ETHIOPIAN FOOD & DRUG AUTHORITY

iLICENSE USER MANUAL

A practical guide on how to use eRIS- iLicense to manage licensing activities for the Ethiopian Food & Drug Authority

Version 2.0 February, 2023

DOCUMENT CONTROL SHEET

Project Details

Project Name:	iLicense User Manual		
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Revision History

Revision Date	Document Version	Change Summary

Approvals

This document requires the following approvals:

Name	Signature	Title	Date of Issue	Version

ACRONYMS

API	Application Program Interface
COC	Certificate of Competency
EFDA	Ethiopian Food and Drug Authority
eRIS	Electronic Regulatory Information System
FMOH	Federal Ministry of Health
SPA	Single Page Application

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DOCUMENT OVERVIEW

Purpose of this Document

This document is a manual designed to provide a step-by-step guide on how to use the iLicense application. iLicense is a web-based tool that allows importers, exporters, wholesalers, and manufacturers to apply for a certificate of competency and for EFDA to approve these applications.

iLicense is a component of the Electronic Regulatory Information System (eRIS). eRIS was designed and implemented to facilitate the licensing, inspection, registration, and import permit processes for medicines, food, cosmetics, and medical devices. eRIS is the umbrella system at EFDA and is composed of sub-systems that work together:iLicense, iInspect, iRegister, iImport, iClearance, and iVerify. Fully online, both applicants and EFDA use eRIS and its sub-component systems to manage the licensing, registration, and import application processes using this shared portal.

How This Document Should Be Used

This document should be used as a reference guide for using iLicense to complete licensing tasks. This document is a living document; any changes to its contents will be handled through a formal change control procedure.

Targeted Users of the Document

Primary users of this document include individuals and groups with responsibility for either applying for (applicants) or managing licenses (EFDA).

Scope of this Document

The scope of this document will be limited to the iLicense application only.

i-LICENSE OVERVIEW

Electronic Regulatory Information System Overview

Over 21,500 unique items flow through Ethiopia's health commodity supply chain under the private sector, NGOs, and governmental institutions, supplying around 29,200 service delivery points (hospitals, health centers, pharmacies, drug stores, and health posts) across the country. The Ethiopian Food and Drug Authority (EFDA) is responsible for ensuring the quality, safety, and/or efficacy of medicines, food, cosmetics, and medical devices. It oversees the licensing, market authorization, and import permit approval for both medical and food products for a wide variety of vendors from multiple countries. The EFDA is the National Regulatory Body of Ethiopia, which operates under the direction of the Ministry of Health (MOH).

The complexity of EFDA's organization and its work, its size, the numbers and quantities of products, and the variety of tasks it is charged with (registration, quality testing, inspection, importation, post market surveillance, pharmacovigilance, etc.) require rigorous implementation of and adherence to laws, policies, and processes to ensure success in achieving its mission.

Technology plays a pivotal role in facilitating and maintaining both implementation and adherence. EFDA is building a technology infrastructure that links the various tasks it undertakes under one unbroken chain of information, from licensing and registration to import and quality assurance.

The Electronic Regulatory Information System (eRIS) was designed and implemented to facilitate the licensing, inspection, registration, and import permit processes. eRIS is the umbrella system at EFDA and is composed of sub-systems that work together: iLicense, iInspect, iRegister, iImport, iClearance, and iVerify. Fully online, both applicants and EFDA use eRIS, and its sub-component systems to manage the licensing, registration, and import application processes using this shared portal.

iLicense is an online application developed for the EFDA that allows importers, exporters, wholesalers, and manufacturers to apply for a certificate of competency and for the EFDA to approve these applications online. This application is designed to manage the licensing process for all entities who wish to manufacture, register, import, and distribute food and medical products in Ethiopia—from the start of a licensing application to approval. The iLicense tool is designed to expedite the licensing process for both the EFDA and applicants, including manufacturers, importers, and wholesalers.

The Digital Health Activity - John Snow Inc. (DHA-JSI) developed and implemented iLicense in partnership with and under the direction of the EFDA and the Ethiopian Pharmaceuticals Supply Service (EPSS).

iLicense Overview

iLicense, a critical part of eRIS, is an open-source, web-based application used to digitize the process of securing certificates of competency (COCs). This tool allows:

- Importers, exporters, wholesalers, and manufacturers apply for COCs required to register or import products into Ethiopia.
- EFDA to accept, review, and authorize these applications.

Throughout the licensing process, it is also used to manage decision-making, associated documents, and communication between EFDA and applicants. Once a facility is registered via iLicense, it enters the market authorization and import permitting process, which is managed via the other components of the eRIS (iRegister and iImport applications).

Intended Users

iLicense is designed to make the licensing process more efficient, effective, and transparent. Anyone who is involved in the licensing process should have access to this tool.

Primary users include:

- Importers, exporters, wholesalers, and manufacturers who are interested in being licensed to receive a Certificate of Competency in order to import medicines, food, cosmetics, and medical devices into Ethiopia. This cohort includes: manufacturers, importers, exporters, wholesalers licensed in Ethiopia. Currently, there are more than 918 manufacturers, 4,618 importers, 612 exporters, and 1,344 wholesalers licensed in Ethiopia.
- EFDA employees are those who direct day-to-day management and review of the licensing processes. These staff include: Inspectors, Inspector Team Leaders, CSO, CSO Team Leaders.
- Stakeholders who need data for decision making at different levels, e.g. EFDA management, FMOH management.

The screens/functionalities will differ for each user based upon the following set of roles/privileges.

Key Features

iLicense automates the flow of information and coordinates key activities within and across the licensing workflow. This includes:

- New Application – Request, review, and approve facility licenses.
- Renewal – Request, review, and approve licenses for existing facilities seeking to renew their certificate.
- Change – Request, review, and approve changes to certificates for existing facilities.
- Alerts and Notifications – Update application status, including approvals.
- Return COC Certificate – Request a return, review and approve license return requests.
- Generate Report – Query reports pertaining to all aspects of applications and licensing. Facility Management – Access and manage facility data.
- User Information Management – Add, update, deactivate user accounts.
- System Configuration – Configure documents, checklists, products, professional information, and other key data used in application forms.

iLicense is used throughout the licensing process to manage decision-making, associated documents, and communication between EFDA and applicants. It ensures transparency within and throughout the licensing process.

Once a facility is registered via iLicense, it enters the market authorization and import permitting processes, which is managed using the iRegister and iImport applications, respectively.

Key Benefits

iLicense offers significant benefits to the licensing process and all impacted parties. These benefits include:

- Improves data quality by preventing multiple points of data entry.
- Provides the directorate full transparency.
- Ability to track an application, spot any flaws, and offer a solution as soon as one is required.
- Centralized license and data management across the organization and involved parties/users.
- Facilitates easy and instant generation of reports for data analysis and decision-making for both management and clients.
- Real-time traceability of license applications.
- Organizational efficiency by generating and allowing easy access to reports like lead time reports and daily status updates

NAVIGATION

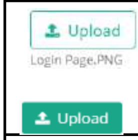
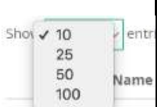
iLicense Acronym / Menu Key

The following acronyms are defined as follows:

ASDP	***Assigned to Pre-Screener***	When an application is assigned to a specific EFDA reviewer.
CERG	***Certificate Generated***	When an application is approved and certificate generated.
FATCH	***Fee Attached***	When the application is successfully attached to the service fee.
PAYV	***Payment Verified***	When a pre-screener has verified the fee attached.
PREF	***Pre-Screening Failed***	When a submitted application has an error and the applicant must edit it as directed by the comment.
PRSC	***Prescreened***	When all required documents are submitted for an application.
UREV	***Payment Verification Failed***	When the attached payment receipt has an error and the applicant must re-attach the payment receipt.
REJ	***Application Rejected***	When the application is not approved to have Certificate of Competency.
RQST	***Requested***	When a new application is created, submitted, and ready for review.
RTA	***Return to Applicant***	When an application has failed inspection, the applicant must make changes according to the Pre-licensing result.
WITH	***Withdrawn***	When an application has been withdrawn and is no longer being reviewed.

Icon Navigation

iLicense uses icons to complete various tasks. These include:

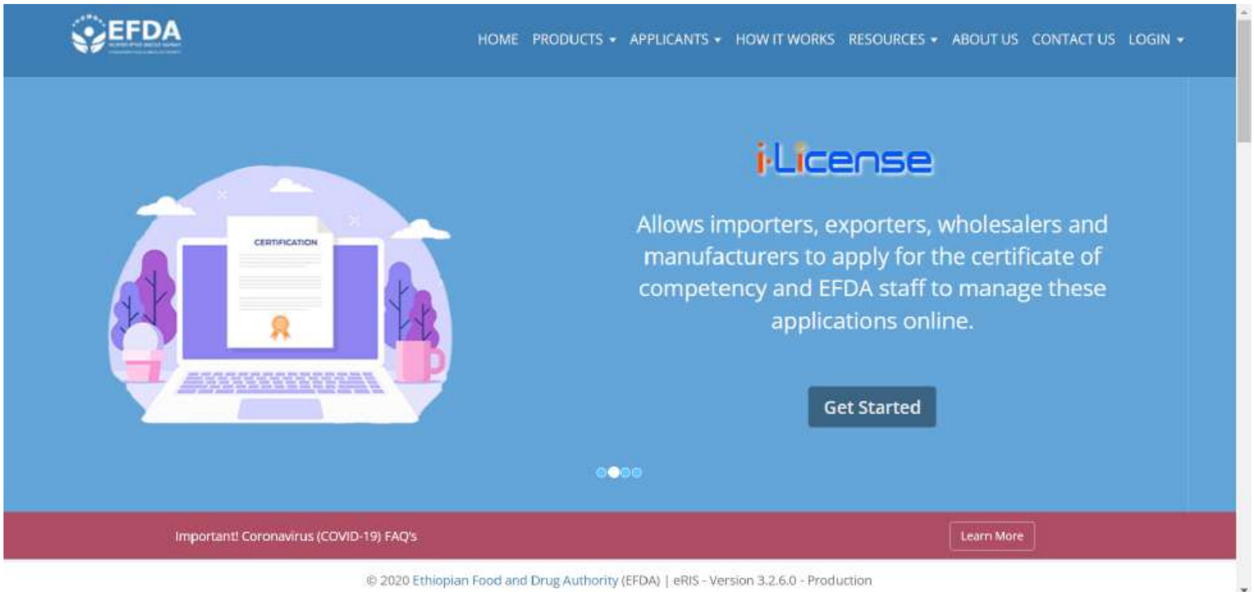
	This icon indicates that a customer service Director/ team leader needs to assign a customer service officer.
	Click on an application number to open a screen that shows application details.
	Click the “upload” button to upload documents associated with the application. If the icon is **green,** then it means you have successfully uploaded documents.
	This icon allows you to preview an uploaded document.
	This icon allows you to download documents attached by the applicant or generated by the system.
	Click this button to start creating a new application.
	This icon indicates that a user is inactive.
	This icon indicates that a user is active.
	This icon allows you to edit a user account
	This icon allows you to add new users.
	This icon allows you to see the number of pages.
	This icon allows you to select the number of pages you want to view.
	This icon allows you to reset your password.

LOGIN ACCESS

Tool Website Address

I-License can be accessed via the internet through this URL: http://www.eris.efda.gov.et/.

Type this address into any browser (e.g., Chrome, Firefox, Internet Explorer, Safari), or click on the above link.



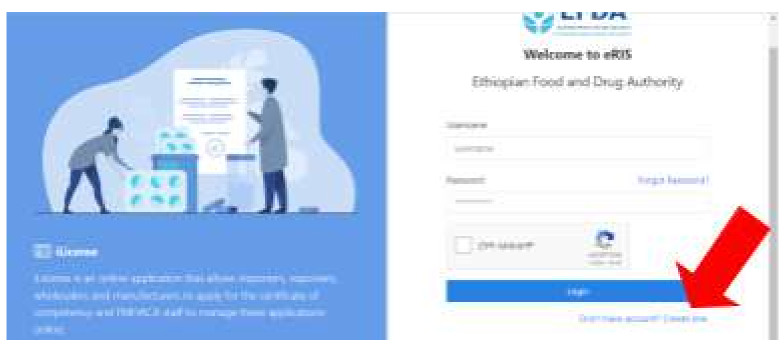
Create New User Account

WHAT:	This process is used to create a new account for applicants so that they can register their facility and process their Certificate of Competency (COC).
WHEN:	When an applicant wants to use iLicense to complete licensing actions.
WHO:	Applicants

NOTE: The account you are about to create will expire if you have not registered your facility.

1. Select **"iLicense"** from the **"Login"** dropdown menu.

2. Click **"Don't have an account? Create one."**



3. Enter:
    a. **First Name**
    b. **Last Name**
    c. **Email**
    d. **Phone Number**
    e. **Create a User Name**
    f. **Create a password.**
    g. **Confirm your password.**

4. Click the **“Submit” button**.

   This will send a confirmation email to the email you registered with. Go to your email account and find this message. Click on the link in your confirmation email to complete the signup process.

Note:

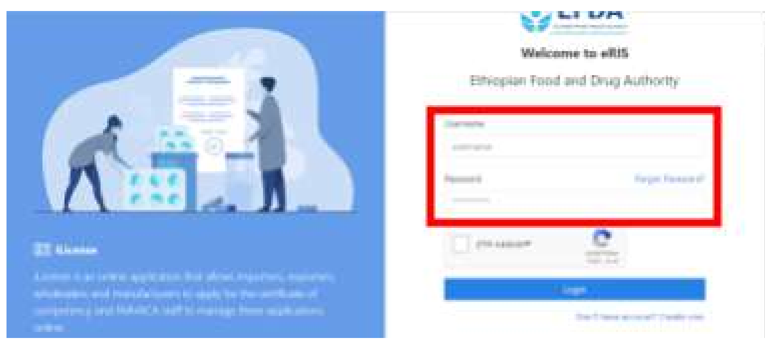
- ***The username and password you enter here is used to login your account. You have to remember it.***
- ***The email address and phone number you enter here will be used to send you notifications and also to recover your password if forgotten. Please use a valid email address and phone number.***

Login

WHAT:	This process is used to login and use iLicense to complete licensing actions.
WHEN:	Whenever a licensing action is needed.
WHO:	Any registered user (EFDA, Applicant, etc.)

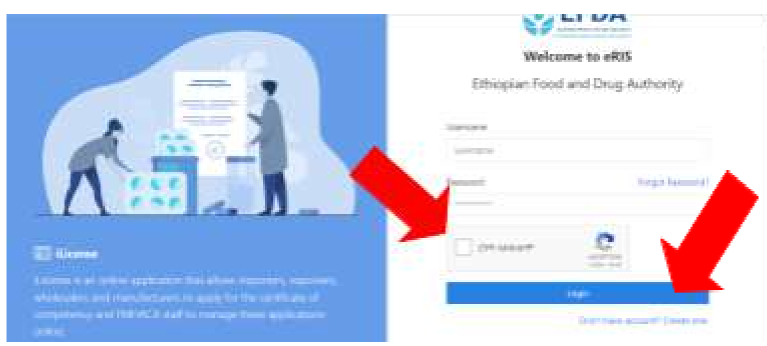
1. Select **“iLicense”** from the **“Login” dropdown menu**.

2. Enter:
    a. **Username**
    b. **Password**



3. Complete the **reCAPTCHA**.

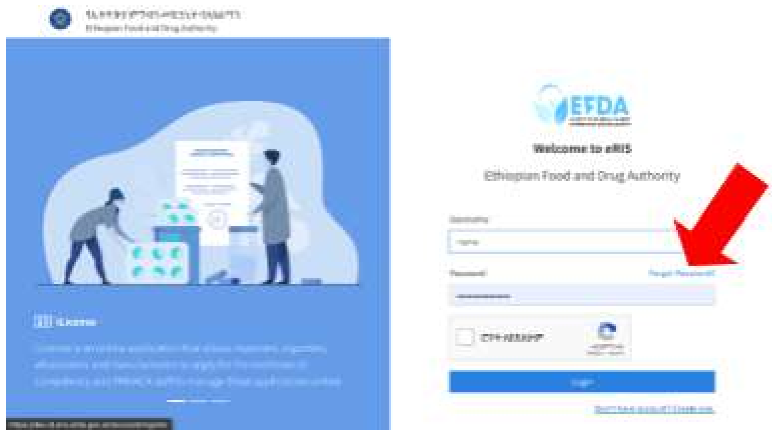
4. Click the **“Login”** button.



Recover Forgotten Password

WHAT:	This process is used to recover a forgotten password.
WHEN:	When a user forgets his/her password.
WHO:	All user type

1. Click on the **"Forgot password?"** icon to recover your forgotten password.



2. Enter your **"Username"**.
3. Click on the **"Submit" button**.
4. Check your email registered with this site – the website will send a secret code to this email to recover your password and start using eRIS again.

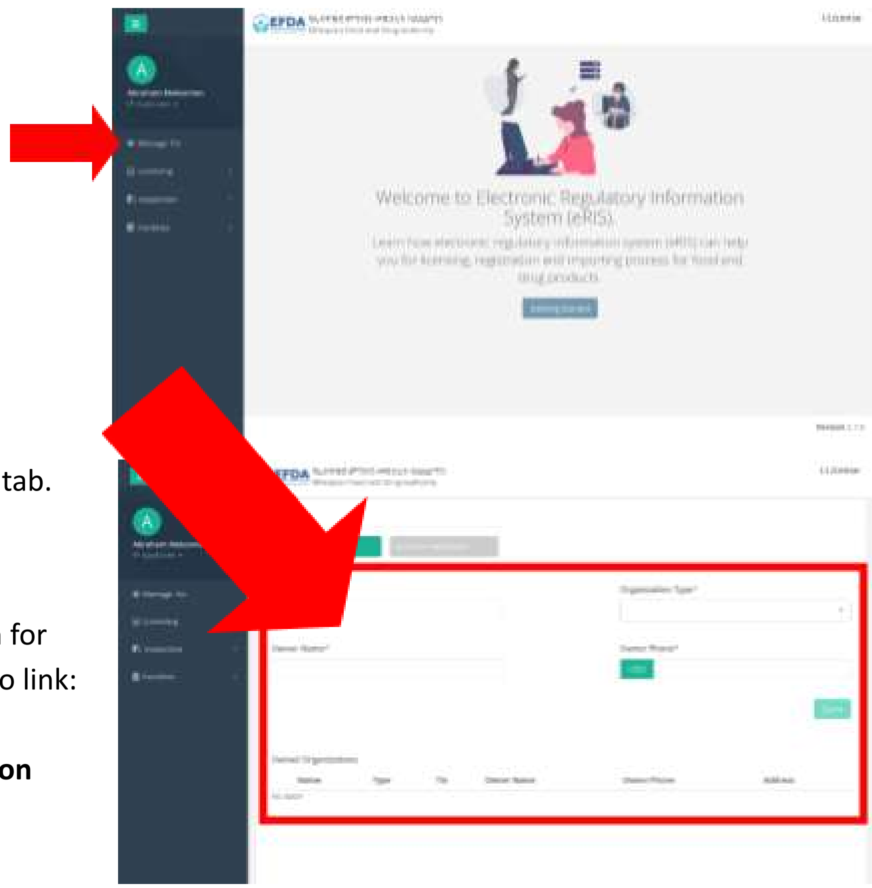
Note: Enter your username exactly;

- ***Do not add any extra spaces.***
- ***Use appropriate capitalization.***

Set Up & Link Account to Facility

WHAT:	This process is used to connect and link iLicense user accounts with specific facilities.
WHEN:	When applicants want to start processing licensing applications and connect facilities with user accounts.
WHO:	Applicants

1. Click **“Manage TIN”**.

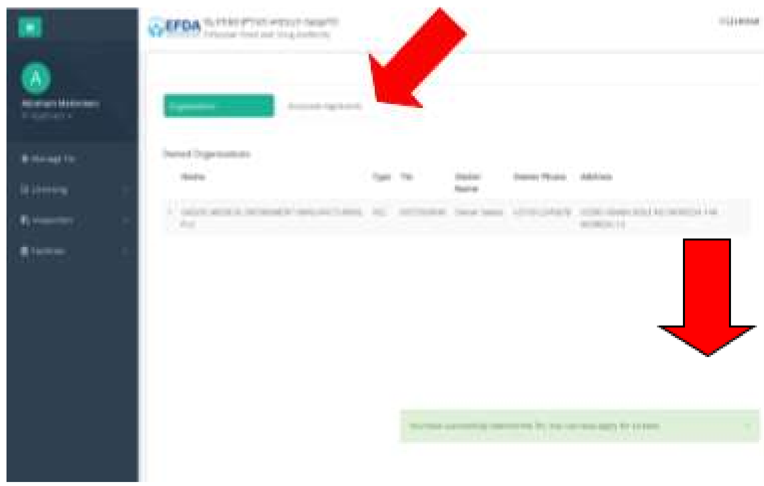


2. Click the **“Organization”** tab.

3. Enter facility information for the employee you wish to link:
    a. **TIN number**
    b. **Select Organization Type**
    c. **Owner Name**
    d. **Owner Phone Number**

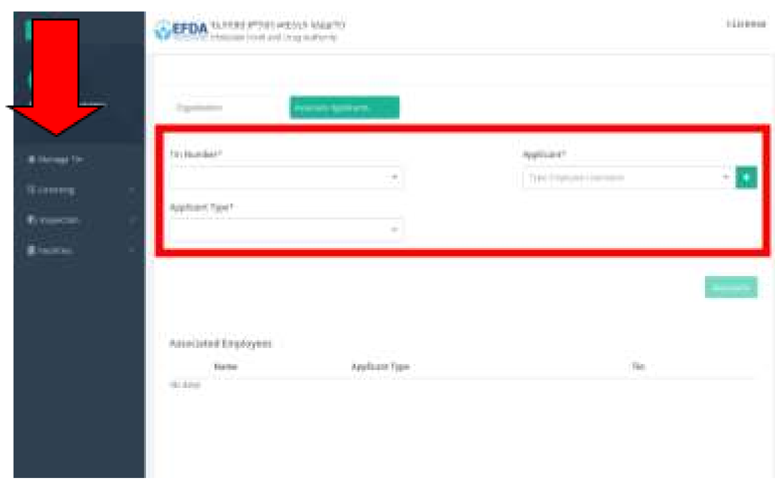
4.Click **“Claim”** when finished.

5. Click the **“Associate Applicants”** tab to create an account for the new employee and associate it with the correct organization/TIN who is processing licensing applications.

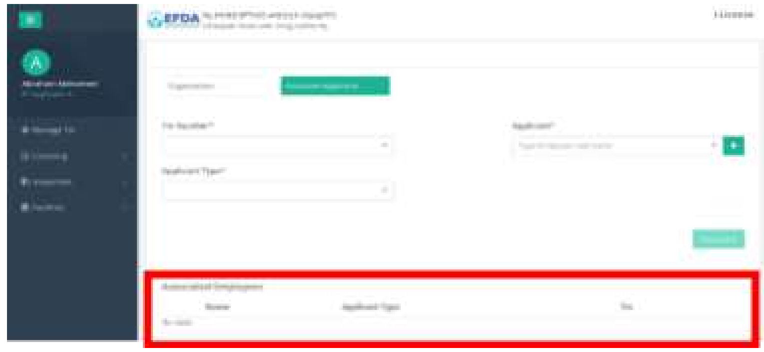


6. Enter information for the new employee, or associate:

   a. **TIN Number**
   b. **Applicant Type**
   c. **Applicant**



i. **<u>If an employee has an account</u>** in eRIS, then search by username or employee name and select the employee.



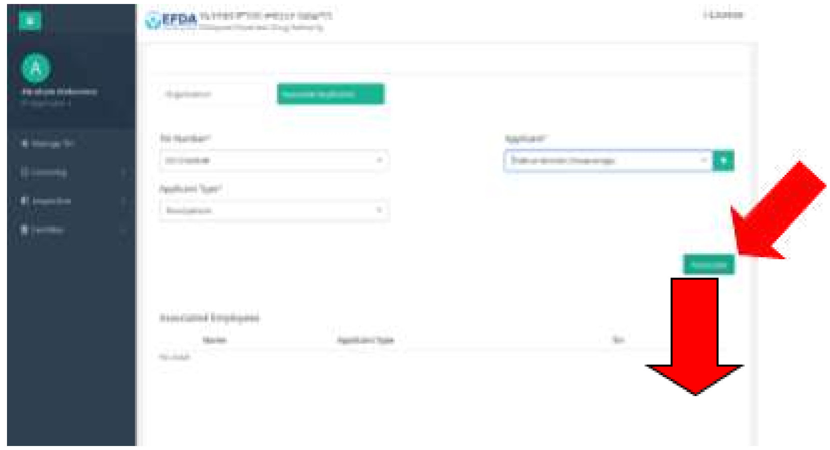
ii. **<u>If an employee does not have an account on eRIS</u>**, create a new account by clicking the plus sign.

Enter **information for the employee**:

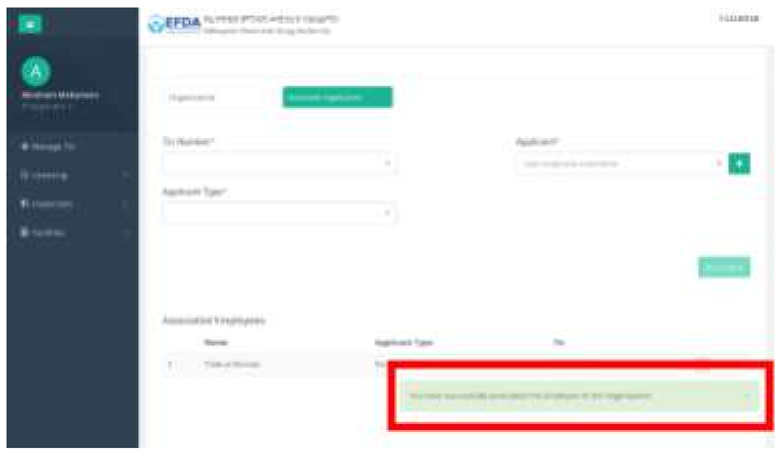
a. First name
b. Last name
c. Username
d. Email address
e. Phone number
f. Address
   - Region
   - Zone/Subcity
   - Woreda
   - Kebele (if any)
   - City (if any)
   - House number (if any)

iii. Click the **"Create"** button.

6. Click the **“Associate”** button.



Note: when an employee is successfully associated, iLicense will display a green box notifying you of the success.

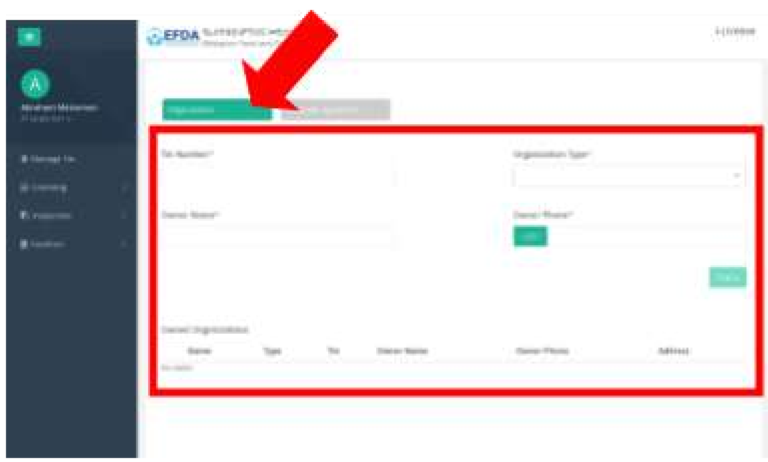


Remove an Employee Account from a Facility

WHAT:	This process is used to remove an employee account from a facility.
WHEN:	When an account is no longer needed.
WHO:	Administrator

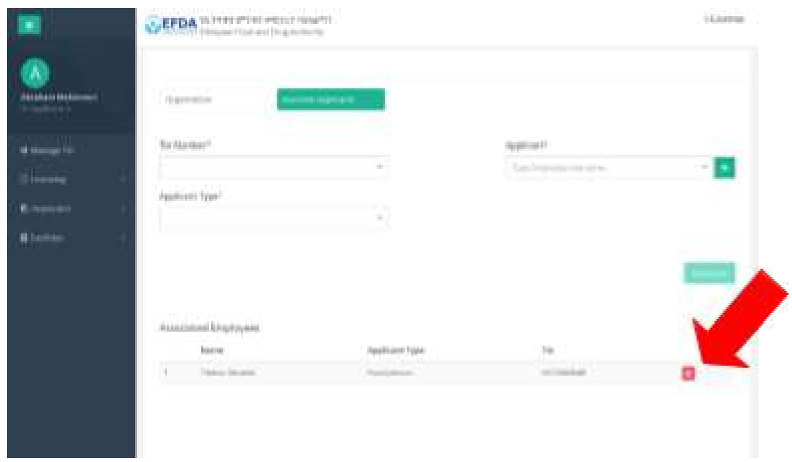
1. Click **"Manage TIN"**.

2. Click the **"Organization" tab**.
3. Enter facility information for the employee you wish to remove:
    a. **TIN number**
    b. **Select Organization Type**
    c. **Owner Name**
    d. **Owner Phone Number**



4. Click the **"Associate Applicants" tab**.

5. Find the **employee you wish to remove**.
6. Click the **"Remove" icon** next to his/her name.
7. Click **"Yes"** when asked if you are sure you want to remove the employee from the associated employees list.

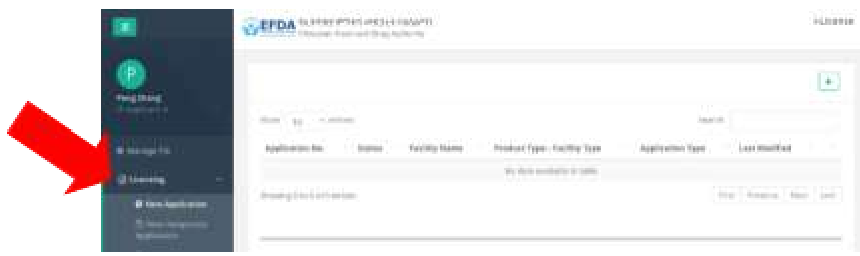


NEW APPLICATIONS

Submit a New Application Request

WHAT:	This process is used to submit a registration request application in order to receive a *Certificate of Competency* (COC).
WHEN:	When applicants want to apply for a *Certificate of Competency* (COC).
WHO:	Applicants

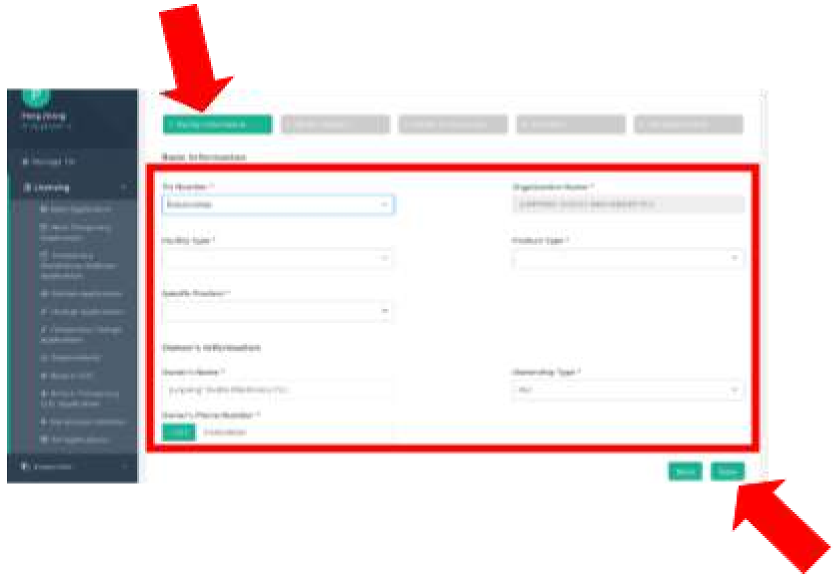
1. Click **“Licensing”**.



2. Click either **“New application”** or the **“+” icon**.

3. Enter **“Facility TIN Number”**.
4. Click the **“Next” button** when finished.

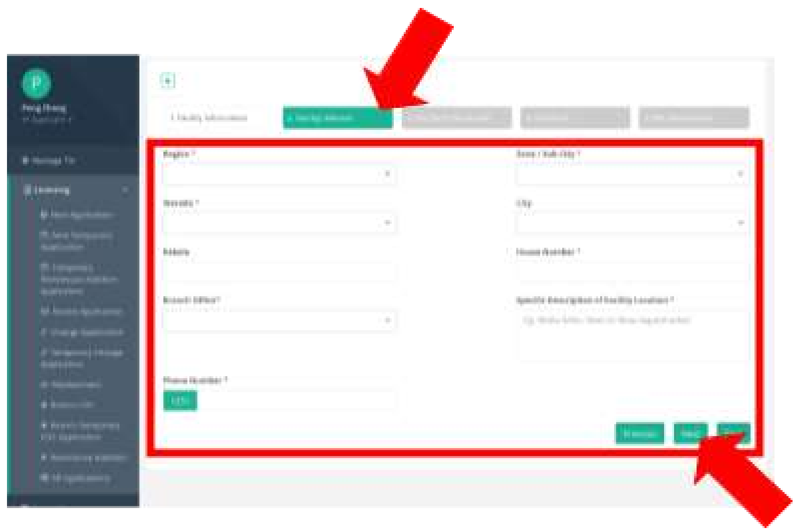
5. Click the **“Facility Information” tab**.



6. Enter the facility’s information:
    a. **Organization Name**
    b. **Facility Type**
    c. **Product Type**
    d. **Owner’s Name**
    e. **Ownership Type**
    f. **Owner’s Phone Number**

7. Click the **“Next” button.**

8. Click the **“Facility Address” tab.**



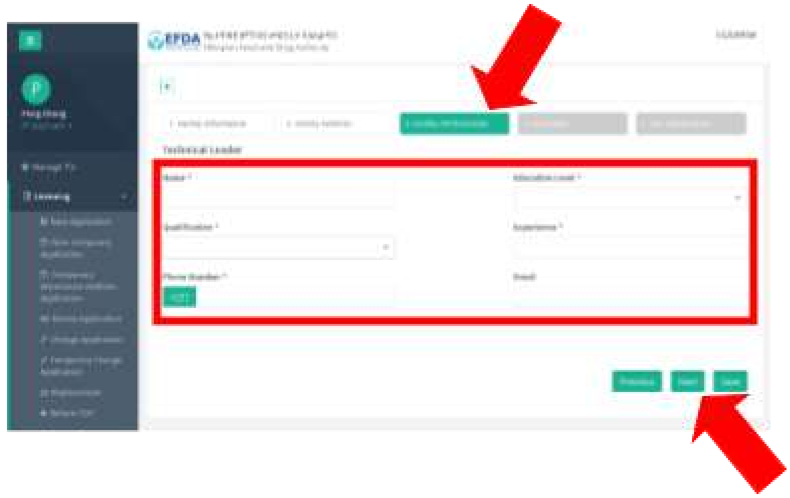
9. Enter the facility address:
    a. **Region**
    b. **Zone/ Subcity**
    c. **Woreda**
    d. **City**
    e. **Kebele**
    f. **House Number**
    g. **Phone Number**
    h. **Specific Description of Facility Location**

10. Click the **“Next” button**.

11. Click the **“Facility Professionals” tab**.

12. Enter the information for the facility professional:
    a. **Name**
    b. **Education Level**
    c. **Qualification**
    d. **Experience in Years**
    e. **Phone Number**
    f. **Email**

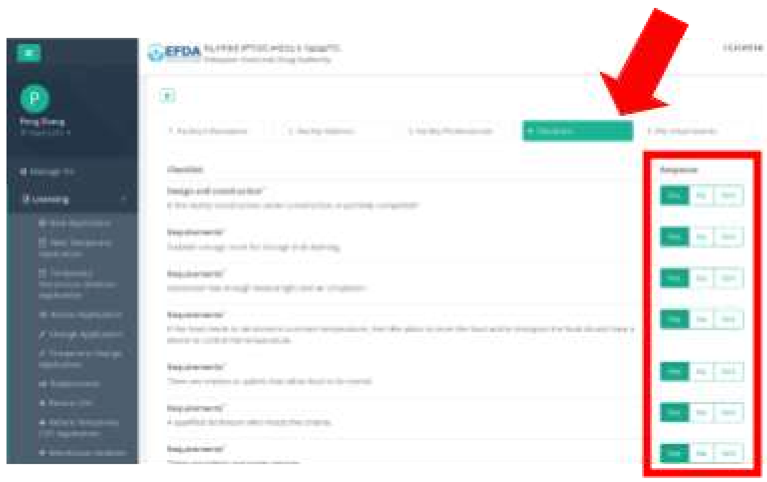
13. Click the **“Next” button.**



14. Click the **“Checklists” tab**.

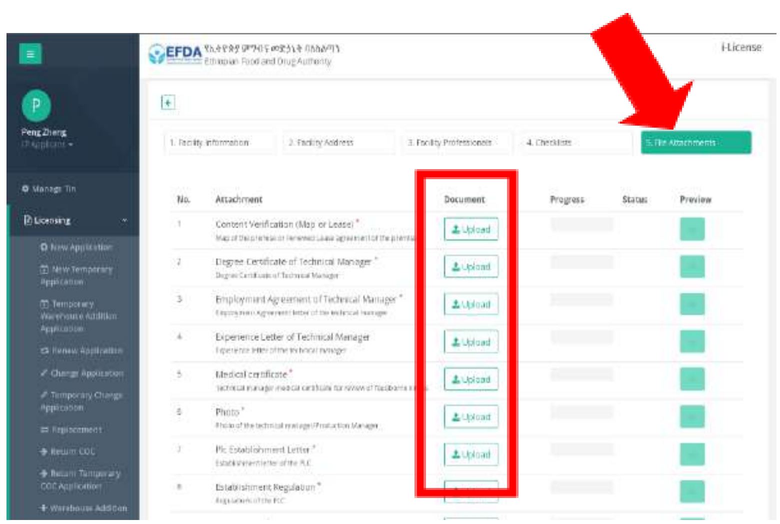
15. Fill out the checklist form by responding **“Yes”** or **“No”** or **“NA”** (Not Applicable”) for each item.

16. Click the **“Next” button.**



17. Click the **“File Attachments” tab**.

18. Click the **“Upload” button** next to each item to upload associated files and attach them.



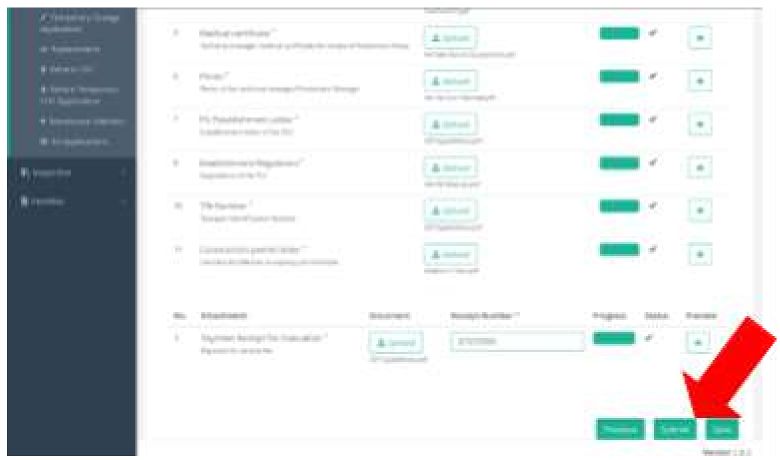
Note:

- ***When you see a checkmark appear then you will know the attachment is uploaded.***

- ***You can click on the Preview button (eye icon) to open and preview the uploaded attachment.***

19. Click the **"Submit" button** when finished.

20. Wait for the system to register your application.

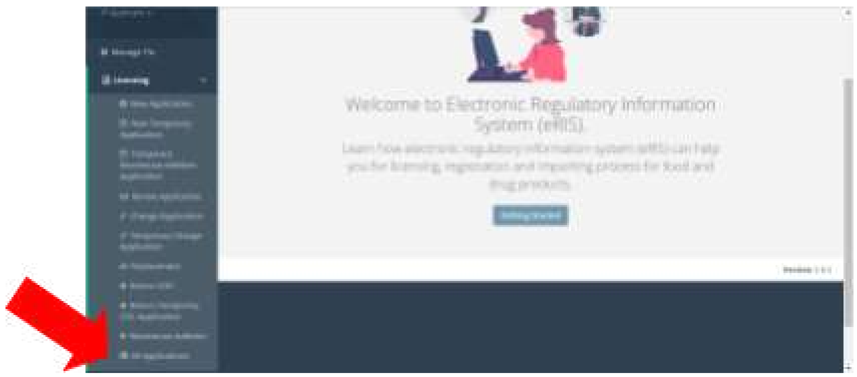


21. Your application is accepted when the notification **"Application submitted successfully"** appears in the bottom right of the screen.

Withdraw an Application to Edit

WHAT:	This process is followed when an applicant edits an application.
WHEN:	Before an application is assigned to the screener.
WHO:	Applicant

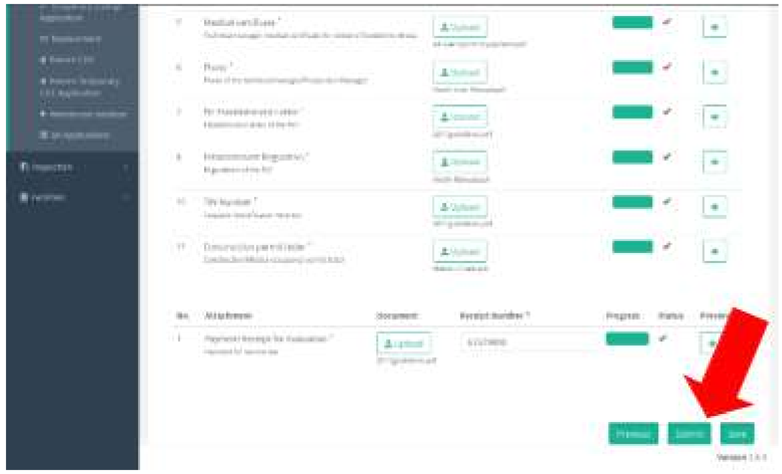
1. Click on **“Licensing”**.
2. Click on **“All Application”**.



3. Find the application with the **“Requested” status** which needs to be edited.
4. Click on the **Application Number** to open it.

5. Click the **“Edit” button**.
6. Make **edits**.

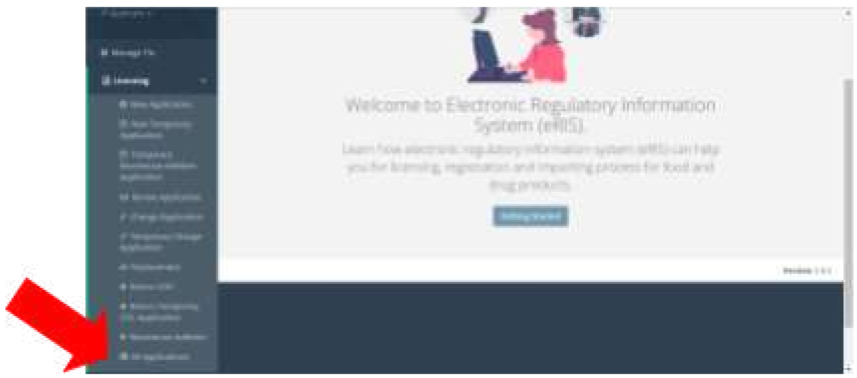
7. Click **"Submit"** when finished.



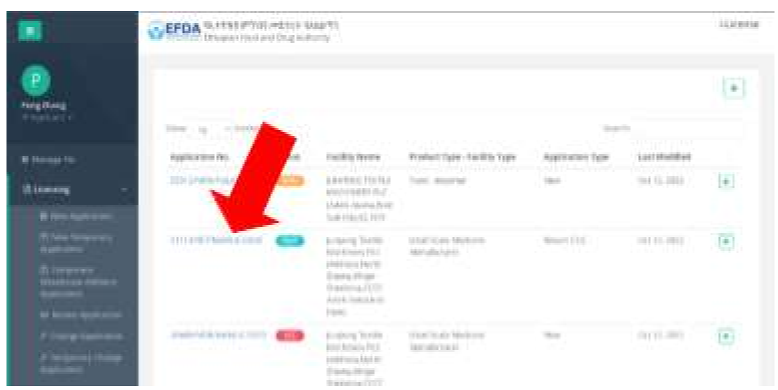
Withdraw an Application to Cancel

WHAT:	This process is used when an applicant withdraws an application to: edit and resubmit it or cancel it.
WHEN:	Before an application is assigned to the screener.
WHO:	Applicant

1. Click on **"Licensing"**.
2. Click on **"All Application"**.



3. Find the application with the **"Requested" status** which needs to be withdrawn.
4. Click on the **Application Number** to open it.

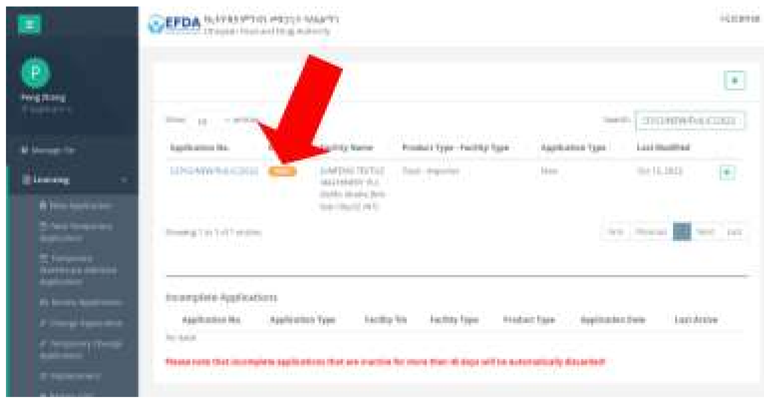


5. Click the **"Withdraw" button**.

6. Enter the **reason** for why it is being withdrawn in the **“Comment” box**.

7. Click the **“Withdraw” button**.

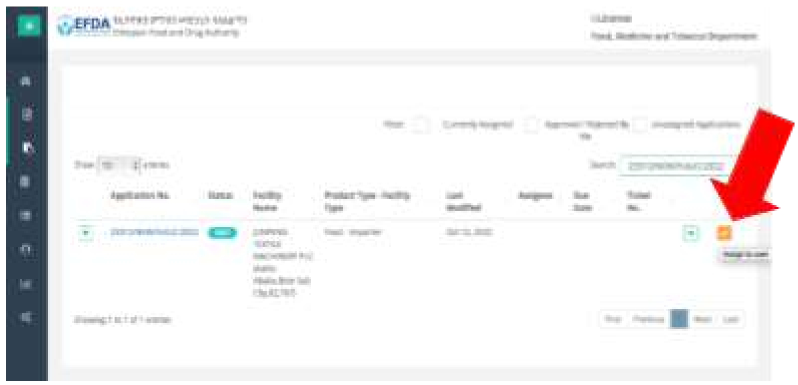
8. Now, the application status will be **changed to “Withdrawn”.**



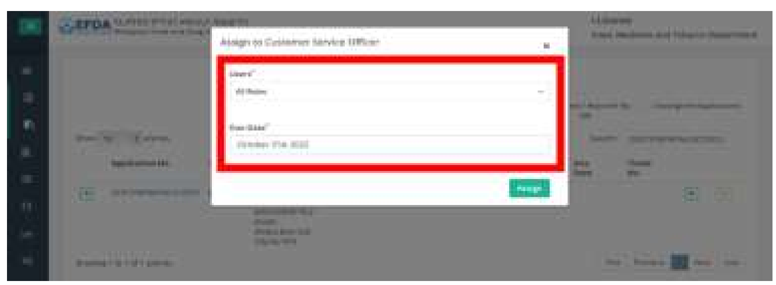
Assign Application to Customer Service Officer (CSO)

WHAT:	This process is used by the CST to assign incoming application requests to a CSO.
WHEN:	After the applicant finishes his or her application.
WHO:	Customer Service Team Leader

1. Find the application that needs to be assigned.
2. Click the **"Assign to User" box**.



3. Assign a **"User"**.
4. Set a **"Due Date"** for the application to be reviewed by.



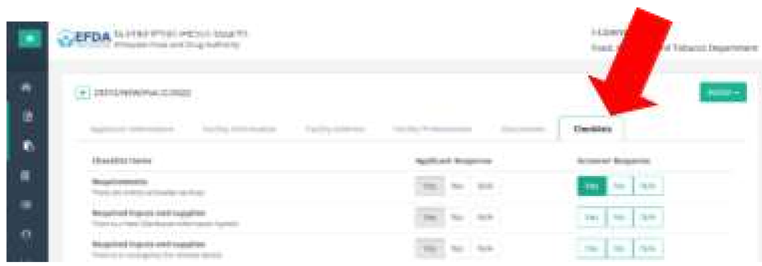
5. Click the **"Assign" button** to complete the assignment process.

   Now the application is assigned.

Screen Application for Pass or Fail

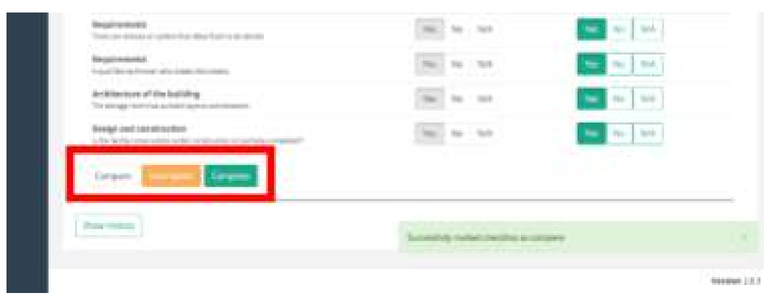
WHAT:	This process is used by the CSO to review and “pass” or “fail” an application.
WHEN:	When an application is assigned and ready for review.
WHO:	CSO

1. Open the application which needs to be reviewed.
2. Click on the **“Checklist” tab.**



3. Screen and **fill in the checklist** for each listed item.

4. Click on the **“Compare” button**.



5. When finished completing the checklist:

    a. **<u>If complete</u>**, click the **"Complete" button** so the application review process can continue.

    b. **<u>If NOT complete,</u>** click the **"Incomplete" button** so it can be returned to the applicant.

6. Click the **"Action" button** and select the result of the review:
    - **a. Pass Screening**
    - **b. Fail Screening**
    - **c. Delete Application**

Comment on “Pass” or “Fail” Action

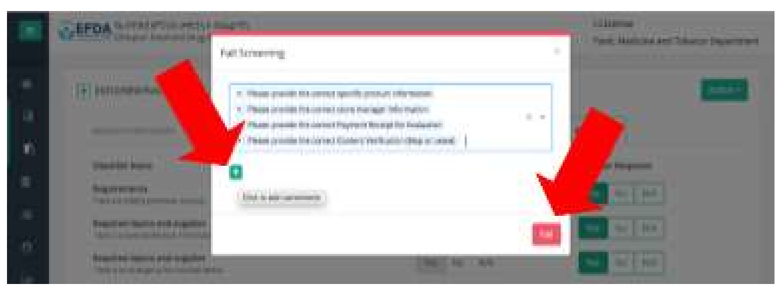
WHAT:	This is the process where the CSO comments on an application before passing it.
WHEN:	After the CSO marks an application as “pass” or “fail”.
WHO:	CSO

Once a decision is made to either pass or fail an application, the CSO must provide a reason.

“Fail” Applications—

1. Open the application which needs to be reviewed.
2. Select **“Fail Screening”** from the dropdown menu.

3. Click the **“+” icon** and **select as many reasons** as you want for why the screening failed.
4. Click the **“Fail” button** when finished.



“Pass” Applications—

1. Select **“Pass Screening”** from the dropdown menu.

2. Enter any **required comments** related to the “Pass” designation.

3. Click the **“Pass” button**.

Assign Application to Inspector

WHAT:	This is the process where the Inspection Team Leader assigns an inspection to an inspector.
WHEN:	After the CSO marks an application as "pass," its status is "pre-screened."
WHO:	Inspection Team Leader

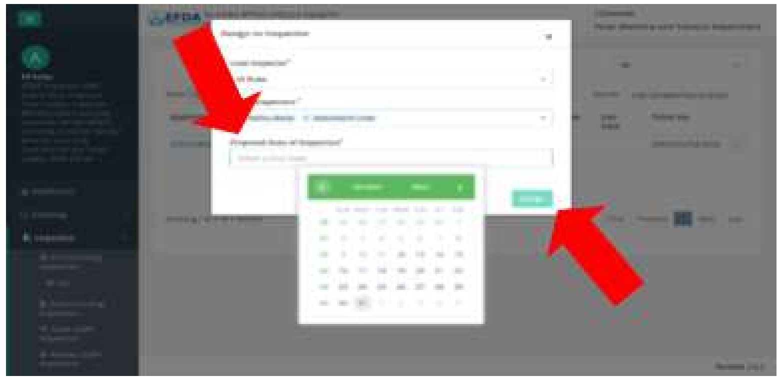
1. Click **“Inspection”**.
2. Click **“Pre-inspection”**.
3. Click **“List”**.

4. **Find the application** that needs to be assigned.
5. Click the **“Assign to Inspector” box**.

6. Select:
    a. **Lead Inspector**
    b. **Other Inspectors**
    c. **Proposed Date of Inspection**

7. Select a **“Proposed Date of Inspection”.**

8. Click the **“Assign” button**.



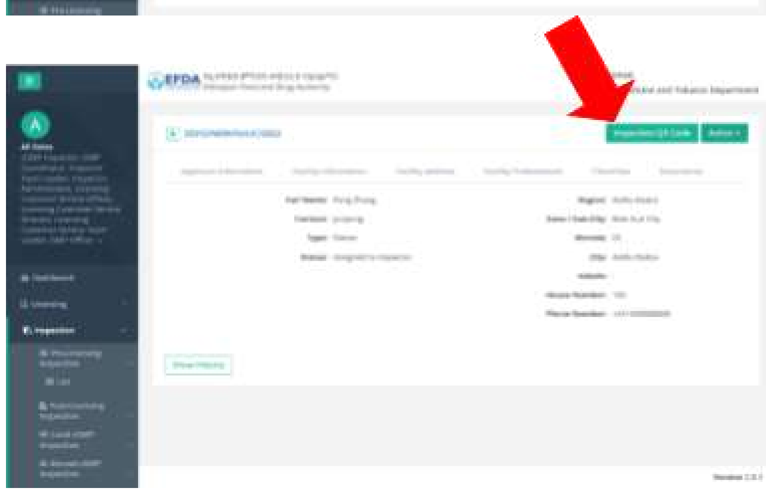
Conduct Inspection

WHAT:	This is the process where the Inspector passes or fails an application.
WHEN:	After the Inspector Team Leader assigns application to Inspector.
WHO:	Inspector

1. Select **“Inspection”**.
2. Select **“Pre-inspection”**.
3. Select **“List”**.

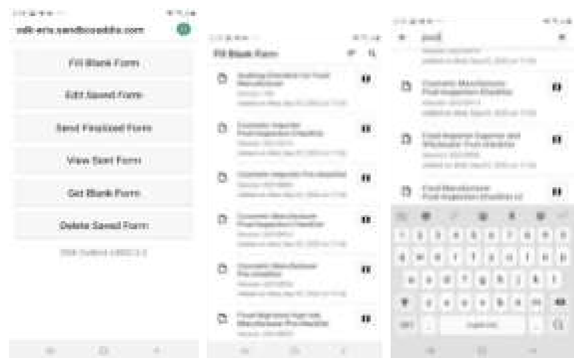
4. Click on the **number of the application** that needs to be inspected.

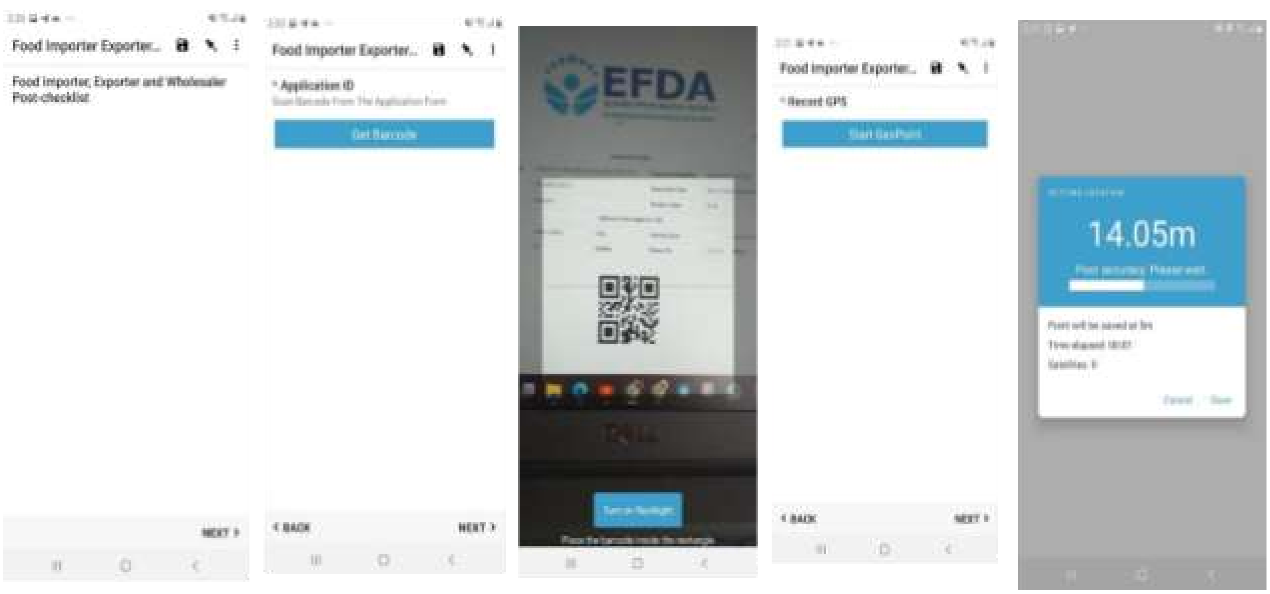
5. Click on the **“Inspection QR Code” button**.

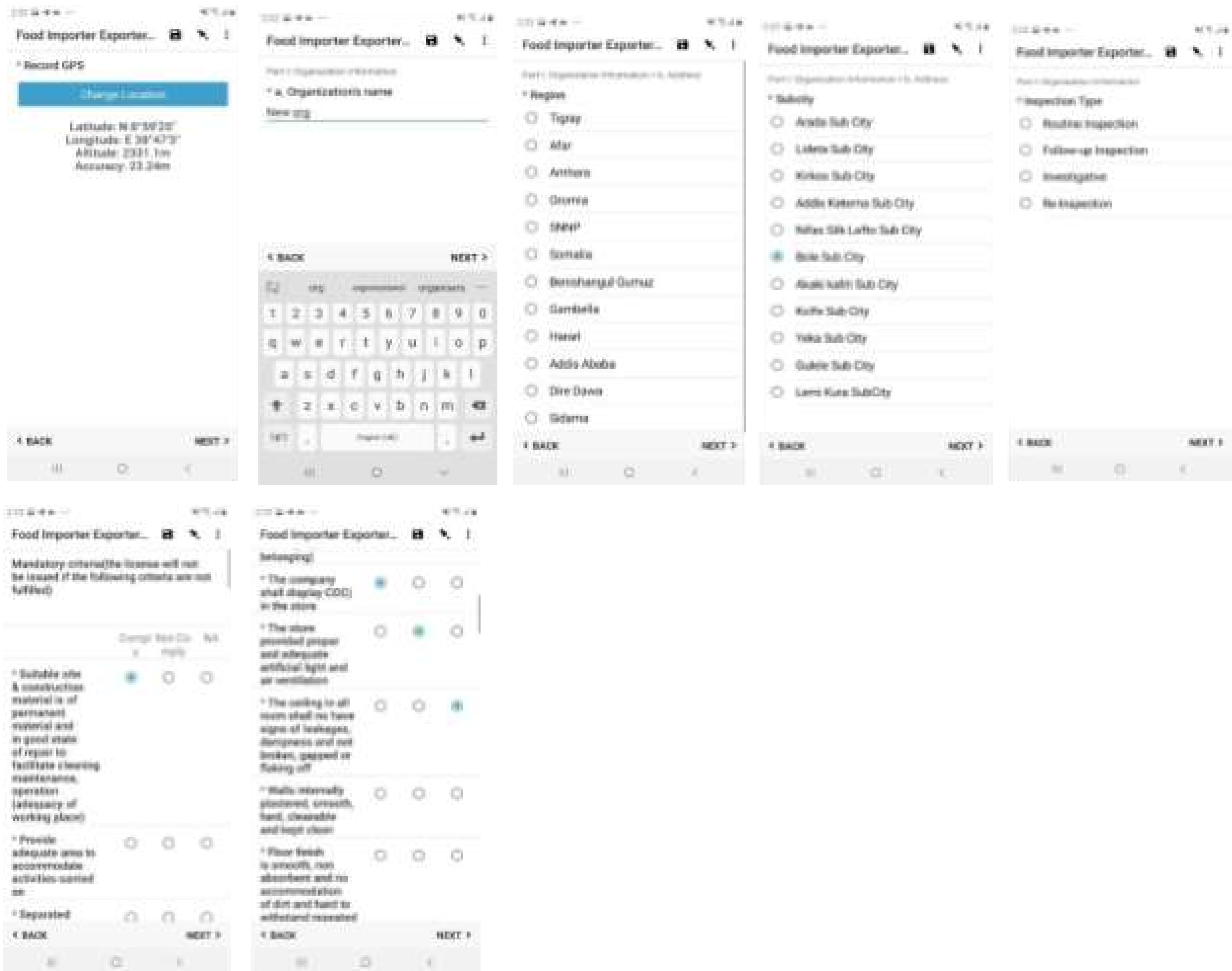


6. Scan the **QR code** to conduct inspection.

7. Fill in the **ODK form** for inspection using the ODK application on your mobile or tablet device.
   a. Click on the fill-in blank form and **search for the checklist needed**.
   b. After selecting the correct checklist, continue **filling out the form**.

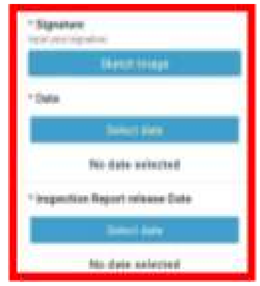




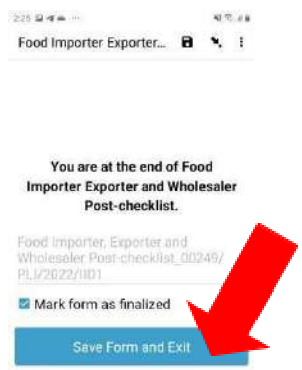


8. Submit **application** form:
    a. Note "comply" status: **"Comply" or "Not Comply"** (provide reason if it does not comply).
    b. **Confirm agreement by checking the box.**
    c. **Enter your details** (name, position, signature).

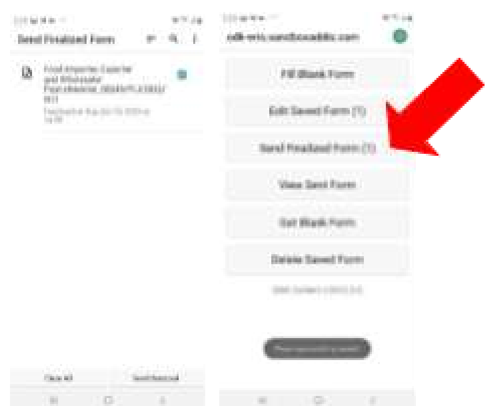
d. **Sign and date** the form.
e. **Enter the release date** of the Inspection Report.



f. Check the box **"Mark Form as Finalized"**.
g. Click **"Save Form and Exit"** when finished.



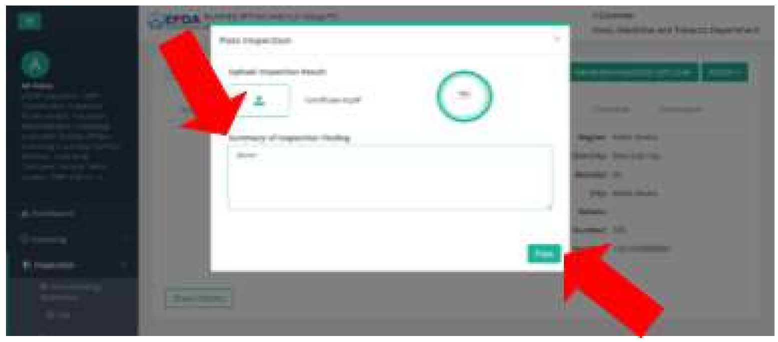
9. Send a **finalized form of the application to iInspect** after submitting the results of the inspection conducted via ODK.



10. Click on the **“Action” dropdown menu** and select:
    a. **Pass Inspection**
    b. **Fail Inspection**
    c. **Request for FIR**
    d. **Reject Inspection**

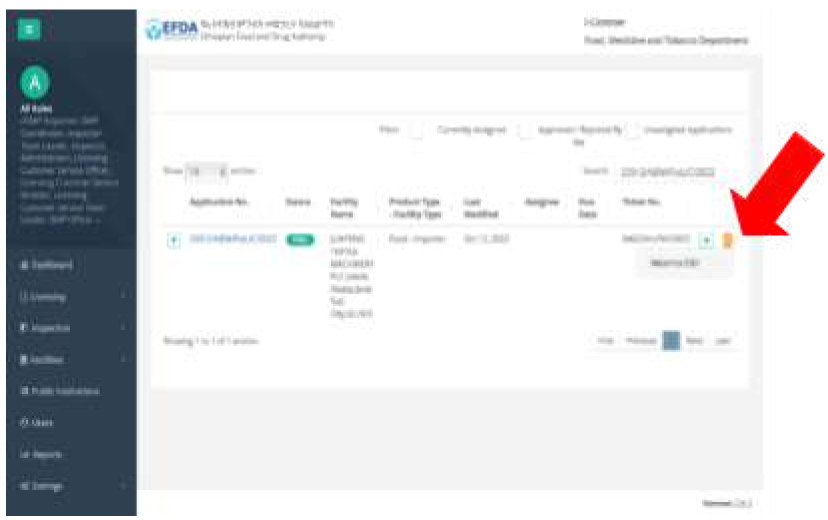
11. Enter a **summary of the inspection** findings.

12. Click the **“Pass” button**.



Note – Inspector can ‘Return to CSO’ if the document is not correct before conducting inspection by:

1. ***Select “Licensing”.***
2. ***Select “All Applications”.***
3. ***Search for the application number.***
4. ***Click on the corner icon.***
5. ***Click “Return to CSO."***

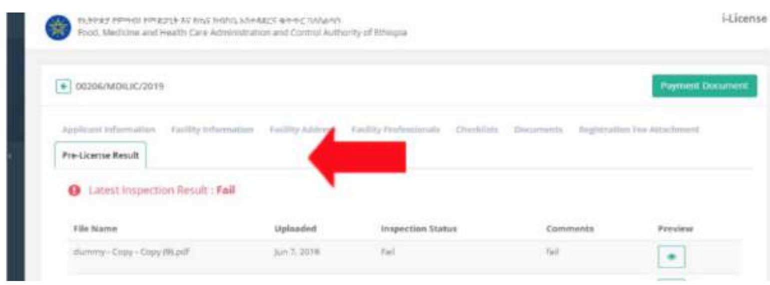


Attach Application Fee for Inspection

WHAT:	This is the process where applicants attach service fees for additional inspections.
WHEN:	After his/her inspection review has failed.
WHO:	Applicant

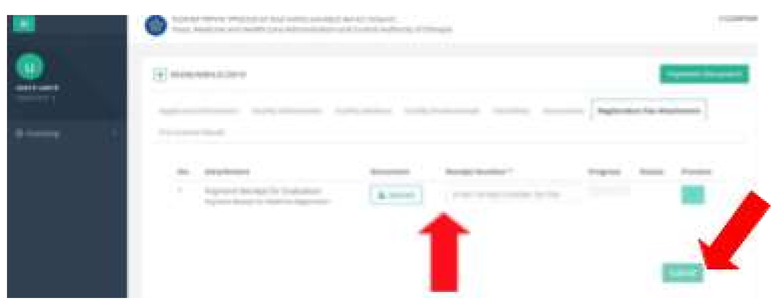
1. Click **“Licensing”.**
2. Find the application that is noted as **“Return to Applicant”**.
3. Click the **“eye” icon** to open the application.

4. Make necessary updates.
5. **Attach the receipt.**



6. **Type in the receipt number**
7. Click the **“Submit” button**.

Now your application status will be **“Fee Attached”.**

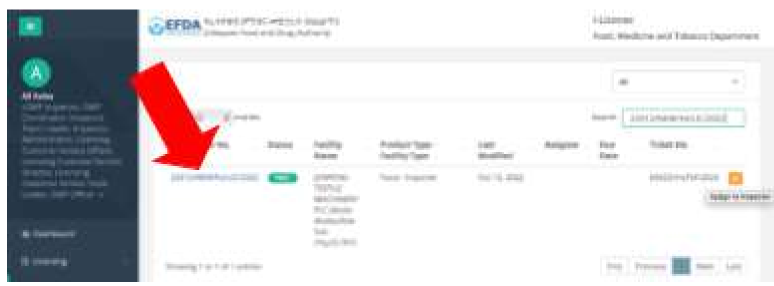


Submit Inspected Application for Approval

WHAT:	This process is where an application is: approved or returned.
WHEN:	Takes place after the Inspector passes an application.
WHO:	Inspection Team Leader

1. Select **"Inspection"** from the main menu.
2. Select **"Pre-inspection"**.
3. Select **"List"**.

4. Click on the **number of the desired application** to open it.



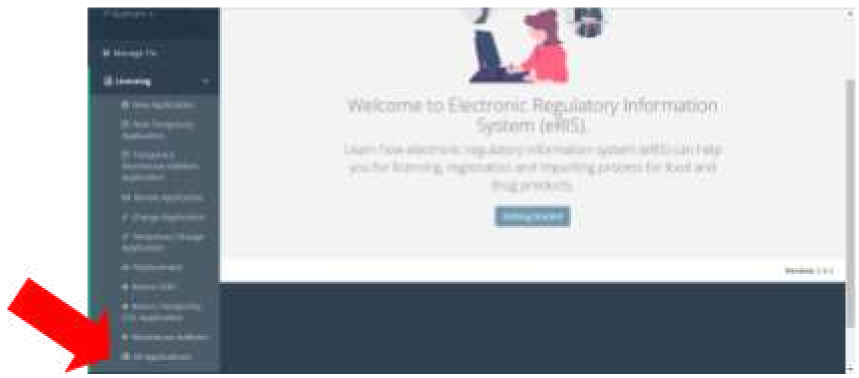
5. Click on the **"Action" dropdown menu** and select:
   a. **Submits for Approval**
   b. **Returns to Inspector**
   c. **Returns to CSO**

6. Add **comments for why** the action was taken in the provided pop-up box.

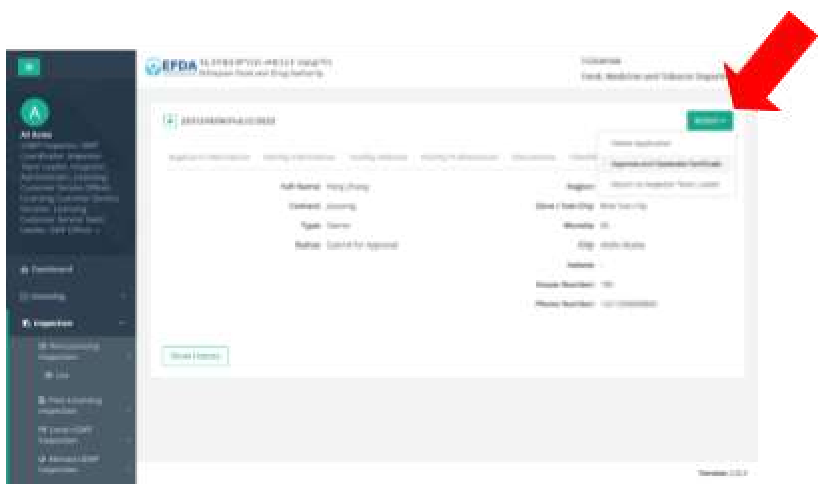
Approve or Disapprove Application

WHAT:	The process where the Director: (1) approves an application and generates a Certificate, or (2) disapproves an application and returns it to the Inspector Team Leader.
WHEN:	After the Inspector Team Leader passes an application.
WHO:	Director

1. Click on **"Licensing"** on the main menu.
2. Click on **"All applications"**.

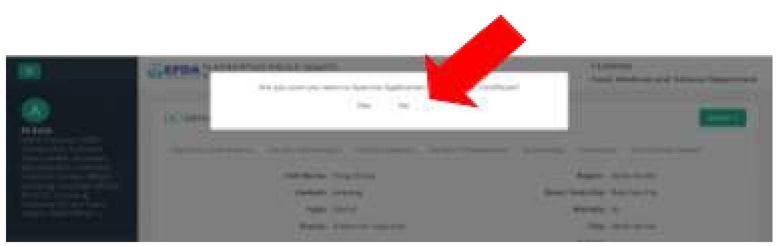


3. Find and open the **application**.
4. Click on the **"Action" dropdown menu**.
5. Select one of the following:
   a. **Delete Application**
   b. **Approve and Generate Certificate**
   c. **Return to Inspector Team Leader**



6. Click "**Yes" or "No"**.

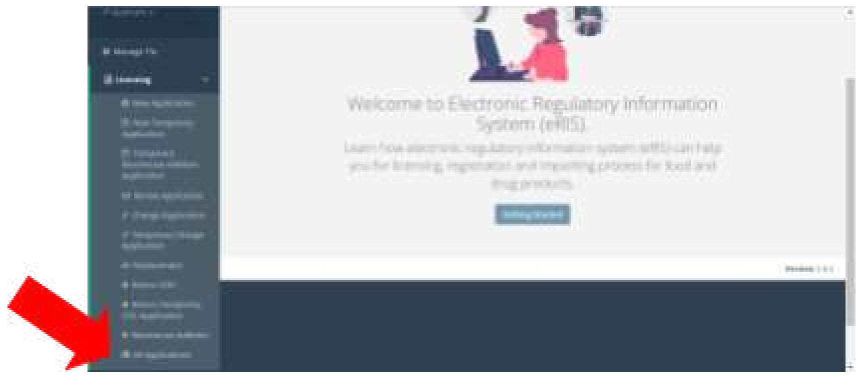
   If you click "Yes", this will generate a "Certificate of Competency".



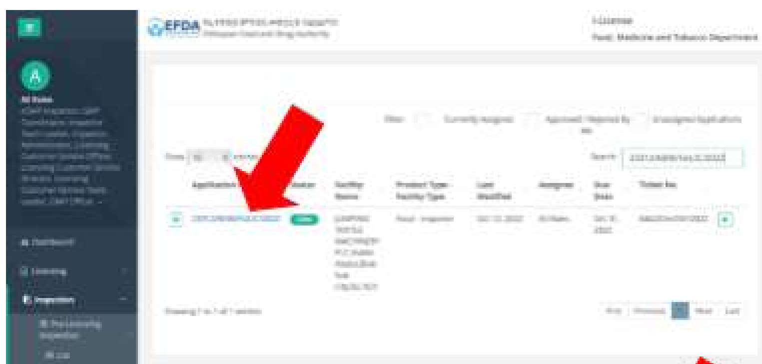
Preview COC

WHAT:	This is the process where the Director views the generated certificate.
WHEN:	After the Director approves an application.
WHO:	Director

1. Click on **“Licensing”**.
2. Click on **“All applications”**.



3. Find and open the **application**.



4. Click on the **“Preview Certificate” button**.

This will open the certificate.

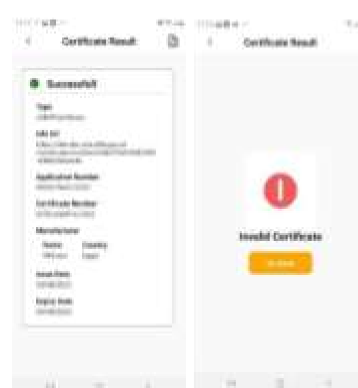
Scan QR Code for Verification

WHAT:	This is the process where the user views and verifies the generated certificate.
WHEN:	After the Certificate has been generated.
WHO:	Applicant, CSO Team Leader, CSO, Inspector Team Leader, Inspector, Director

NOTE – To complete this process, you must have iVerify downloaded on your mobile phone. You can download iVerify from the Google Play Store for the Android version (an iOS version is under development) in English and/or Amharic: https://play.google.com/store/apps/details?id=com.eris.iverify

1. **Open iVerify** and access the application.
2. Click the **“Verify Document” button**.
3. **Scan the QR code** (generated by eRIS) that is displayed on the Certificate.

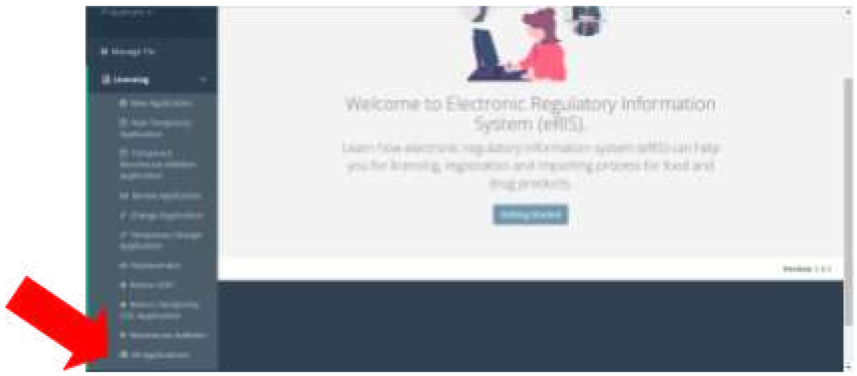
4. Compare the data displayed by the **QR code scan**:
    a. ***If the document is legal*** then the data matches the QR scan and iVerify displays **“Successful”**.
    b. ***If the document is illegal/fake*** then the data does not match and iVerify displays “**Invalid Certificate”**.



Suspend, Cancel, or Void Local GMP

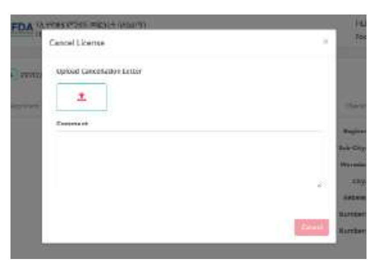
WHAT:	This is the process where the Director Suspends, Cancels, or Voids a COC.
WHEN:	After the COC has been issued.
WHO:	Director

1. Click on **“Licensing”**.
2. Click on **“All applications”**.



3. Find and open the **application**.
4. Click on the **“Action” button**.

5. Select one of the 3 actions:
   a. “Cancel”
      i. Select **“Cancel”** from the dropdown menu.
      ii. Upload the **Suspension Letter**.
      iii. Add any relevant **comments**.
      iv. Click the **“Cancel” button**.



b. “Void”

i. Select ***“Void”*** from the dropdown menu.
ii. Add any relevant ***comments***.
iii. Click the ***“Void Certificate” button***.

c. “Suspend License”

i. Select ***“Suspend License”*** from the dropdown menu.
ii. Upload the **“Suspension Letter”.**
iii. Add any relevant ***comments***.
iv. Click the ***“Suspend” button***.

Request a License Renewal

WHAT:	This process is used to submit renewal request applications for a COC.
WHEN:	Whenever applicants want to renew a COC.
WHO:	Applicant

1. Click on **"Licensing".**
2. Click on **"Renewal Application".**

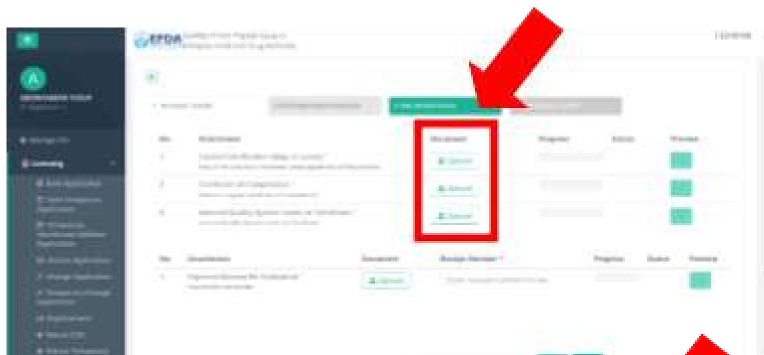
3. *Under the "Renewal Details" tab,* select the Facility Name from the **"Facility Name" dropdown menu**.

4. Click on the **"Next" button** after selecting the correct facility.

5. *Under the “Self Inspection Checklist” tab,* complete the **checklist** by selecting **“Yes”** or **“No”** or **“Not Applicable”** for each item.

6. Click the **“Next” button** when finished with the checklist.

7. *Under the “File Attachments” tab,* click on the **“Upload” button** to upload any necessary attachments.



8. A **checkmark** will display when the attachment is successfully uploaded.

9. Click the **“Next” button** when finished uploading attachments.

10. *Under the “Declaration Letter” tab,* **check the box** next to *“I agree with the Declaration above”*.

11. Click the **“Submit” button** to submit the license application.

12. When the application is successfully submitted, you will see the message: ***“Application submitted successfully”.***

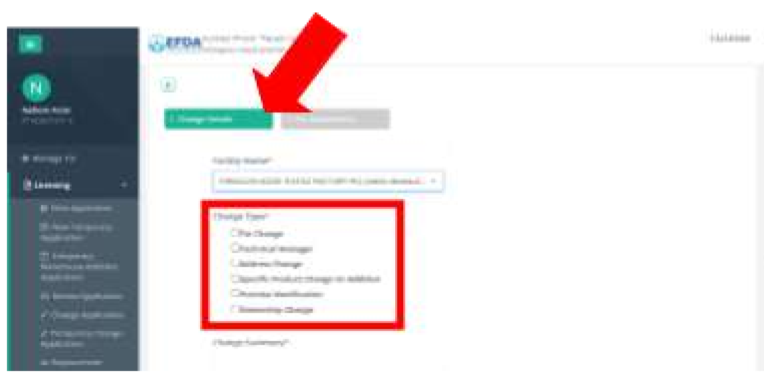
Request a License Change

WHAT:	This process is used to submit change request applications online in order to apply changes to a COC.
WHEN:	Whenever the applicant wants to change their COC.
WHO:	Applicant

1. Click on **“Licensing”.**
2. Click on **“Change Application”.**

3. *Under the “Chance Details” tab,* select the Facility Name from the “Facility Name” dropdown menu.
4. Click the **“Save” button**.

5. **Check the box** next to the change type to be applied:
   a. **Tin change**
   b. **Technical Manager**
   c. **Address Change**
   d. **Specific Product Change or Addition**
   e. **Permission Modification**
   f. **Ownership change**



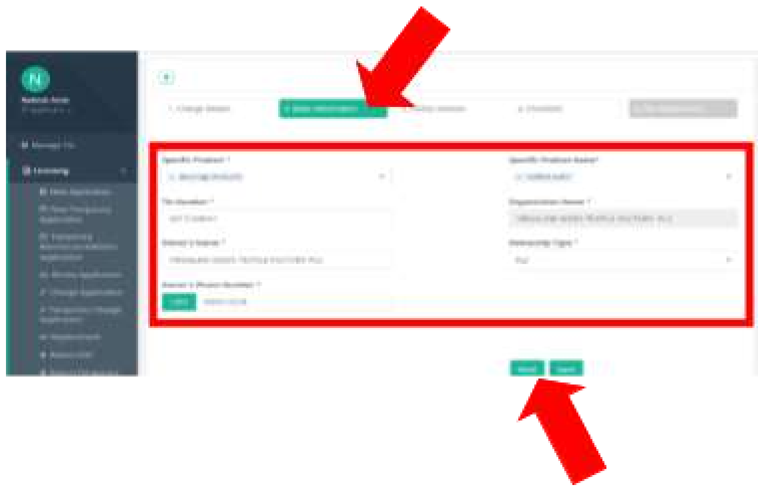
6. Enter a summary of changes in the **"Change Summary" text box**.

7. Click the **"Save" button** when finished.

As applicable, make the edits to:

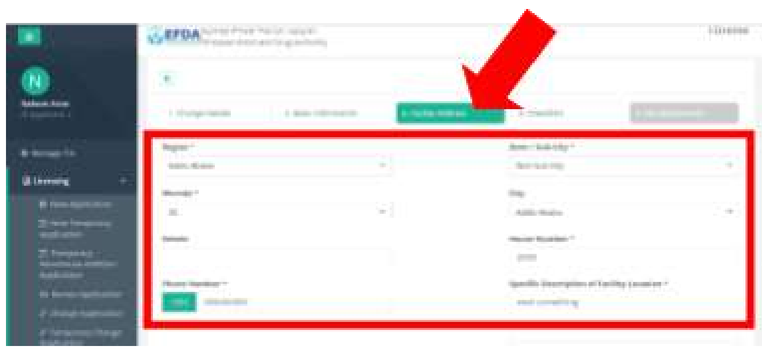
8. *Under the "Basic Information" tab,* edit data pertaining to: **Specific Product, TIN Number, Owner's Name, Owner's Phone Number, Specific Product Items, Organization Name, Ownership Type.**

9. Click the **"Next" button** when finished.



10. *Under the "Facility Address" tab,* edit data pertaining to: **Region, Woreda, Kebele, Phone Number, Zone/Sub-City, City, House Number, Location Description**.

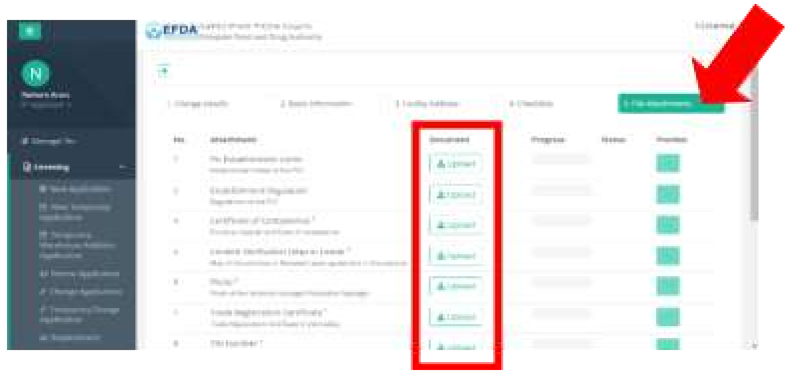
11. Click the **"Next" button** when finished.



12. *Under the "Checklists" tab,* respond **"Yes", "No", or "NA"** to each checklist item.

13. Click the **“Next” button** when finished.

14. *Under the “File Attachments” tab,* upload any necessary **attachments**.

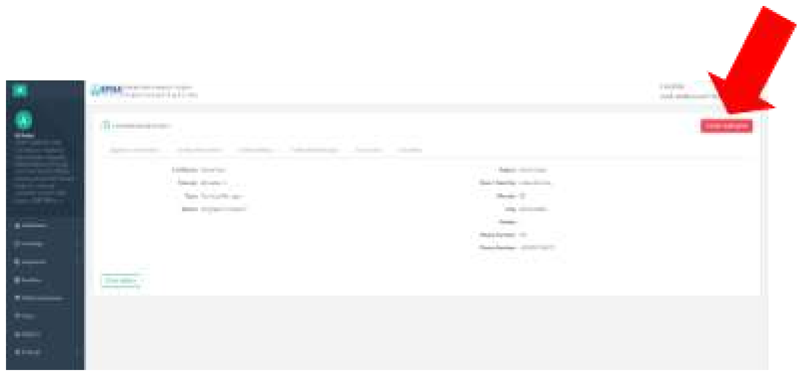


15. Click on the **“Submit” button** to submit your application for the change made.

List of Deleted Applications

WHAT:	This process is used to delete an application.
WHEN:	Whenever a user wants to delete an application.
WHO:	Director, Team Leader

1. **Find the application** you want to delete.
2. Click on the **"Delete" button.**



3. Type any required comments about the deletion into the **"Comment" text box**.
4. Click the **"Delete Application" button.**

LICENSE REPLACEMENT & RETURN

Request a License Replacement

WHAT:	This process is used to submit replacement requests for a COC.
WHEN:	Whenever a COC replacement is needed.
WHO:	Applicant

1. Click on **“Licensing”.**

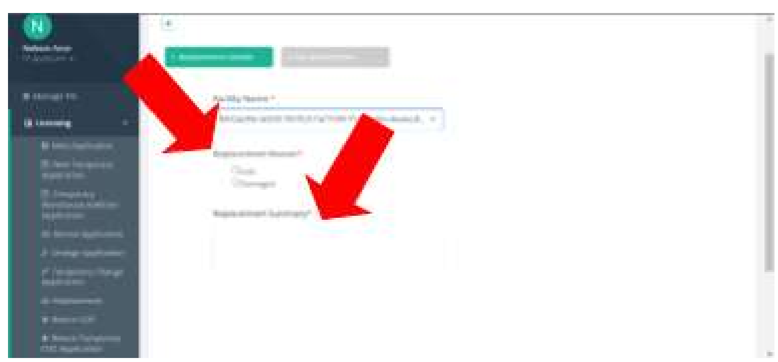
2. Click on **“Replacement”.**

3. *Under the “Replacement Details” tab,* type the facility name into the **“Facility Name” text box**.

   Find **your facility**.

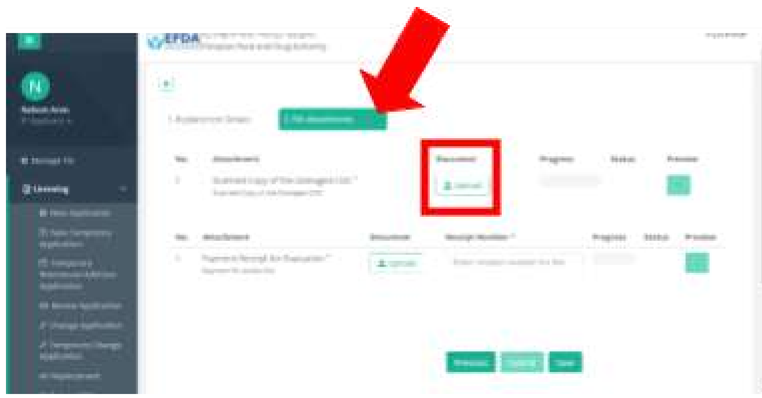
4. Select the **reason for replacement**: “Lost” or “Damaged”.

5. Type a short summary into the **Replacement Summary” text box**.

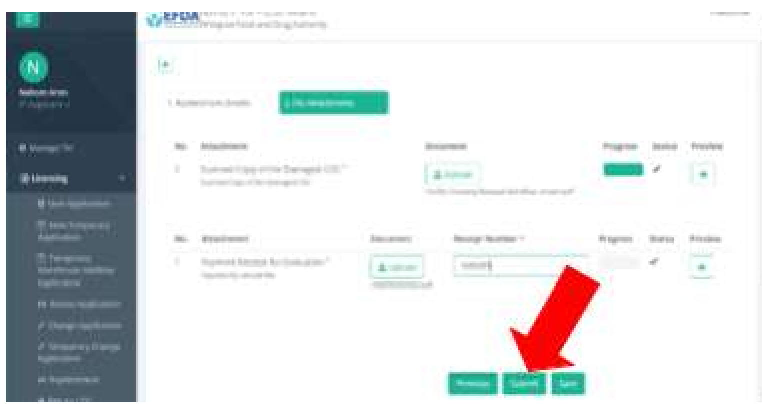


6. Click on the **“Next” button**.

7. *Under the “File Attachments” tab,* upload any **required documentation**.



8. Click on the **“Submit” button** to submit your request for a replacement



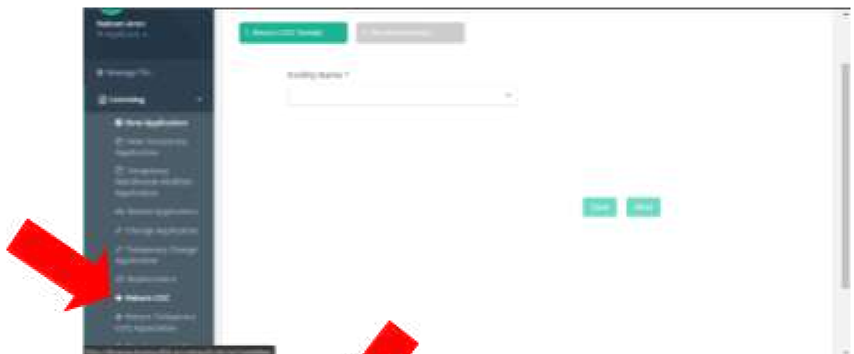
Request a License Return

WHAT: This process is used to submit a COC return request.

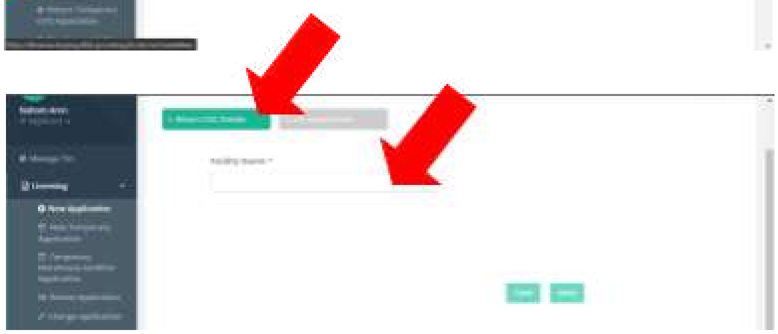
WHEN: Whenever an applicant needs to return a COC.

WHO: Applicant

1. Click on **“Licensing”.**
2. Click on **“Return COC”.**

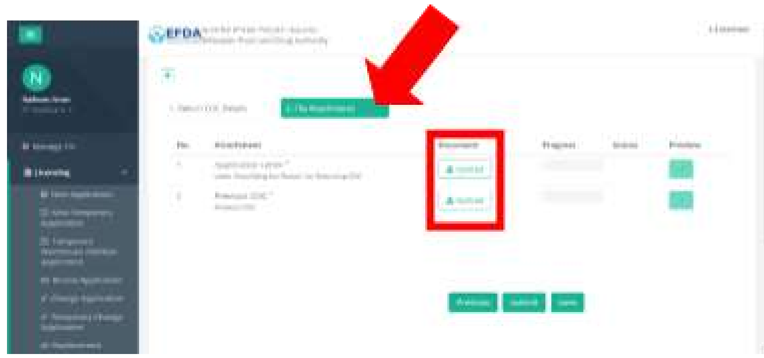


3. *Under the “Return COC Details” tab,* type the facility name you are looking for into the **“Facility Name” text box**.



4. Type a reason for the return into the **“Reason for Return COC” text box**.
5. Click the **“Next” button.**

6. *Under the "File Attachments" tab,* attach any necessary attachments using the **"Upload" button**.



7. Click on the **"Submit" button** to request for a return *COC.*

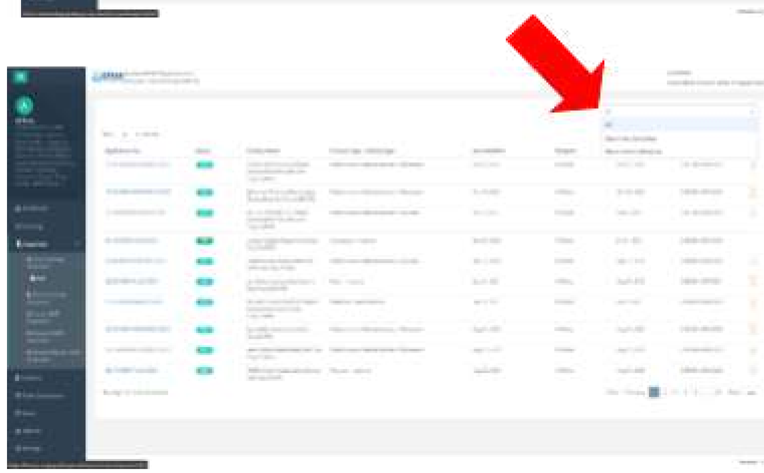
QUARANTINE APPLICATION

Undo a Quarantined Application

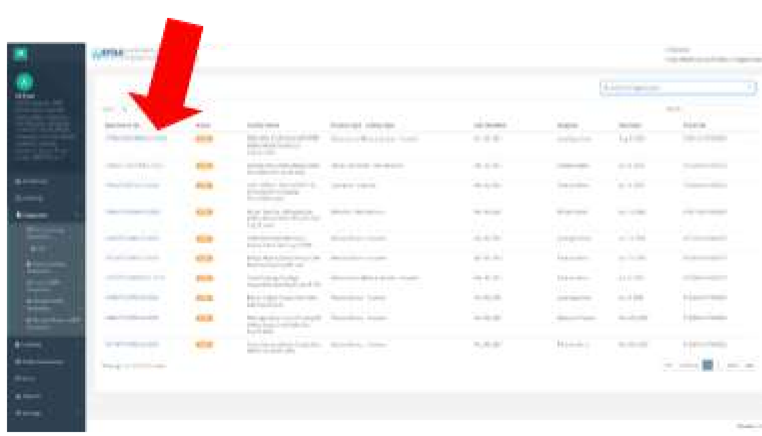
WHAT:	This process is used to undo an application quarantine.
WHEN:	At any point in the application process.
WHO:	Team Leader, Director

1. Click on **"Inspection".**
2. Click on **"Pre-Licensing Inspection".**

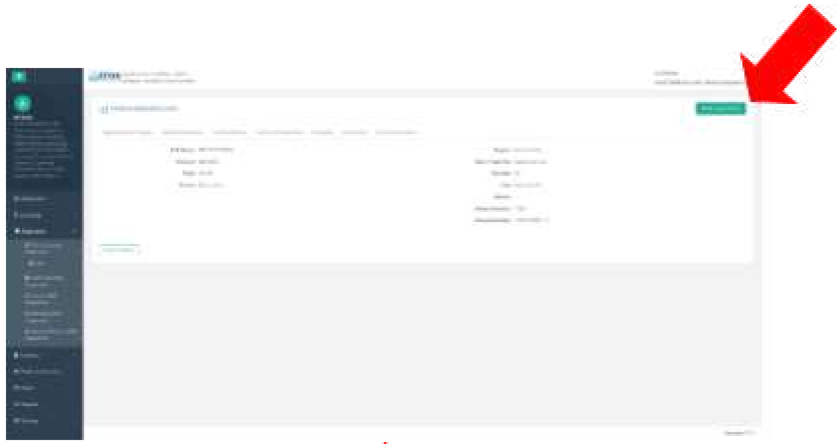
3. Click on the filter dropdown menu to filter for **"Quarantine Applications"**.



4. Click on the **quarantined application** you are looking for.



5. Click on the **"Undo Quarantine" button** to undo a quarantine application.



6. Type the reason for undoing a quarantine into the **"Undo Quarantine" text box**.

7. Click on the **"Undo Quarantine" button**.

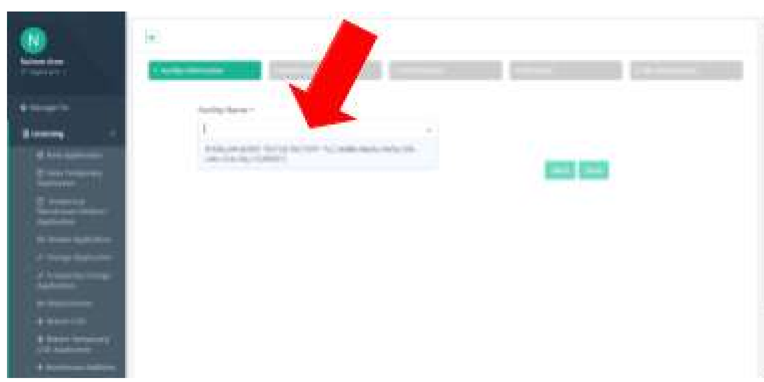
FACILITY MANAGEMENT

License Warehouse Addition Request Process

WHAT:	This process is used when an applicant requests warehouse addition on an existing COC application.
WHEN:	Whenever an applicant needs to add a warehouse.
WHO:	Applicant

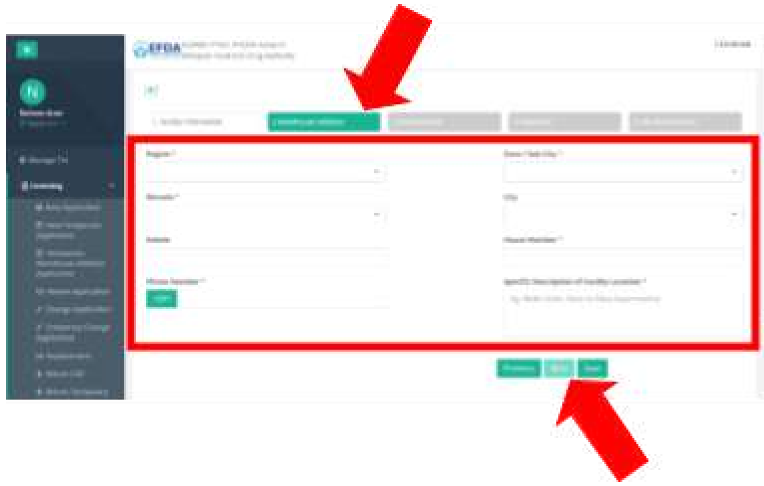
1. Click on **"Licensing".**
2. Click on **"Warehouse Addition".**

3. *Under the "Facility Information" tab,* type the facility name you are looking for into the **"Facility Name" text box** and select it from the dropdown menu.



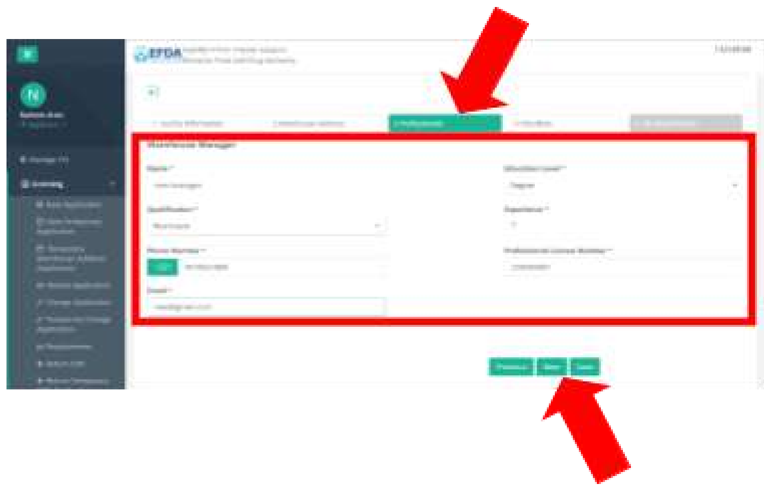
4. Click the **"Next" button**.

5. *Under the "Warehouse Address" tab,* enter **address information**:
    a. **Region**
    b. **Woreda**
    c. **Kebele**
    d. **Phone Number**
    e. **Zone/Sub-City**
    f. **City**
    g. **House Number**
    h. **Any specific location details**



6. Click on the **"Next" button** to continue.

7. *Under the "Professionals" tab,* enter data about the **Warehouse Manager**:
    a. **Name**
    b. **Qualification**
    c. **Phone Number**
    d. **Email**
    e. **Education Level**
    f. **Experience**
    g. **Professional License Number**

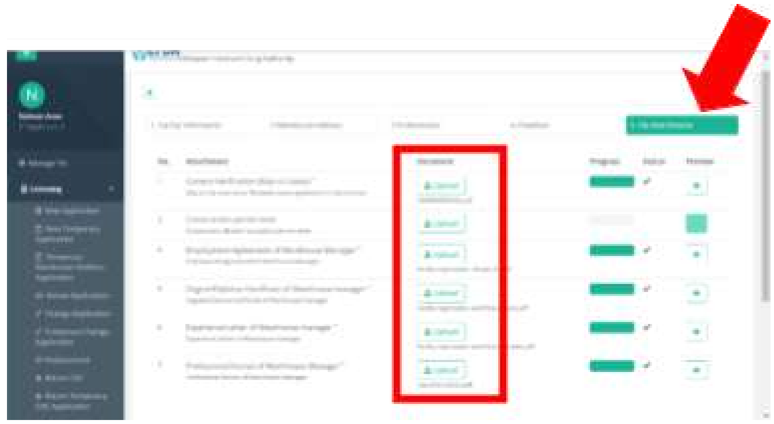


8. Click on the **"Next" button** to continue.

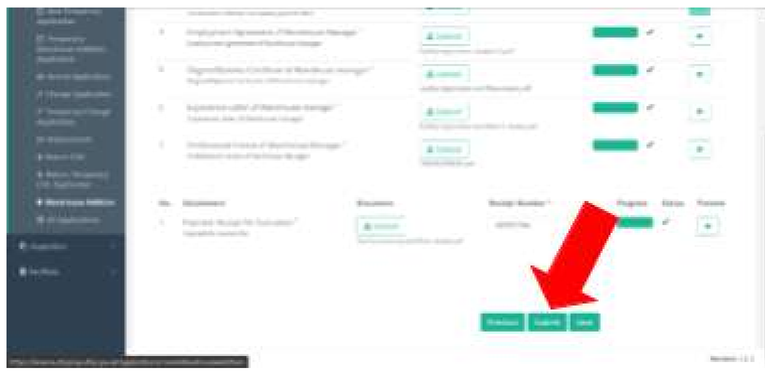
9. *Under the "Checklists" tab,* answer **"Yes" or "No" or "N/A"** for each checklist item.

10. Click on the **"Next" button** to continue.

11. *Under the "File Attachments" tab,* click the **"Upload" button** to upload any necessary documents.



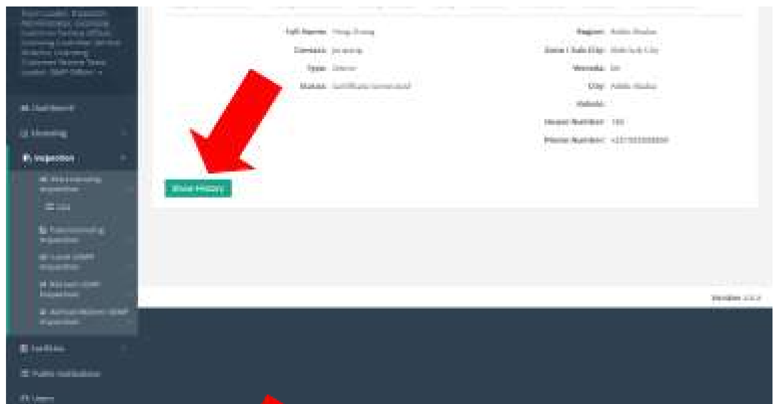
12. Click the **"Submit" button** when finished to submit this new information.



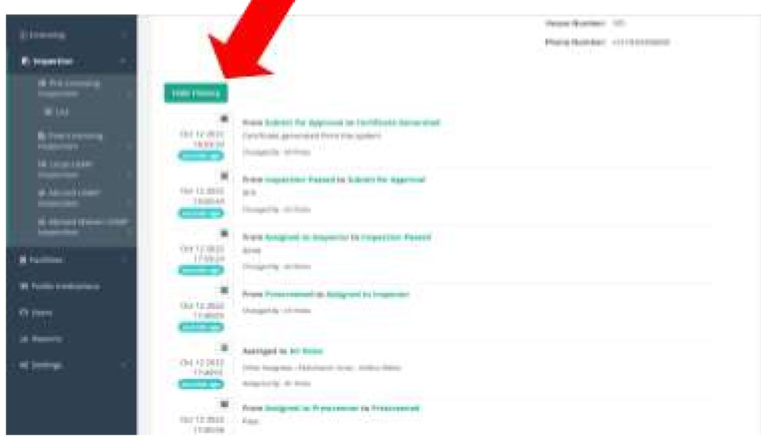
View Facility History

WHAT:	This is the process where the user views the facility history.
WHEN:	Whenever needed.
WHO:	Applicant, CSO Team Leader, CSO, Inspector Team Leader, Inspector, Director

1. Find and select the application.
2. Click the "**Show History" button**.
3. View **history** of the application.



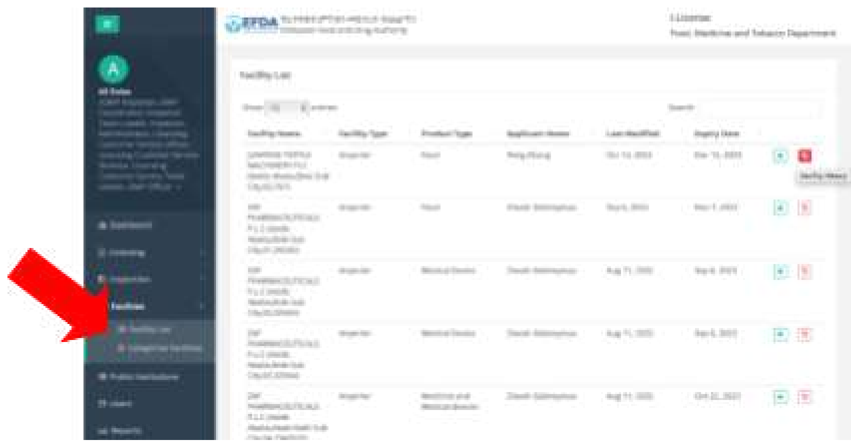
4. When finished, click the **"Hide History" button** to collapse the data and hide the history.



View List of Facilities (Internal)

WHAT:	This is the process where the user views the facility list.
WHEN:	Whenever needed.
WHO:	CSO Team Leader, CSO, Inspector Team Leader, Inspector, Director

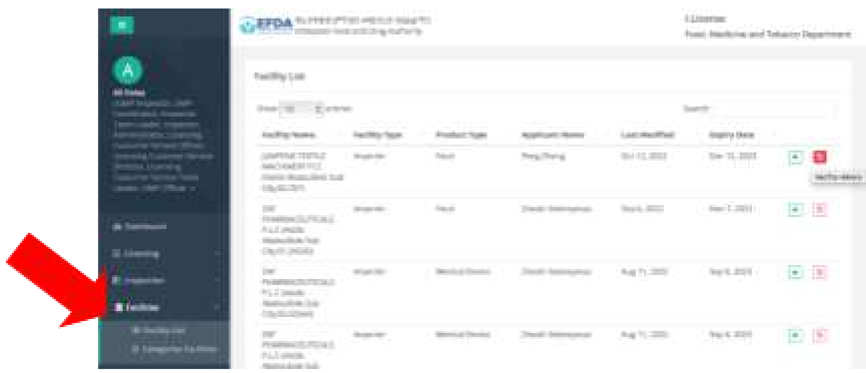
1. Click on **“Facility”**.
2. Click on **“Facility List”**.



Categorize Facilities

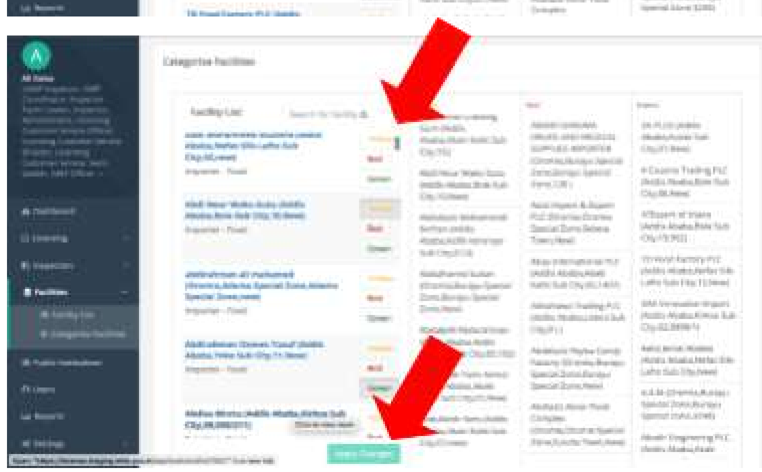
WHAT:	This is the process where the user categorizes a facility.
WHEN:	Whenever needed.
WHO:	CSO Team Leader, CSO, Inspector Team Leader, Inspector, Director

1. Click on **"Facility"**.
2. Click on **"Facility List"**.



3. **Find the facility** that needs to be categorized (you can search for it using the "Search for Facility" text box).

4. Click on either:
   a. **Green**
   b. **Yellow**
   c. **Red**
5. Click the **"Apply Change" button**.



View Public Institutions

WHAT:	This is the process where the user views Public Institutions.
WHEN:	Whenever needed.
WHO:	CSO Team Leader, CSO, Inspector Team Leader, Inspector, Director

1. Click on **“Public Institution”.**
2. View the list of public inspections.

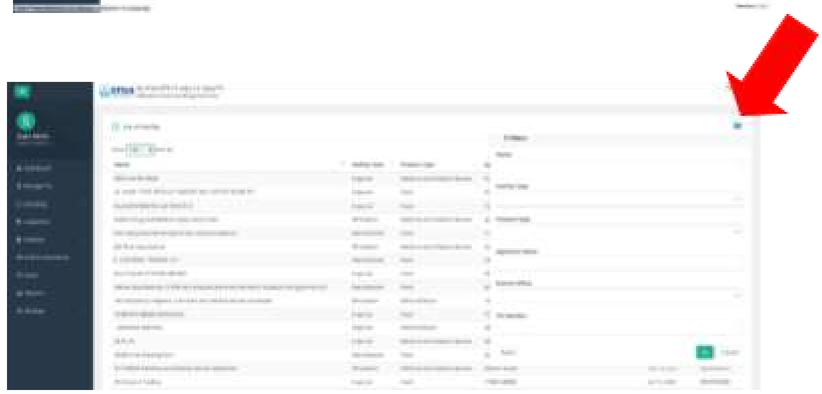
REPORTING & DASHBOARDS

List of Reports

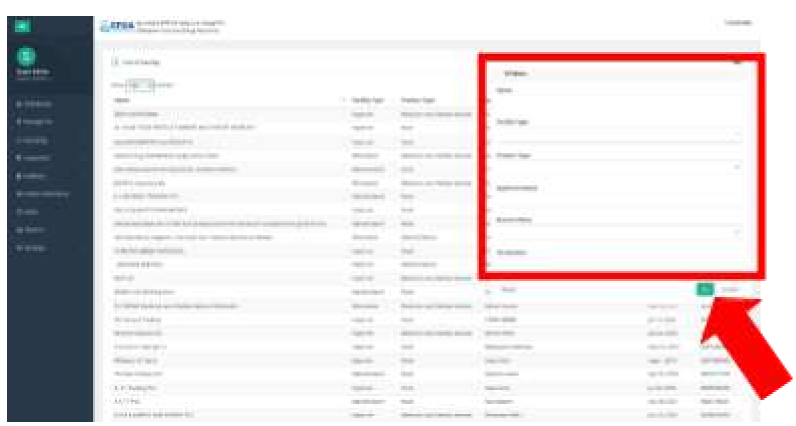
WHAT:	This process is used when a user wants to view the list of reports.
WHEN:	Any time data is needed.
WHO:	Administrator, Team Leader, Director

1. Click on **“Reports”.**
2. Click on the **report** you want to access for use.

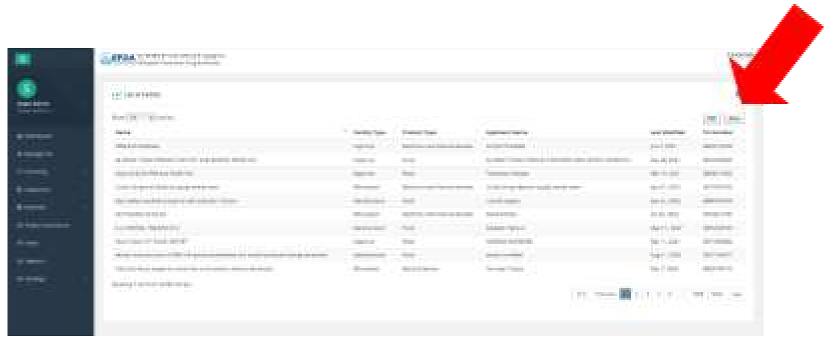
3. Click on the **icon on the top right** to filter for the specific data /report you need.



4. Fill in the **filter data fields** to create the report you need.
5. Click the **“Go” button** to query this specific report.



6. Click on the **PDF and/or Excel button** to download the report in whichever (or both) formats you need.

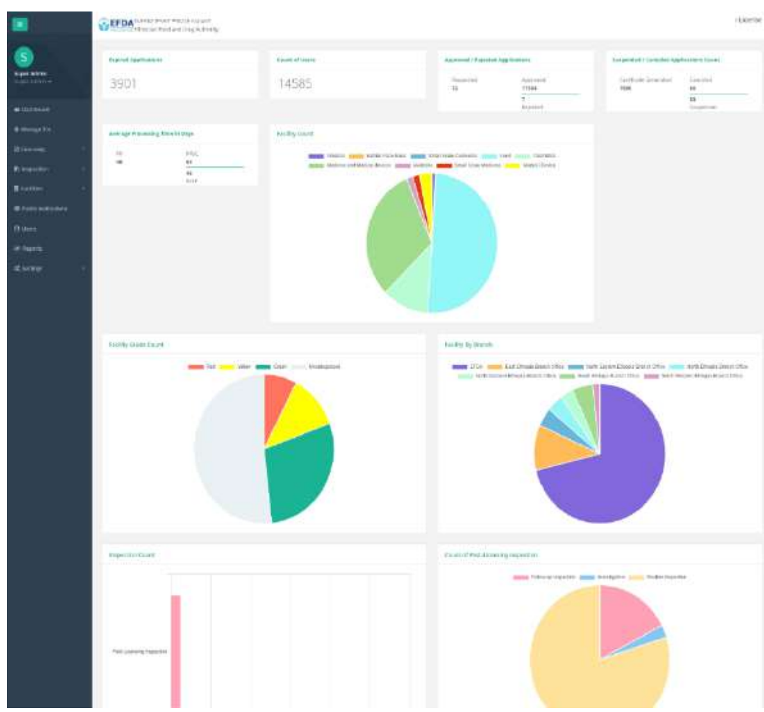


Dashboard

WHAT:	This process is used when a user wants to view dashboard reports.
WHEN:	Anytime dashboard data is needed.
WHO:	Administrator, Team Leader, Director

1. Click on **"Dashboard".**

2. Review the data as displayed on the Dashboard screen.



TOOL MANAGEMENT

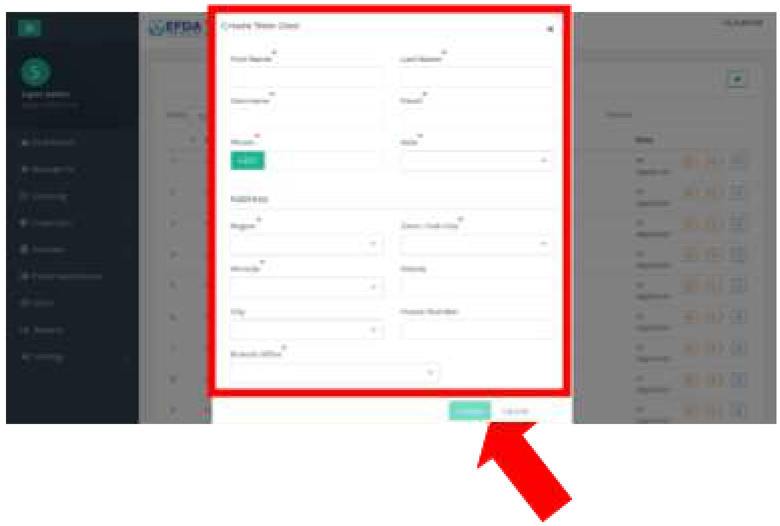
Create New User

WHAT:	This process is used to create new internal and external accounts for eRIS users.
WHEN:	When a new account is needed.
WHO:	Administrator

1. Click on **“Users”.**

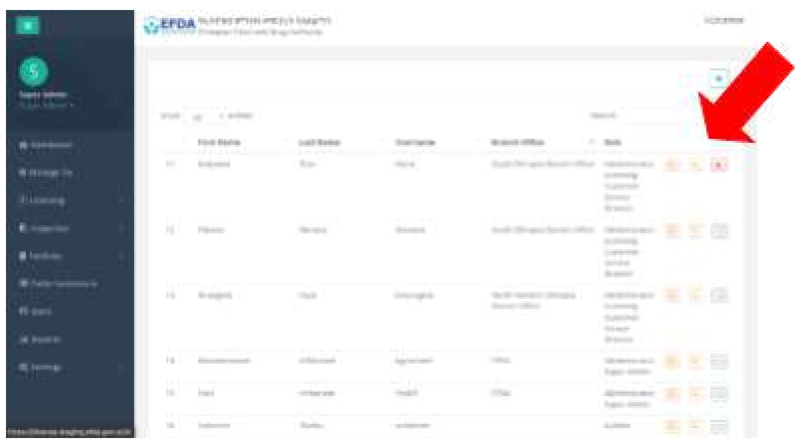
2. Click the **“+” icon**.

3. Enter information for the **new user** application:
    a. **First name**
    b. **Last name**
    c. **Username**
    d. **Email**
    e. **Phone**
    f. **Role (select form the dropdown)**
    g. **Address - Region**
    h. **Address - Zone / Sub-City**
    i. **Address - Woreda**
    j. **Address - Kebele**
    k. **Address - City**
    l. **Address - House Number**
    m. **Address - Branch Office**



4. Click the **"Create" button**.

5. Click on the **"Activation" icon** to activate a user account.

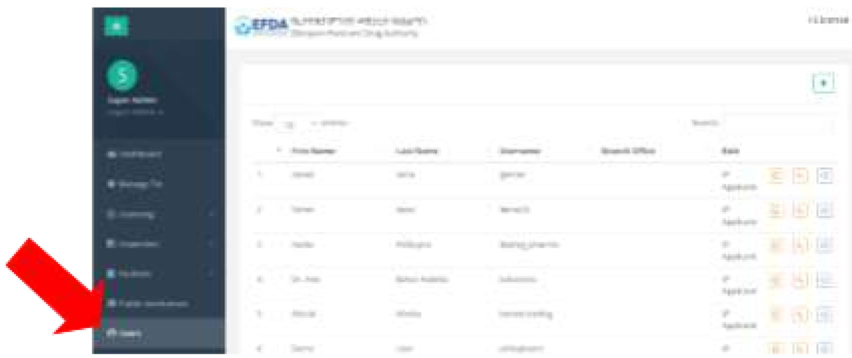


6. Click the **"Yes" button** when asked *"Are you sure you want to activate this user?"*

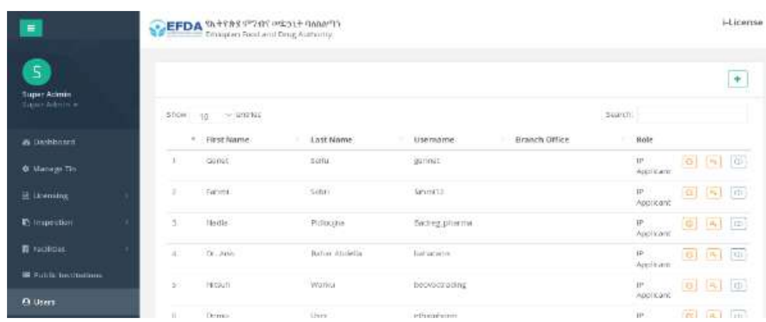
Deactivate User

WHAT:	This process is used to deactivate an internal and/or external account of an eRIS user.
WHEN:	Whenever needed.
WHO:	Administrator

1. Click on **“Users”.**



2. **Find the user** you need to deactivate.



3. Click on the “**Deactivation” icon** to deactivate a user account.

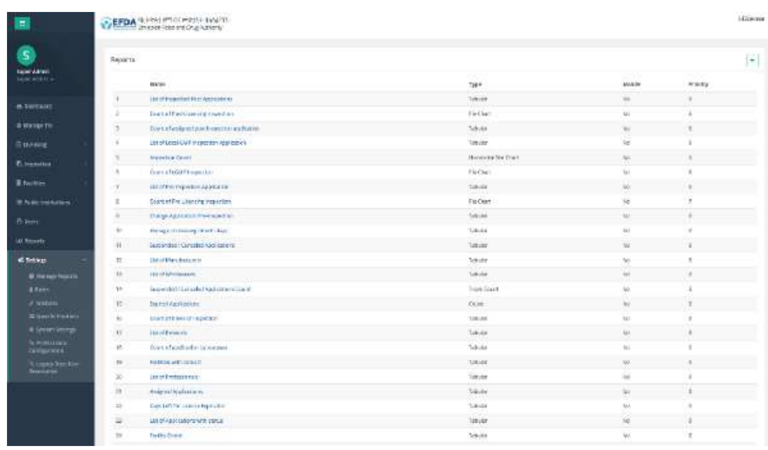
4. Click the **“Yes” button** when asked for *“Are you sure you want to deactivate this user?”*

Edit User Access Settings

WHAT:	This process is used when a user wants to access settings.
WHEN:	Whenever settings need to be viewed/edited.
WHO:	Administrator

1. Click **"Settings".**

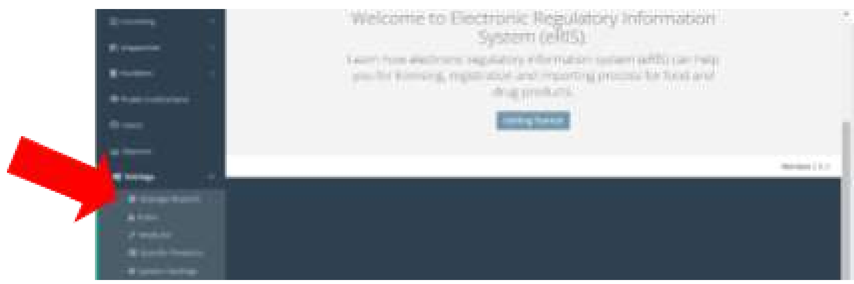
2. Select the type of setting you need:
   a. **Manage report**
   b. **Roles**
   c. **Module**
   d. **Specific Production**
   e. **System Settings**
   f. **Professional Configuration**
   g. **Legacy Data User Association**



Create a New Report Module

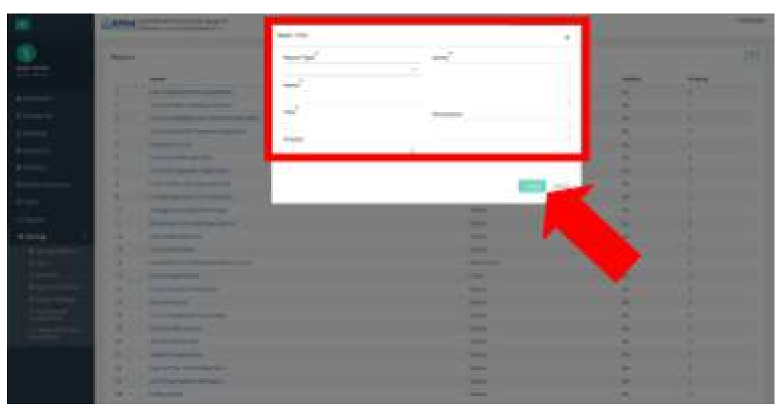
WHAT:	This process is used to create a report.
WHEN:	Whenever you need to create a report.
WHO:	Administrator

1. Click on **"Settings".**
2. Click on **"Manage Report".**



3. Click on the **"+" icon**.

4. Enter **basic information** for the new report:
   a. **Report Type**
   b. **Query**
   c. **Name**
   d. **Title**
   e. **Description**
   f. **Priority**



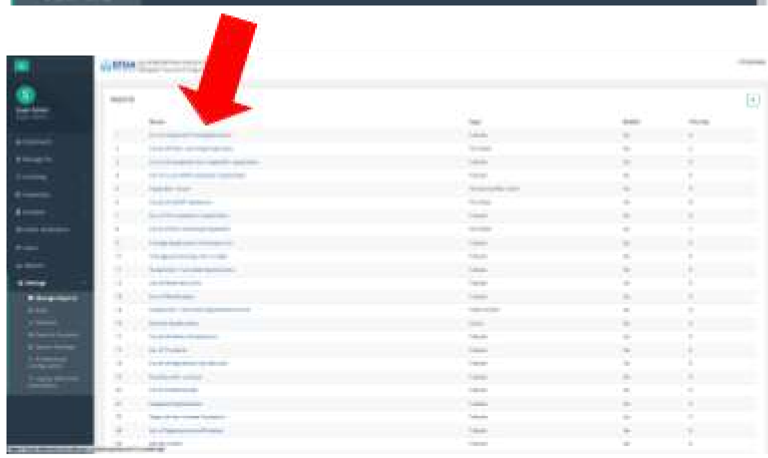
5. Click on the **"Update" button** after filling in all fields.

Edit Report Module

WHAT:	This process is used to edit a report module.
WHEN:	Whenever an edit is needed.
WHO:	Administrator

1. Click on **“Settings”.**
2. Click on **“Manage Report”.**

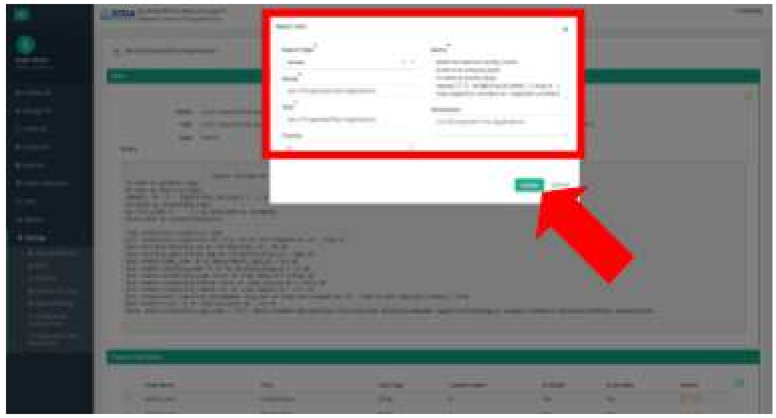
3. Click on the **report** that you want to edit.



4. Click on the **“Edit” icon**.

5. Edit the report's **"Basic Information"** as needed.

6. Click on the **"Update" button** to submit the edited information.

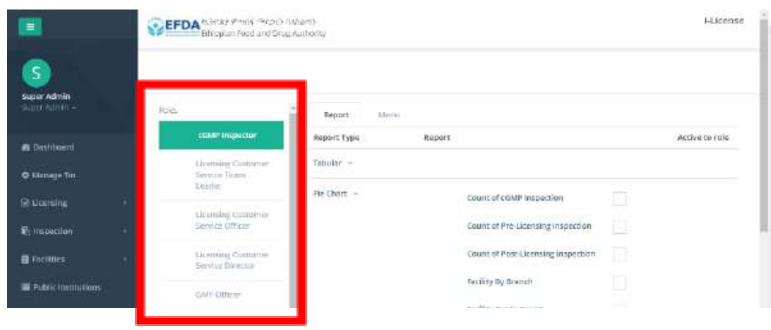


Edit Report Access for Roles

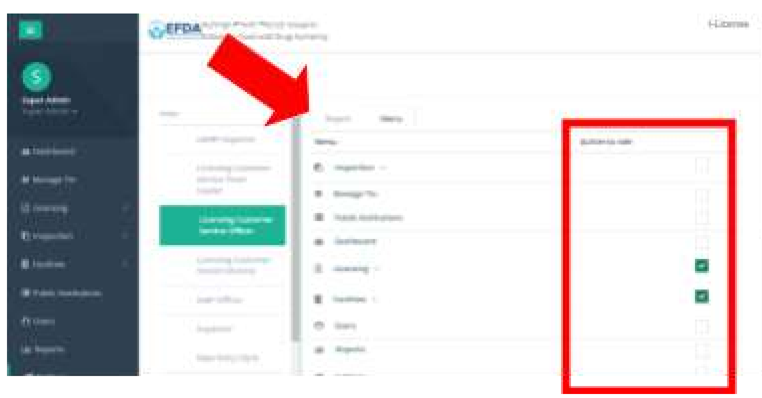
WHAT:	This process is used to edit report access for a report.
WHEN:	Whenever an edit is needed.
WHO:	Administrator

7. Click on **"Settings".**
8. Click on **"Roles".**

9. Select the **type of role** you want to edit.



10. Under the **"Report" and/or "Menu" tab**:
    a. ***Activate:*** click the box next to whichever report or menu this role CAN have access to.
    b. ***DE-activate:*** UN-check the box next to whichever report or menu this role CANNOT have access to.



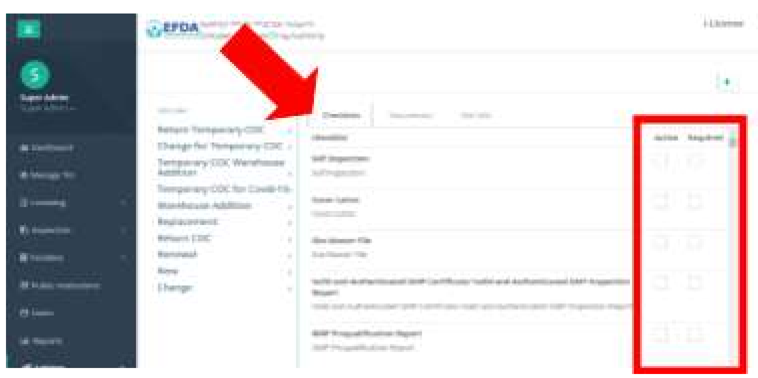
Modules

WHAT:	This process is used to edit a module.
WHEN:	Whenever an edit is needed.
WHO:	Administrator

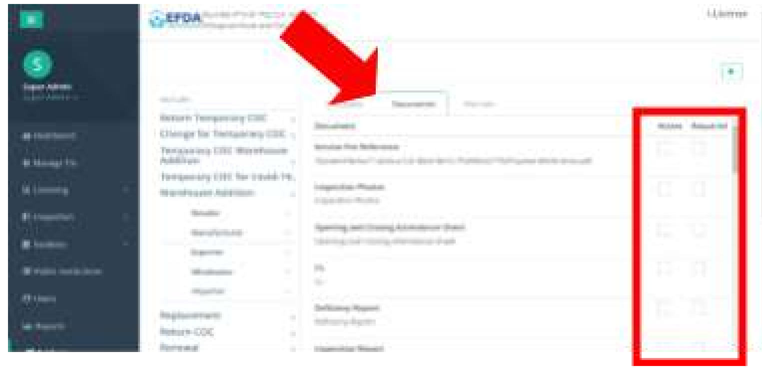
1. Click on the **"Settings".**
2. Click on the **"Module".**

3. Select the **"Module Category"** you want to edit.

4. *Under the "Checklists" tab,* check the **"Checklist Type"** that should be:
   a. **Active, and/or**
   b. **Required**



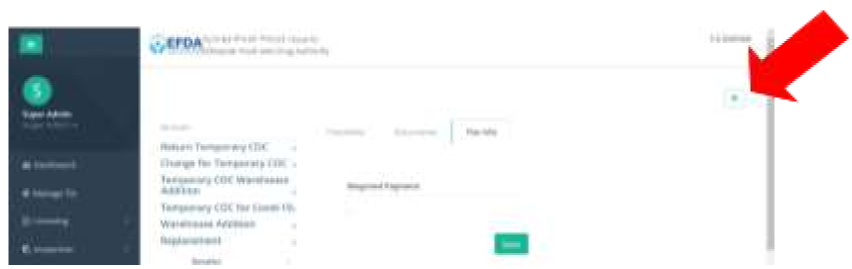
5. *Under the "Documents" tab,* check the **"Document Type"** that should be:
    a. **Active, and/or**
    b. **Required**



6. *Under the "Free Info" tab,* complete:
    a. **Required Payment**
    b. **Outside Addis Ababa**

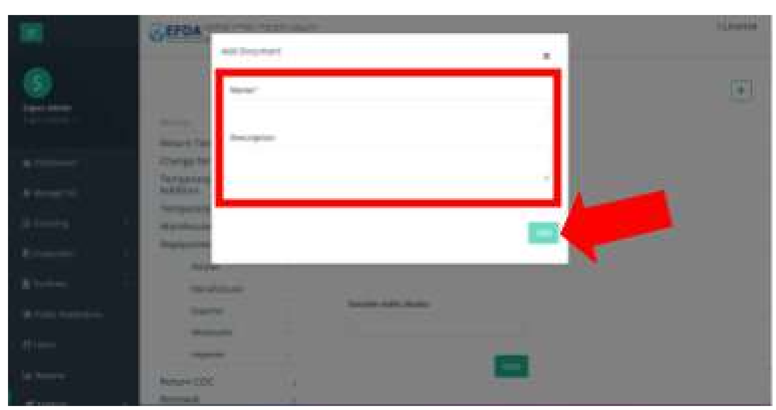
7. Click the **"Save" button** for each**.**

8. *As needed,* click on the **"+" icon** to add any additional documents that are required.



9. Enter:
    a. **Name**
    b. **Description**

10. Click the **"Add" button**.

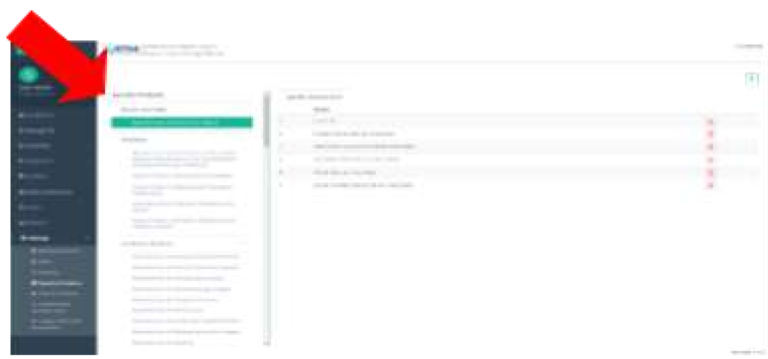


Add Product

WHAT:	This process is used to edit a specific product.
WHEN:	Whenever an edit is required.
WHO:	Administrator

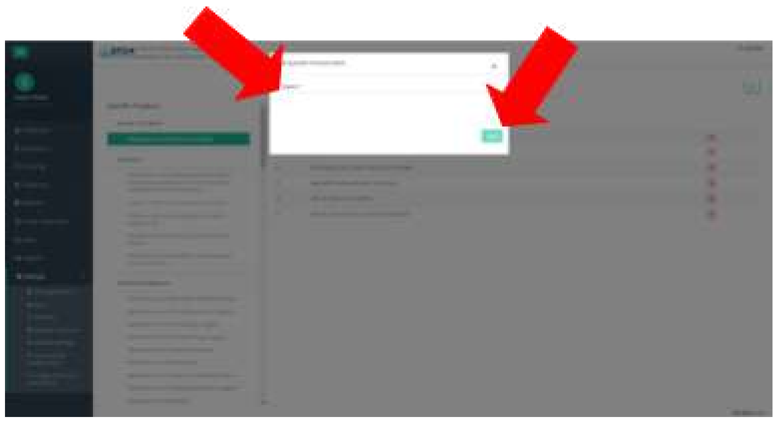
1. Click on the **“Settings”.**
2. Click on **“Specific Products”.**

3. Click on the **“Specific Product” category** to find the correct category for the new product to be assigned to.



4. Click on the **“+” icon**.

5. Enter the **name of the specific product**.



6. **Click the “Add” button.**

Edit System Settings

WHAT:	This process is used to edit the system settings.
WHEN:	Whenever an edit is required.
WHO:	Administrator

1. Click on the **"Settings".**

2. Click on **"System Setting".**

3. As needed, edit the number for:
    a. **GPS Distance Threshold**
    b. **Renewal Period**
    c. **Renewal with Fine Period**
    d. **Late Renewal Fine Amount**

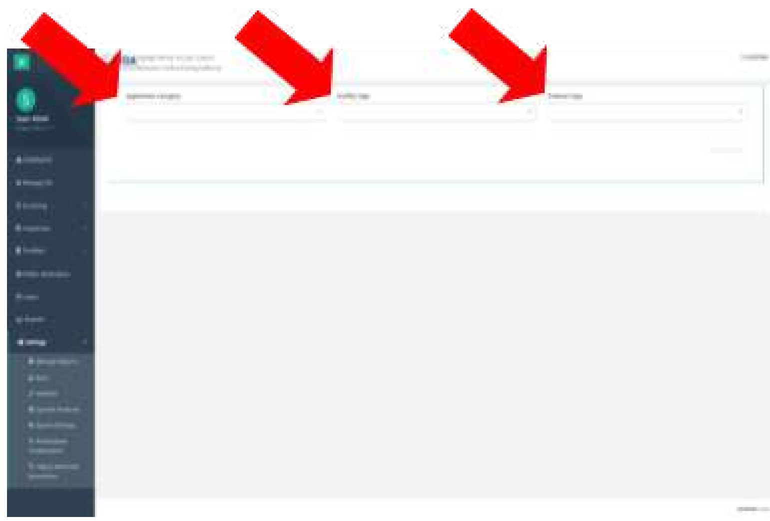
4. Click the **"Save" button** after each edit.

Edit Professional Configurations

WHAT:	This process is used to edit professional requirements for an application type.
WHEN:	Whenever an edit is required.
WHO:	Administrator

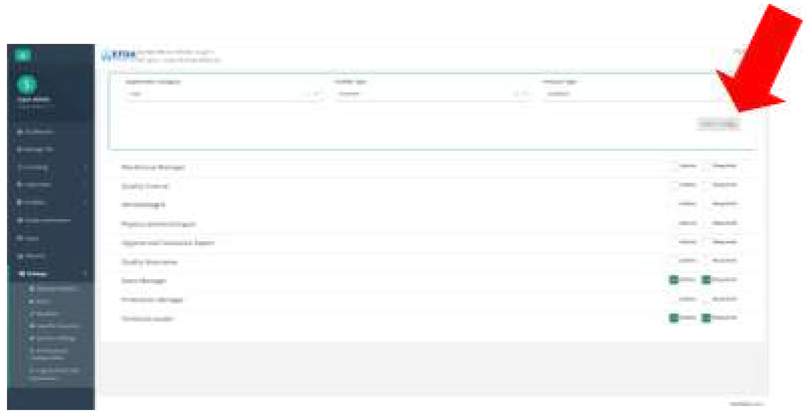
1. Click on **"Settings".**
2. Click on **"Professional Configuration".**

3. Filter categories to locate the profession that needs to be edited:
   a. **Application Category**
      i. Temporary COC for Covid 19
      ii. Warehouse addition
      iii. New
   b. **Facility Type**
      i. Importer
      ii. Exporter
      iii. Manufacturer
      iv. Retailer
      v. Wholesaler
   c. **Product Type**
      i. Food
      ii. Medicines
      iii. Medical device

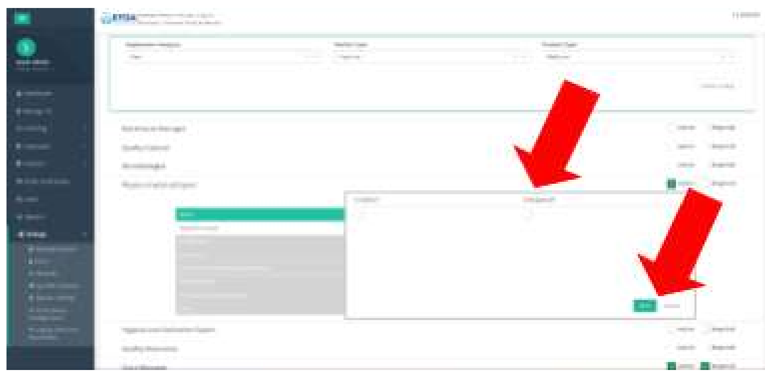


iv. Medicines & medical device
v. Cosmetic
vi. Tobacco

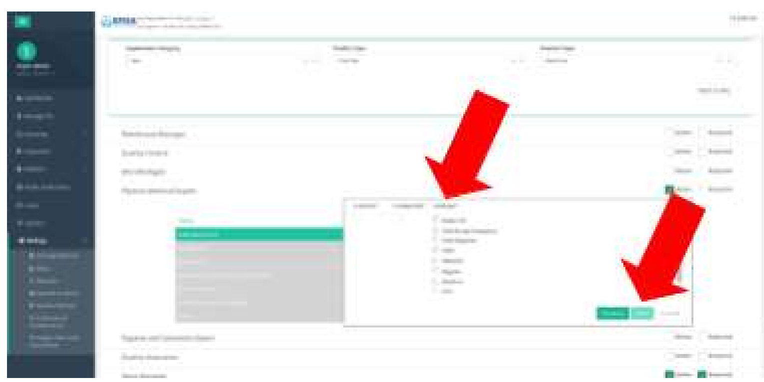
4. Click on the **"Fetch Configuration" button**.



5. Click on a **role**.
6. Click the box if it is: **"Active" and/or "Required".**
7. Click the **"Next" button**.



8. Click the **"Degree"** that is required.
9. Click the **"Next" button**.



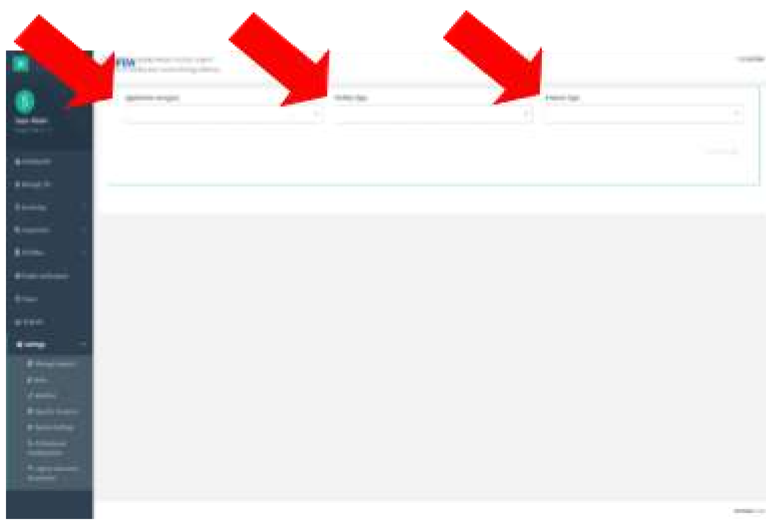
10. Click the **"Submit" button** when finished.

Activate / Deactivate Professional Configuration

WHAT:	This process is used to edit professional requirements for an application type.
WHEN:	Whenever an edit is required.
WHO:	Administrator

1. Click on **"Settings".**
2. Click on **"Professional Configuration".**

3. **Filter categories** to locate the profession that needs to be activated / deactivate:
    d. **Application Category**
        i. Temporary COC for Covid 19
        ii. Warehouse addition
        iii. New
    e. **Facility Type**
        i. Importer
        ii. Exporter
        iii. Manufacturer
        iv. Retailer
        v. Wholesaler
    f. **Product Type**
        i. Food
        ii. Medicines
        iii. Medical device

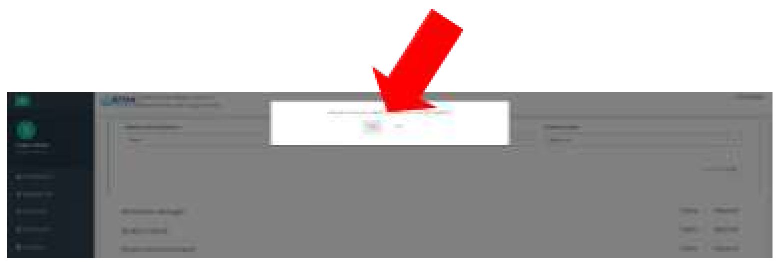


iv. Medicines & medical device
v. Cosmetic
vi. Tobacco

Find the **role**.

4. Click the box if it is: **“Active” and/or “Required”.**

5. Click on the **“Yes” button** when asked if you are sure you want to activate or deactivate it.



Legacy Data User Association

WHAT:	This process is used to submit a COC renewal request application using a legacy certificate.
WHEN:	Whenever an applicant wants to renew a COC using legacy data.
WHO:	Administrator

1. Click on **"Settings".**
2. Click on **"Legacy Data User Associations".**

3. Search for the facility you want using the **"Search for Facility…" text box**.

   If you want, you can search for the facility using the email address of an applicant associated with the facility.

4. Type the facility email address in the **"Facility Email" text box**.
5. Click the **"Save" button**.