DRAFT FDA CIRCULAR
No. _____

TO : ALL PRIVATE AND GOVERNMENT ESTABLISHMENTS ENGAGED IN THE BUSINESS, SERVICE, OR COMMERCIAL APPLICATION OF PESTICIDES FOR PURPOSES OF NON-AGRICULTURAL PEST CONTROL AND OTHER CONCERNED STAKEHOLDERS AND PARTIES

SUBJECT : Implementing Guidelines for the Issuance of License to Operate as Pest Control Operators for Non-Agricultural Purposes, Certification of Pesticide Handlers, and for Other Purposes

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In line with the implementation of Administrative Order No. 2019-0010, entitled "Guidelines on the Regulation of Operators of Pest Control, Certification of Pesticide Handlers, and Accreditation of Their Training Providers" issued on 18 June 2019, the Food and Drug Administration (FDA) hereby provides the following guidelines for compliance of all concerned establishments:

I. GUIDELINES

1. Issuance of License to Operate

1.1 Filing of Applications

1.1.1 Applications for the issuance of License to Operate (LTO) as Pest Control Operator (PCO), and its renewal and/or variation shall be submitted through the FDA e-Portal System.

1.1.2 A Username and Password shall be secured in order to access the FDA e-Portal System as specified in *Annexes A, A.1 & A.2* of this Circular.

1.1.3 PCO establishments shall follow the licensing procedure as prescribed in *Annex B* of this Circular.

1.1.4 PCO establishments shall submit the documentary requirements for the issuance of LTO as specified in *Annex B of Administrative Order No. 2019-0010, "Guidelines on the Regulation of Operators of Pest Control, Certification of Pesticide Handlers, and Accreditation of Their Training Providers"*.

1.1.5 SPH and PH applicants shall comply with the qualifications and documentary requirements for certification as specified in *Annex C of Administrative Order No. 2019-0010, "Guidelines on the Regulation of Operators of Pest Control, Certification of Pesticide Handlers, and Accreditation of Their Training Providers"*.

1.1.6 In the absence of availability of FDA-accredited trainings for SPH and PH, the PCO establishment shall submit copy of any proof of attendance to training/s of their Supervising Pesticide Handler (SPH) and Pesticide Handler (PH) related to urban pest management issued by the Fertilizer and Pesticides Authority (FPA) or any reputable organization within the last five (5) years from issuance of this Circular, in lieu of the required copy of ID of FDA-certified SPH and PH.

1.1.7 All applications shall be deemed filed upon payment of required fees and charges.

1.2 Evaluation

The evaluation of all applications for license and certification shall be based on satisfactory compliance to the applicable requirements or appropriate standards.

1.3 Inspection

1.3.1 Inspection of PCOs by FROO may be prior to the issuance of LTO or within the validity period of the issued license as part of the post-licensing inspection procedure.

1.3.2 During inspection, the PCO establishment shall be required to present the following documents:

1.3.2.1 Standard Operating Procedures (SOPs)

1.3.2.2 Documents relating to the procurement of FDA-registered Household/Urban Pesticides

1.3.2.3 Documents relating to the Schedule of PCO activities

1.3.2.4 Risk Management Plan and Safety Training Plan for Supervising Pesticide Handlers (SPH), Pesticide Handlers (PH), and other personnel

1.3.2.5 Training Certificates of SPH, PH, and other personnel

1.3.2.6 Environmental Clearance, if applicable

1.3.2.7 Contract Agreements, if applicable

1.4 Decision on Application

1.4.1 The appropriate authorization shall be issued to the applicant establishment or individual who satisfactorily complied with all applicable requirements and standards.

1.4.2 The application shall be disapproved if upon evaluation, it was found that the applicant establishment or individual has failed to satisfactorily meet the applicable requirements and standards.

1.4.3 Applications with incomplete requirements shall automatically be disapproved and requests for reconsideration shall not be entertained.

1.4.4 The disapproval of an application is without prejudice to re-application. However, disapproval of application shall mean outright forfeiture of payment.

1.5 Validity of Authorizations

1.5.1 Initial license and certification shall be valid for three (3) years.
1.5.2 Renewed license and certification shall be valid for three (3) years.

1.6 Renewal and Variation of Authorizations

1.6.1 The renewal of LTO shall be done prior to the expiration of its validity. For renewal applications with no change in the particulars of the PCO establishment, automatic renewal shall be permitted.
1.6.2 Renewal applications for LTO filed up to one hundred twenty (120) days after the expiration date shall still be processed but shall be subject to the appropriate surcharge or penalty as provided in the Implementing Rules and Regulations (IRR) of RA 9711. Renewal applications filed thereafter shall no longer be processed and shall undergo the process of initial application subject to the appropriate surcharge or penalty.
1.6.3 An LTO that has expired but with duly paid renewal application shall be deemed valid until the FDA has rendered its decision on the paid renewal/revalidation application.
1.6.4 Variations to the status of the PCO establishment shall require a notice in the form of a letter to FDA and shall be verified during post-licensing inspections.

1.7 Grounds for Disapproval of Application, Suspension, Revocation and Cancellation of Issued Authorization

The following shall be grounds for the disapproval of application, or suspension, revocation and cancellation of issued license and certification:

1.7.1 The PCO establishment or its representative made misrepresentations, false entries or withheld any relevant data;
1.7.2 The PCO establishment or its representative violated the declaration and oath of undertaking it agreed upon the submission of their application;
1.7.3 The PCO establishment or its representative violated the terms and conditions of its LTO;
1.7.4 The application requirements or post-licensing inspections show that the PCO establishment does not meet the required technical requirements and appropriate standards;
1.7.5 Such other analogous grounds or causes as determined by FDA.

2. Standards Applicable for PCO Establishments, SPH and PH

The FDA shall continuously develop, issue and update the standards applicable for PCO establishments, SPH and PH.

For purposes of this Circular, the PCOs, SPH and PH shall ensure compliance to safety standards and requirements (as may be applicable), including but not limited to:

- IRR of Chapter XVI – "Vermin Control" of the Code on Sanitation of the Philippines (Presidential Decree 856), and its future amendments
- Republic Act No. 6969, otherwise known as the "Toxic Substances and Hazardous and Nuclear Wastes Control Act of 1990" and IRR
- International Conventions, Treaties and Protocols (ie. Basel, Rotterdam, Stockholm, etc.)
- Internationally-acceptable standards based on World Health Organization (WHO), Food and Agriculture Organization of the United Nations (FAO), International Organization for Standardization (ISO), etc.

3. Postmarketing Surveillance

PCO establishments, SPH and PH shall be subject to postmarketing surveillance activities of the FDA. Appropriate regulatory actions shall be imposed upon erring establishments, or individuals.

4. Responsibilities of PCO Establishments

4.1 PCO establishments shall be responsible for ensuring the safe conduct and execution of their pest control activities.

4.2 PCO establishments shall not permit SPH and PH that are not FDA-certified to carry out pest control activities.

4.3 PCO establishments shall ensure use of FDA-registered household pesticides for the intended purpose in their pest control activities.

4.4 PCO establishments shall ensure that integrated vector management principles are applied in the management of pest.

4.5 PCO establishments shall provide accurate pest control advice, disclose chemicals to be used, inform re-entry interval, and provide pest control report to their clients.

4.6 PCO establishments shall keep records of their pest control activities and made them readily available upon audit by FDA.

4.7 PCO establishments shall keep inventory of pesticides, and pest control equipment including number and type of equipment

4.8 PCO establishments shall provide suitable storage facility, vehicle, personal protective equipment (PPE), application equipment, signage on PCO, and disposal of waste and empty containers. Specific conditions and requirements are prescribed in *Annex C* of this Circular.

4.9 PCO establishments shall report and coordinate with FDA on matters of PMS including but not limited to: (a) serious adverse events such as serious injury/illness resulting to hospitalization or death that can reasonably be attributed to the conduct of their pest control activities; (b) pesticide resistance; (c) and/or other related health issues arising from their pest control activities.

5. *Processing Time*

Applications shall be processed in accordance with the approved FDA Citizen's Charter.

6. *Fees and charges*

Applications for the issuance of license and certification shall follow the schedule of fees specified in *Annex E of AO 2019-0010, "Guidelines on the Regulation of Operators of Pest Control, Certification of Pesticide Handlers, and Accreditation of Their Training Providers"*, and its future amendments.

II. EFFECTIVITY DATE

This Circular shall take effect fifteen (15) days following the completion of its publication in two (2) newspapers of general circulation and submission of a copy hereof to the University of the Philippines Office of the National Registry (UP-ONAR).

ROLANDO ENRIQUE D. DOMINGO, MD, DPBO
Director General, Food and Drug Administration

DTN: 20180911165038

Annex A

General Guidelines in Using the FDA e-Portal System V.2

1. To access the FDA E-Portal, an applicant must appropriately secure a user account through the procedure outlined below:
    - 1.1 Accomplish the Authorization Letter for the e-LTO User Account application (refer to Annex A.1).
    - 1.2 Follow the link below: **bit.ly/ePortal2** (refer to Annex A.2).
    - 1.3 Provide all the required information in the user's registration form.
    - 1.4 Attach the signed and notarized Authorization (refer to Annex A.1) in pdf file format, to the registration form.
    - 1.5 The User Account credentials shall be sent to the email address provided in the registration form. The User Account credentials is valid for one (1) year.
    - 1.6 Issuance of the User Account is within three (3) working days upon receipt of the complete and compliant request.

2. Security and integrity of user accounts shall be the responsibility of the regulated entity. Applicants must ensure only authorized personnel can access their provided user accounts.

3. Applicants shall use their user accounts, in accordance with existing laws, FDA rules and regulations. FDA reserves the right to suspend and cancel user accounts found to be in violation of laws, FDA rules and regulations.

4. The applicant shall ensure that the information and documents uploaded to the system and submitted to FDA are true, correct, updated, and complete.

5. In the application forms, fields marked with red asterisks (*) are required to be filled-in. Mark required fields with N/A, if not applicable.

6. Documents uploaded to the system must conform to the following specifications:
    - 6.1 Documents/ files/ information uploaded must be free from bugs, viruses, and the like that may compromise the FDA system.
    - 6.2 Documents must be scanned and saved in PDF file format at 100-150 dots-per-inch (dpi)
    - 6.3 Filenames of documents shall be less than 40 characters in length, and shall not contain the following characters: \ ? / : * " > < I."

Annex A.1

Template for the Authorization Letter

[COMPANY LETTERHEAD]

(DATE)

The Director General
Food and Drug Administration
Civic Drive, Filinvest City
Alabang, Muntinlupa City

Dear Director General:

In accordance with Republic Act No. 9711 and other related issuances, we _____ (Company Name) with business address at _____ hereby authorize _____ (Name of Company Representative or Qualified Personnel) as the account holder of e-LTO and shall be responsible for all applications submitted through the e-LTO system.

I hereby undertake and warrant that the data and information submitted in connection with this application as well as other submissions in the future including variations are true, correct, and reflect the total information available.

_____
(Owner/President/CEO/Authorized Officer)

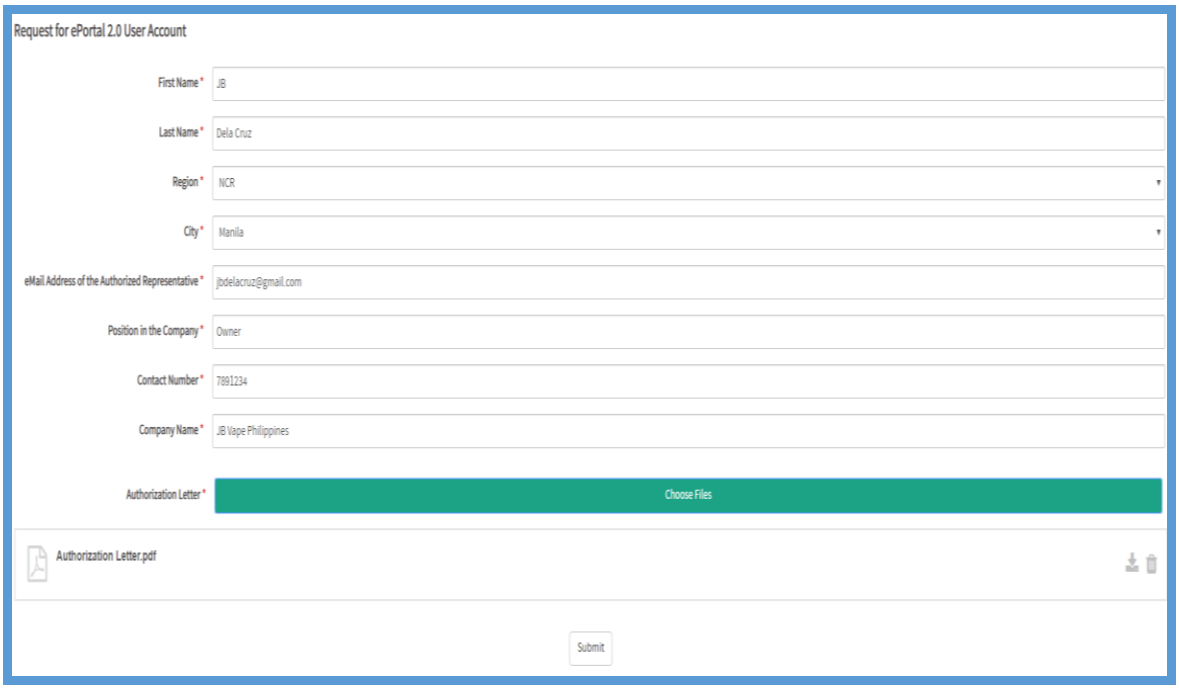
Subscribed and sworn to me this ____ day of _____ at _____.

_____
Notary Public

Doc No _____
Page No _____
Book No _____
Series of _____

Annex A.2

Online User's Registration Form

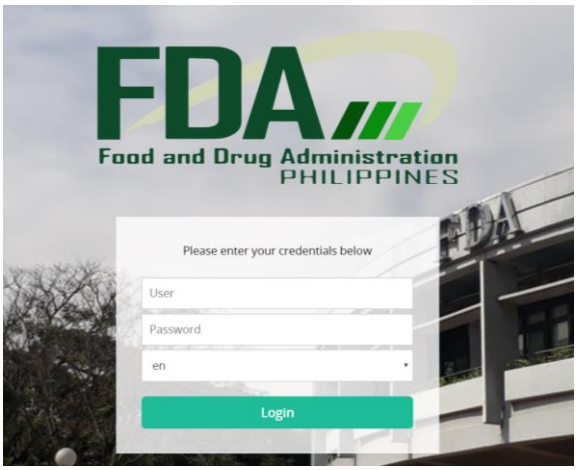
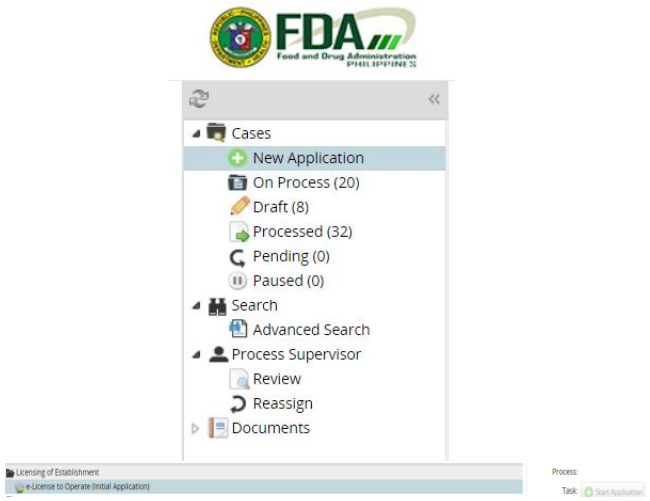
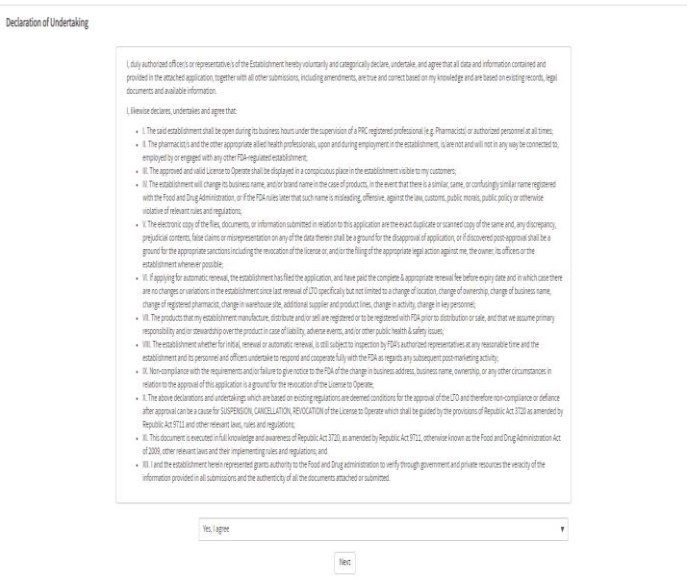


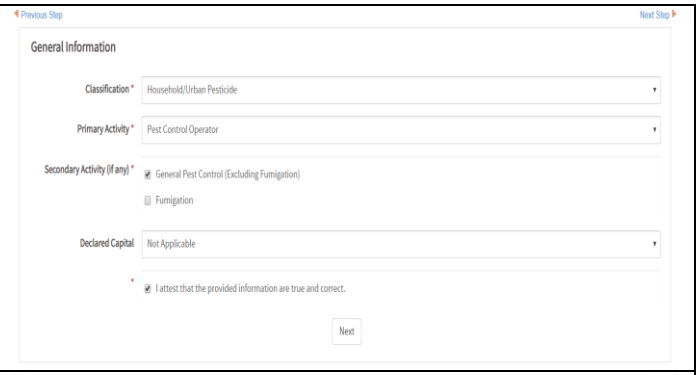
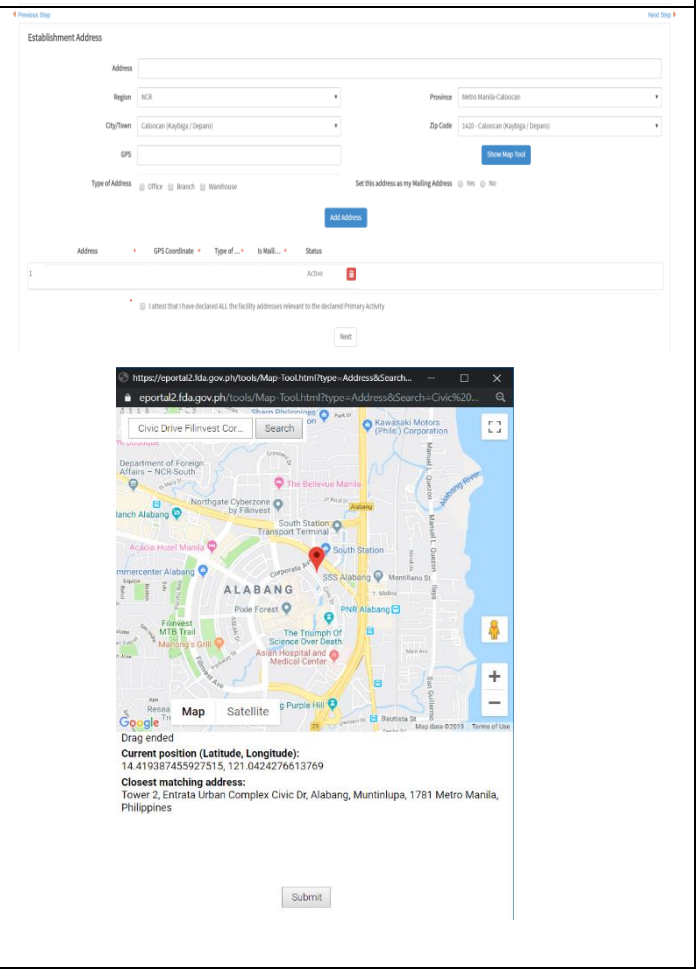
The Form can be accessed thru the link below:

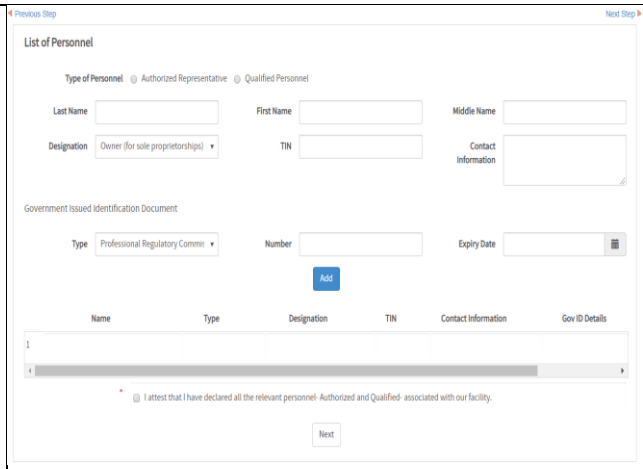
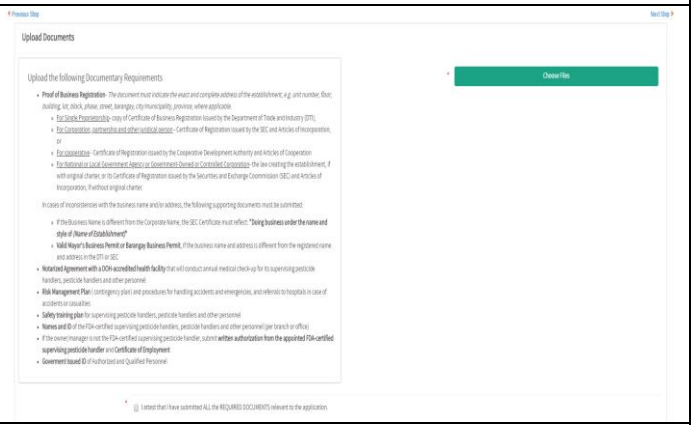
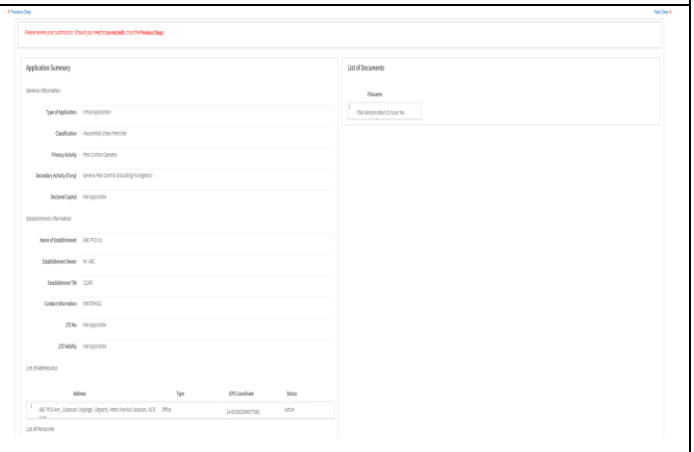
bit.ly/ePortal2

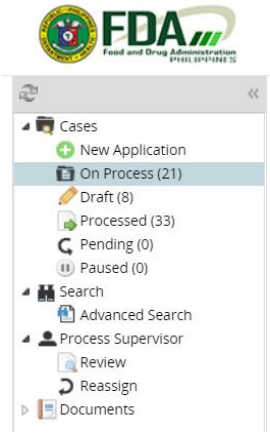
Annex B

Submission of LTO Application Thru the FDA e-Portal V.2

1. Access the FDA e-Portal V.2 at https://eportal2.fda.gov.ph 2. Log-in by entering the issued username and password.	
3. In the HOME tab, select New Application in the navigation pane and click e-License to Operate (Initial Application) to proceed to the LTO application form.	
4. Accomplish the application form as provided in parts by the application wizard. Fill-in the fields as completely as possible. Fields marked with a red asterisk (*) are required to be filled-in. Mark required fields with N/A, if not applicable. • Declaration - Proceed with the application by selecting your response using the drop-down list and click 'Next'.	

• General Information - Select the applicable classification and primary activity of the applicant establishment. Tick the secondary activity and select the declared capital. To continue to the next step, tick the box to certify all information is true and correct, then 'Next'.	
• Establishment Information - Fill-in the necessary information. All provided information shall be reflected also on the submitted Proof of Business Name Registration. Tick the box to certify all information is true and correct, then 'Next'.	
• Establishment Addresses – Declare all the addresses of the applicant establishment by ticking the type of address applicable. The applicant may simultaneously tick the office, branch, and warehouse if all three have the same address. Utilize the dropdown list when selecting the region, province, city and zip code. Click Show Map Tool and a separate window will appear showing the GPS map of the address. Move the arrow to the exact location of the establishment. Click 'Submit'. The GPS coordinates will be automatically updated when you move the arrow, then click 'Submit'. Select the desired mailing address by clicking "Set this address as my mailing address" and then click 'Add Address'. Tick the box to certify all information is true and correct, then 'Next'.	

• List of Personnel – Declare the Authorized and Qualified personnel. Select the Type of Personnel and provide the required information. An establishment may add only one (1) Authorized Representative and one (1) or more Qualified Personnel. The Authorized Representative should be the owner of the establishment while the Qualified Personnel must be the Technical Personnel knowledgeable on the operations of the PCO establishment (preferably the Supervising Pesticide Handler). Click 'Add' after every submission of personnel. Tick the box to certify all information is true and correct, then 'Next'.	
• Upload Documents – Upload the required document/s in PDF format. Tick the box to certify all information is true and correct, then 'Next'. Applicants may upload documents simultaneously.	
• Application Summary – It reflects all the declared information and uploaded documents. The applicant establishment may review and recheck the information. If there are corrections to be made, the applicant may revisit the pages of the application form by clicking 'Previous Steps'. The applicant establishment may also view the attached document by clicking its file name.	

• Order of payment – A computer generated document will appear reflecting the appropriate fees and charges. The applicant establishment should save and print a copy of the document as reference for payment. Click 'Next' to continue and delegate the application to payment verification.	
5. The application will undergo evaluation, checking, quality assurance and final recommendation. The application may either be approved (issuance of LTO) or disapproved. The result may be downloaded through the On-Process folder of the applicant establishment. Download and print the document and click 'Next' to end the task.	

Annex C

Specific Conditions and Requirements for Pest Control Operators

The following conditions and requirements prescribed in the "Guidelines on Licensing of Public Health Pest Control Operators" published by the WHO and FAO are hereby adopted for compliance of PCO establishments:

1. Storage facility for pesticides, equipment and materials

    1.1 The storage facility should be secure and locked at all times when not in use.
    1.2 The storage facility should be clean, well ventilated and well lit.
    1.3 The storage facility should be clearly identified with appropriate signage.
    1.4 The storage facility should be equipped with a suitable and well-maintained fire extinguisher and be easily accessible (preferably outside by the entrance).
    1.5 The storage facility should be stocked with suitable cleaning material for chemical spillages and kept in an easily accessible location.
    1.6 The storage facility should be stocked with warning placards to indicate pesticide application, re-entry interval or other hazards.
    1.7 The storage facility should have in stock safety data sheets for each of the chemicals stored and should be readily available for use in emergency.

2. Vehicles
    2.1 The vehicle should, among others, be labelled with the name, address, telephone number, a statement that it is carrying hazardous chemicals and a valid license number of the licensed PCO.
    2.2 The vehicle should have separate, well ventilated cabin for storage of chemicals and contaminated clothing or equipment. These materials should not be stored or transported in the driver's cabin.
    2.3 The part of the vehicle where the pesticide is stored should be able to contain the pesticide in the event of a leakage or spillage.
    2.4 A list of all chemicals with safety data sheets should be kept in an easily accessible location in the vehicle.
    2.5 A well-maintained fire extinguisher, within the expiration date, should be kept in an easily accessible location.
    2.6 The entire vehicle should be clean ad free from pesticide residue.
    2.7 Suitable clean-up materials for chemical spillages should be carried at all times.
    2.8 Emergency telephone numbers should be clearly displayed in a prominent location.

3. Application equipment
    3.1 The application equipment should be clean, well-maintained and free from pesticide residue.
    3.2 The application equipment should be regularly calibrated.
    3.3 The application equipment should be secured to the vehicle to prevent it from moving during transport.

4. Personal protective equipment (PPE)

The following PPE should be made available during pest control operations:

4.1 Appropriate and well-maintained respirators with spare cartridges;
4.2 Clean long-sleeved overalls;
4.3 Washable hats;
4.4 Eye and face protection such as safety glasses, goggles, and a face shield or full-face respirator;
4.5 Chemical-resistant boots, aprons and gloves;
4.6 Soap, towel and at least 10 liters of clean water;
4.7 An adequately stocked first aid kit;
4.8 A spare change of clothing for use in emergency; and
4.9 Suitable containers for contaminated items.

PCO establishments should ensure that appropriate PPE is worn for every pesticide application operation to reduce the risk of health effects from long-term low dose exposures to multiple chemicals. Regular visual checking should be carried out to ensure that PPE is not damaged and that specialist equipment, such as respirators, should be checked in accordance with the manufacturer's recommendation.

5. Signage on pest control operation

PCO establishments should accordingly advise their clients on the precautions to be taken as well as the re-entry interval after the application of pesticides. Appropriate signage should be posted at strategic places, such as entrances of treated premises, to warn the public before the re-entry interval has expired.

6. Disposal of waste and empty containers

PCO establishments should avoid the generation of waste. Spray solutions should not be prepared in excessive amounts. Pesticide containers should be triple rinsed and crushed before disposal and the rinsate used in the spray solution. They should follow the instructions on pesticide labels in their proper disposal, and comply with applicable laws on disposal of pesticides and containers and not put at risk or endanger the lives and safety of humans and animals or contaminate the environments including waterways or water supply.

7. Clean-up of spillages and leakages

If a pesticide leaks or spills, PCO establishments should take appropriate and immediate action to contain the spillage or leakage following national guidelines. The spilled material should be disposed of appropriately. The incident should be reported to FDA.