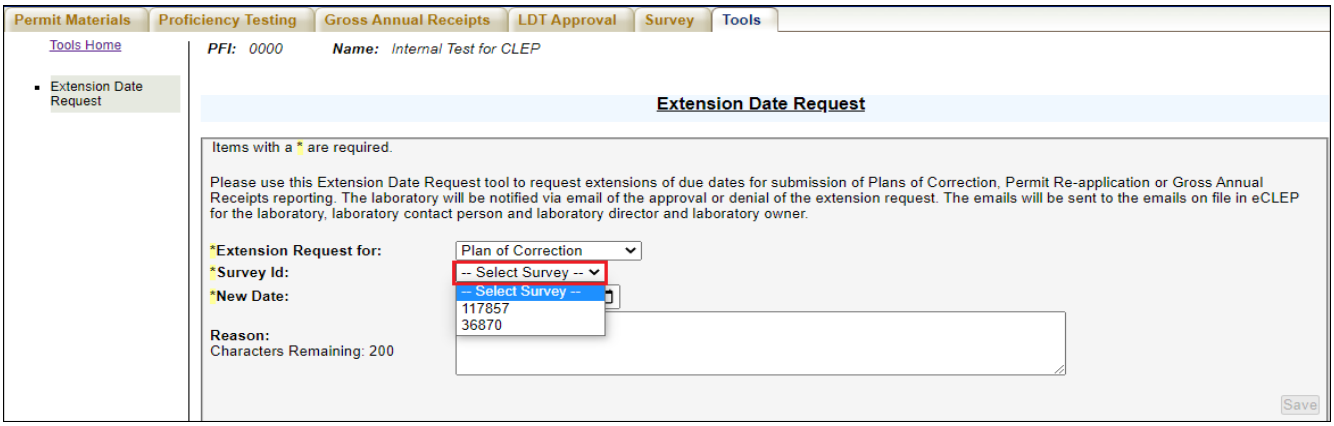
An extension date may be requested for:

- Reapplication – only available during active reapplication period each spring
- Survey(s) with a pending Plan of Correction (POC) from the facility.
- GAR – If it is an active GAR period.
- Blood Services Activity Report (BSAR)

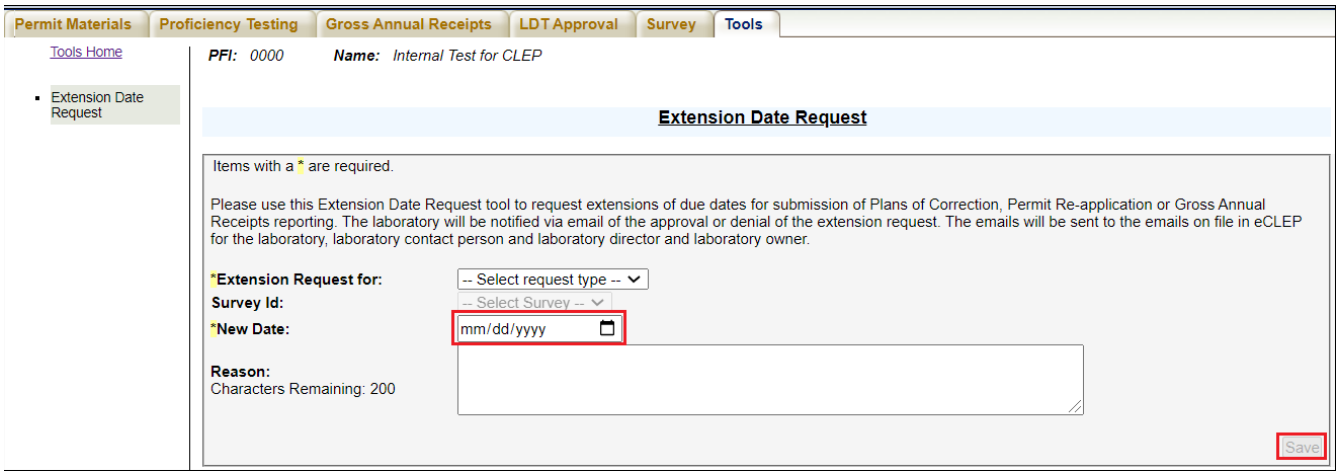
To use this tool, click on the **Extension Date Request** link on the left panel.



- Select the request type from the drop-down menu, **Extension Request for**. Please note that if the type **Plan of Correction** is selected, then the Survey ID must be selected in the next field. The **Survey ID** is the unique ID that is used to identify a Survey and it is available on all the Laboratory Evaluation Report (LER) sent to the Laboratory.



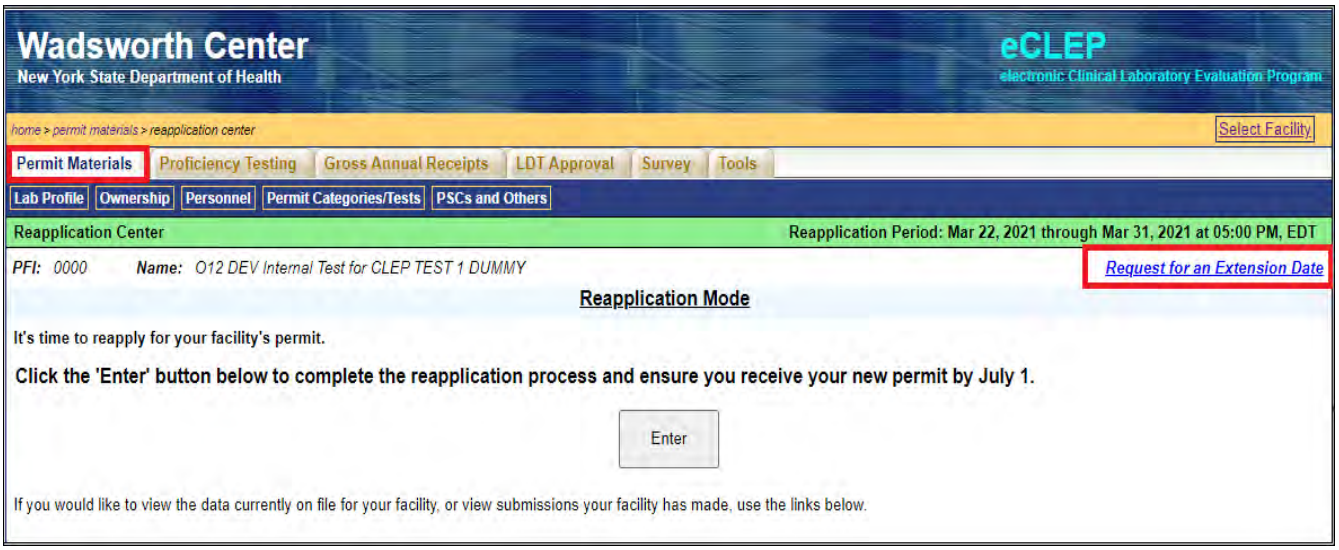
- Enter a proposed date for the extension date in the **New Date** field:



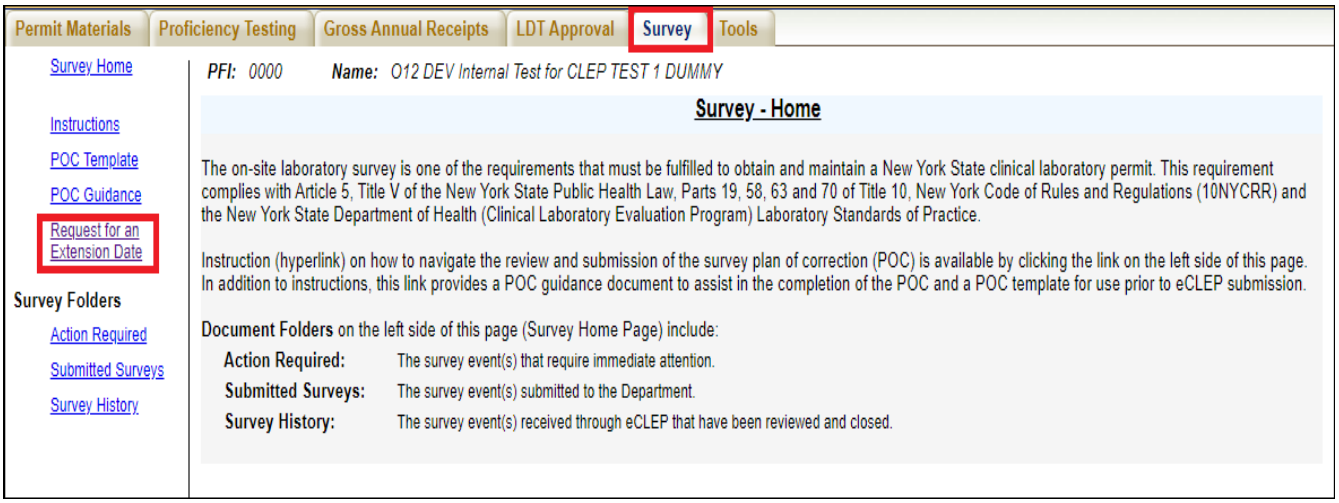
- Use the **Reason** field to add any notes if deemed necessary.
- Clicking the **Save** button, completes the request process for an extension date. No extra step is required.

Additional shortcuts across eCLEP to the Extension Date Request page

On the **Permit Materials** Home page, there is a link to the top right that points to the Extension Request Date page:

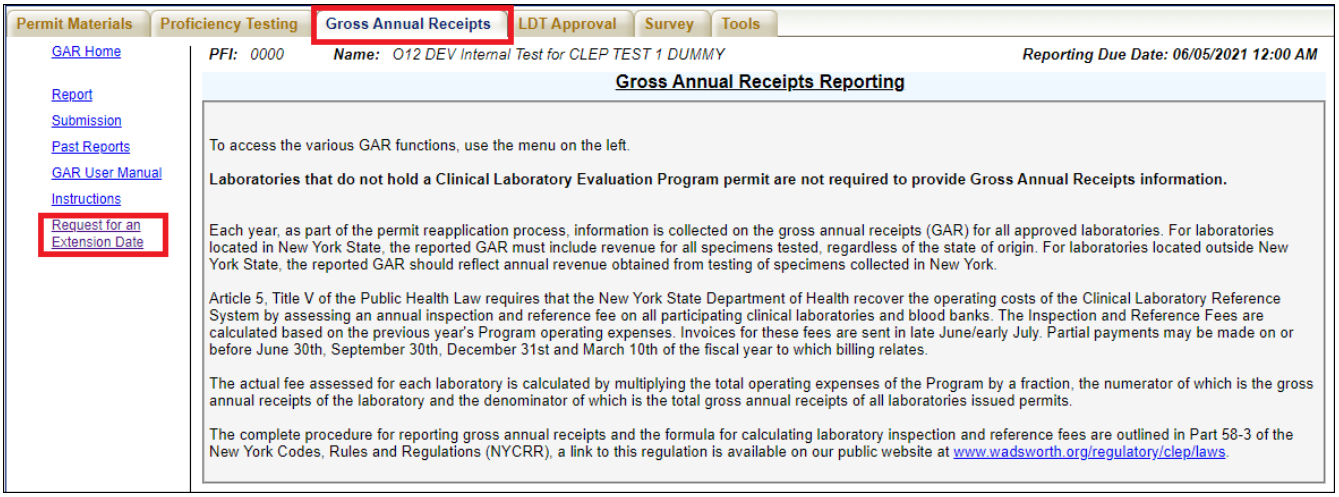


On the **Survey** Home page, there is a link that points to the **Extension Request Date** page on the left panel:

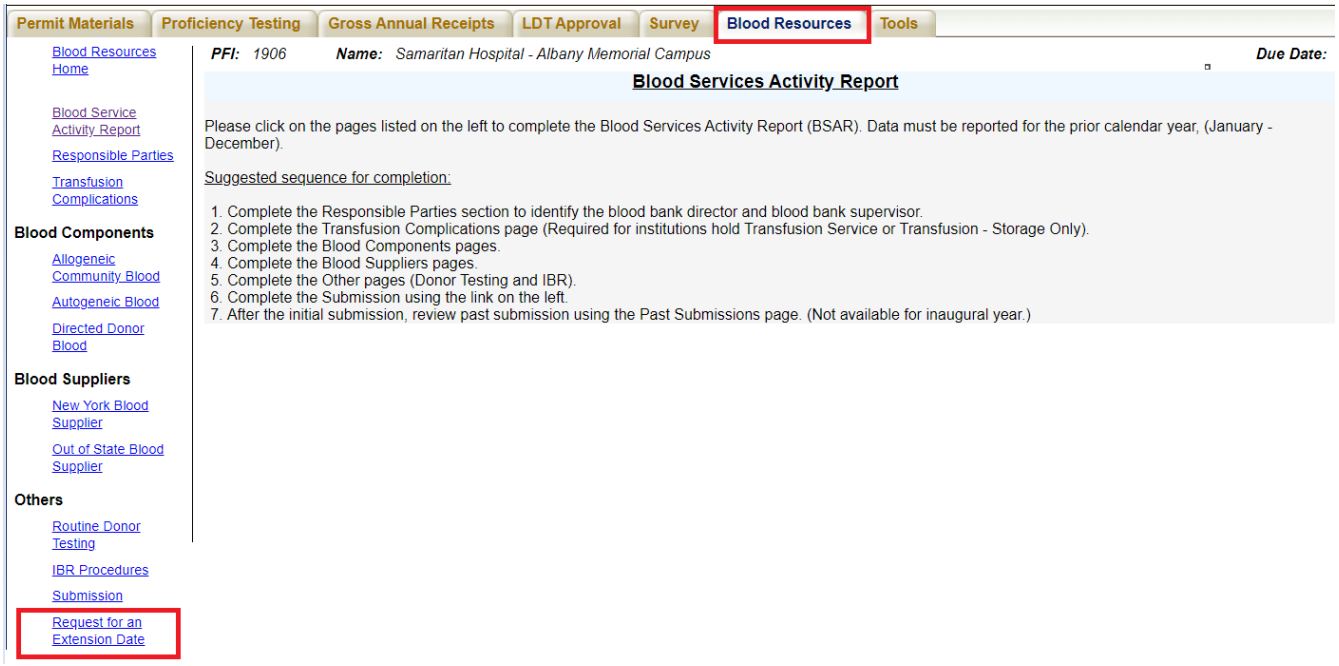


ECLEP MANUAL

On the **Gross Annual Receipts Reporting** Home page, there is a link that points to the **Extension Request Date** page on the left panel:



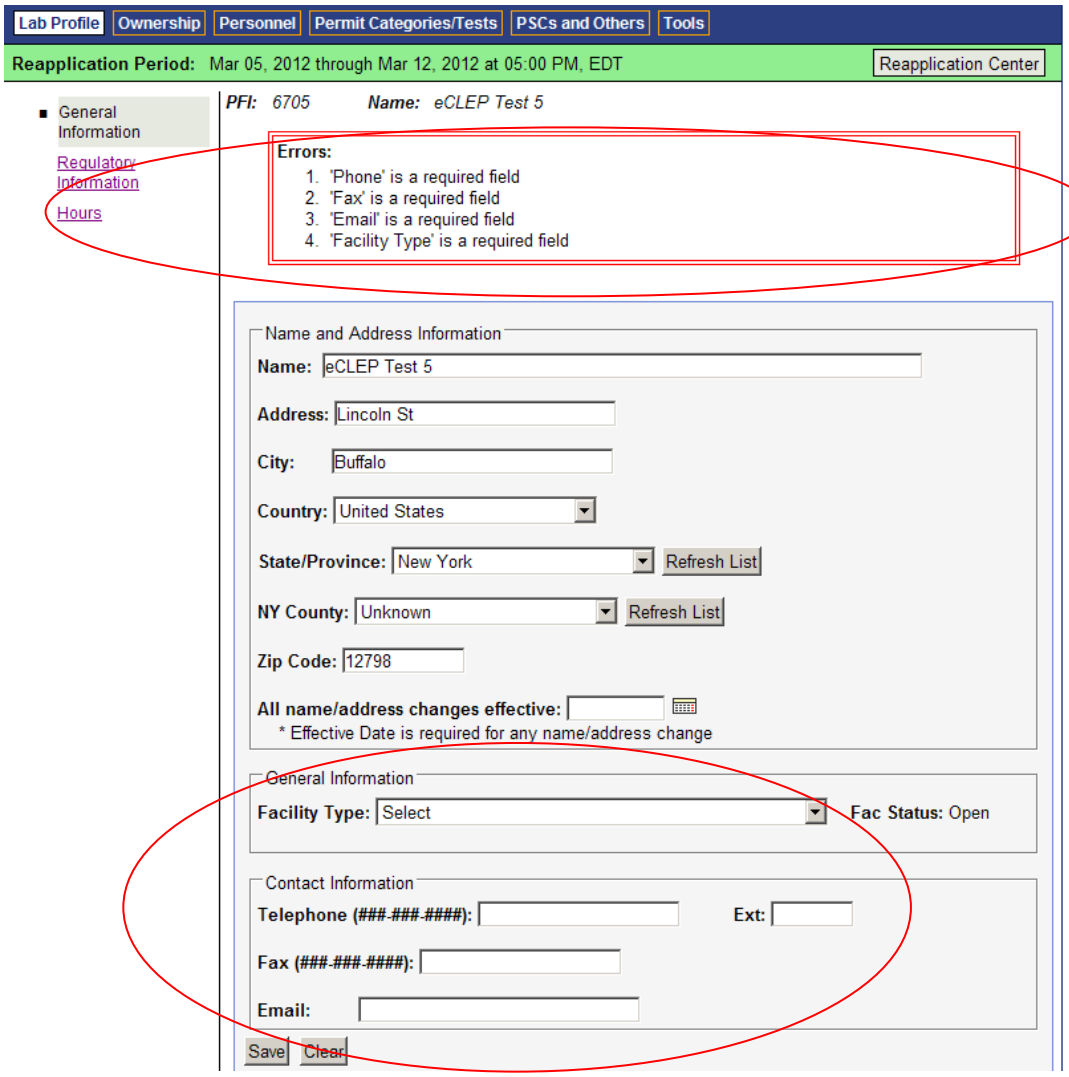
On the **Blood Services Activity Report** Home Page, there is a link that points to the **Extension Request Date** page on the left panel:



Miscellaneous

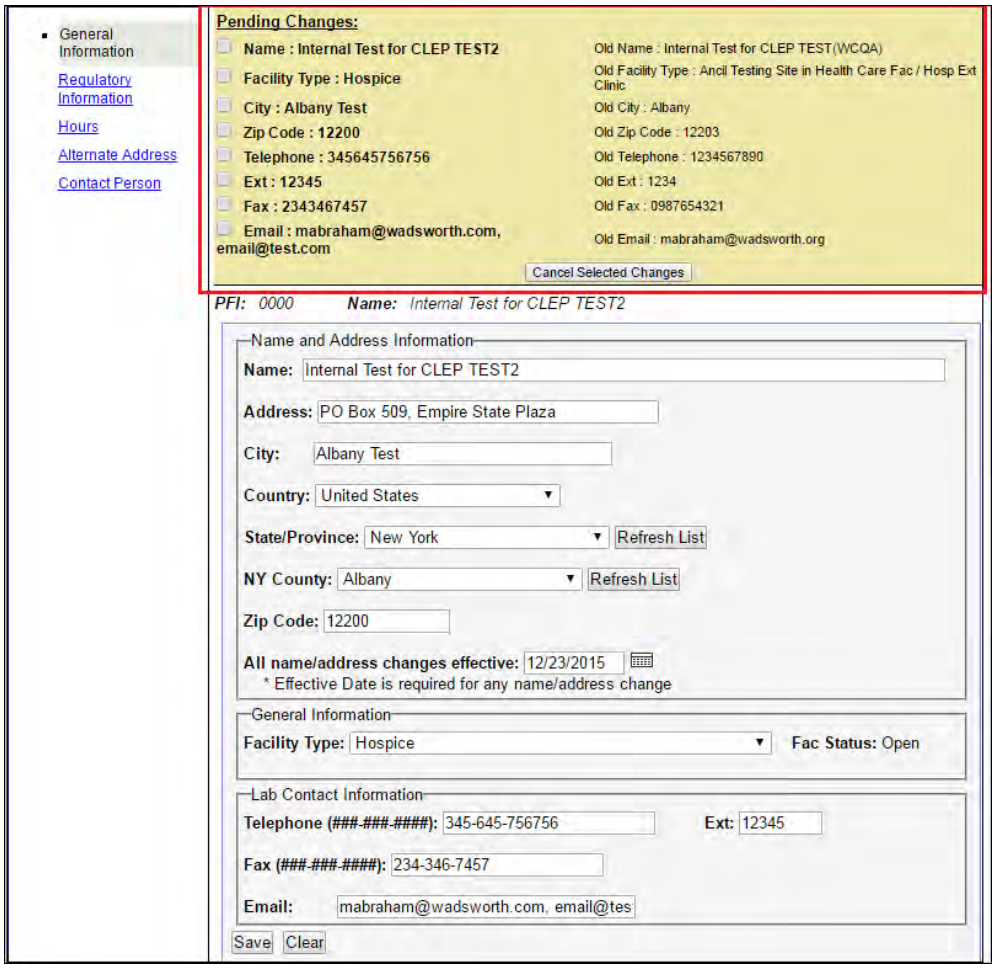
Error Messages

1. Error messages are bordered in red and will appear at the top of the screen after you click **Save** or **Next** or **Finish,** as appropriate. Most text fields without pre-populated information will require a response in order for the page to be saved. Error messages will also prompt you to provide information in the appropriate format, e.g. telephone numbers need to be entered in this format: 123-456-7890.



Pending Changes

2. Saved changes are displayed in the beige/mustard area at the top. It is possible to cancel previously entered changes by selecting one or more of them (click in white box next to name of change) and clicking **Cancel Selected Changes**.



Note: **Pending Changes** are saved so that the reapplication may be continued at a later date/time. To continue a reapplication at a later date/time repeat steps in Steps 1-6 to in *Accessing eCLEP and the Permit Materials Module* of this manual.

If changes are entered but not submitted within one week, the laboratory will begin receiving reminder emails every Monday until the change is either cancelled or submitted.

Request to Re-Open eCLEP

To re-open the eCLEP system from Read-Only mode to either the Reapplication mode or Open mode, please email CLEP at clep@health.ny.gov. Please indicate the laboratory's four digit PFI and the words "Re-Open eCLEP Permit Materials" in the subject line.

HCS Timeout

For security reasons, there are session timeouts after one hour of inactivity and HCS timeouts after eight hours of total connectivity. These timeouts occur without warning. Timeouts take you back to the login page and force you to re-enter your User ID and Password. If a timeout occurs before you hit **Save** on the data entry page, you will lose all your data entry. It is recommended to hit **Save** often while working on long data entry forms.

Exiting eCLEP

There are two ways to exit eCLEP:

1. Close your browser by selecting **File** and **Close** from the browser's menu.
2. Click **Logout** at the top right.
    a. The **You are now logged off** message page displays.

Technical Support

Technical Support is available for eCLEP and for the NYSDOH Health Commerce System (HCS) in the following areas:

Help with HCS Enrollment

For additional assistance contact the Commerce Account Management Unit (CAMU) Help Desk:

(866) 529-1890 (Mon-Fri 8am – 4:45pm)

camu@its.ny.gov

Help with eCLEP

For additional assistance contact the Clinical Laboratory Evaluation Program at **CLEP@health.ny.gov**.

Glossary

Certificate of Qualification (CQ) – a certificate issued by NYSDOH to an individual after the applicant has documented that s/he meets the minimum qualifications as a Laboratory Director set forth in Part 19 of 10NYCRR.

CLEP – Clinical Laboratory Evaluation Program

Delegated Submitter – a person who has been given written authorization by the Laboratory Director to electronically submit facility information on behalf of the Director. A Delegated Submitter will be authorized to enter and submit data electronically using the eCLEP system.

DOH – Department of Health

eCLEP – Electronic Clinical Laboratory Evaluation Program application located on the HCS

Enter Data – Filling out the forms for eCLEP

HCS – Health Commerce System – the Department of Health's secure Internet network that provides data interchange between health care providers and the NYSDOH.

HCS Coordinator – An individual at the laboratory, designated by the laboratory director, who has the responsibility of requesting additional HCS accounts for data entry individuals. The HCS Coordinator also affiliates HCS User IDs with the laboratory for new users and removes the affiliations for users who have left the laboratory.

Laboratory Director – an individual who is responsible for the administration of the technical and scientific operation of a clinical laboratory or blood bank, including the supervision of procedures, reporting of results and responsibilities specified in Subpart 19.3 of 10 NYCRR and Article 5 Title V Section 571 of the Public Health Law. Such person shall possess a Certificate of Qualification issued pursuant to Part 19 of 10 NYCRR. A Director will be authorized to enter, submit and attest to information entered using the eCLEP system.

NYCRR – New York Codes, Rules and Regulations

NYSDOH – New York State Department of Health

PDF – Portable Document Format file – a file format which creates documents with a consistent look. The PDF file format was created by Adobe Systems. Adobe Reader software may be downloaded free-of-charge from: http://www.adobe.com.

Persistent Data – Data which is saved in the database and displayed in eCLEP, such as

PFI – Permanent Facility Identifier that identifies a laboratory

Submit Data – Confirming that the data entered is accurate and submitted.

User ID – An identification for logging on to the HCS