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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

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

9 1.1.7 All applications shall be deemed filed upon payment of required
10 fees and charges.

11 1.2 Evaluation

12 The evaluation of all applications for license and certification shall be
13 based on satisfactory compliance to the applicable requirements or
14 appropriate standards.
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16 1.3 Inspection

17 1.3.1 Inspection of PCOs by FROO may be prior to the issuance of
18 LTO or within the validity period of the issued license as part of
19 the post-licensing inspection procedure.

20 1.3.2 During inspection, the PCO establishment shall be required to
21 present the following documents:

22 1.3.2.1 Standard Operating Procedures (SOPs)

23 1.3.2.2 Documents relating to the procurement of FDA-
24 registered Household/Urban Pesticides

25 1.3.2.3 Documents relating to the Schedule of PCO activities

26 1.3.2.4 Risk Management Plan and Safety Training Plan for
27 Supervising Pesticide Handlers (SPH), Pesticide
28 Handlers (PH), and other personnel

29 1.3.2.5 Training Certificates of SPH, PH, and other
30 personnel

31 1.3.2.6 Environmental Clearance, if applicable

32 1.3.2.7 Contract Agreements, if applicable
33

34 1.4 Decision on Application

35 1.4.1 The appropriate authorization shall be issued to the applicant
36 establishment or individual who satisfactorily complied with all
37 applicable requirements and standards.

38 1.4.2 The application shall be disapproved if upon evaluation, it was
39 found that the applicant establishment or individual has failed to
40 satisfactorily meet the applicable requirements and standards.

41 1.4.3 Applications with incomplete requirements shall automatically be
42 disapproved and requests for reconsideration shall not be
43 entertained.

44 1.4.4 The disapproval of an application is without prejudice to re-
45 application. However, disapproval of application shall mean
46 outright forfeiture of payment.
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1 1.5 Validity of Authorizations
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3 1.5.1 Initial license and certification shall be valid for three (3) years.

4 1.5.2 Renewed license and certification shall be valid for three (3)
5 years.
6

7 1.6 Renewal and Variation of Authorizations
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9 1.6.1 The renewal of LTO shall be done prior to the expiration of its
10 validity. For renewal applications with no change in the
11 particulars of the PCO establishment, automatic renewal shall be
12 permitted.

13 1.6.2 Renewal applications for LTO filed up to one hundred twenty
14 (120) days after the expiration date shall still be processed but
15 shall be subject to the appropriate surcharge or penalty as
16 provided in the Implementing Rules and Regulations (IRR) of
17 RA 9711. Renewal applications filed thereafter shall no longer be
18 processed and shall undergo the process of initial application
19 subject to the appropriate surcharge or penalty.

20 1.6.3 An LTO that has expired but with duly paid renewal application
21 shall be deemed valid until the FDA has rendered its decision on
22 the paid renewal/revalidation application.

23 1.6.4 Variations to the status of the PCO establishment shall require a
24 notice in the form of a letter to FDA and shall be verified during
25 post-licensing inspections.
26

27 1.7 Grounds for Disapproval of Application, Suspension, Revocation and
28 Cancellation of Issued Authorization
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30 The following shall be grounds for the disapproval of application, or
31 suspension, revocation and cancellation of issued license and
32 certification:
33

34 1.7.1 The PCO establishment or its representative made
35 misrepresentations, false entries or withheld any relevant data;

36 1.7.2 The PCO establishment or its representative violated the
37 declaration and oath of undertaking it agreed upon the
38 submission of their application;

39 1.7.3 The PCO establishment or its representative violated the terms
40 and conditions of its LTO;

41 1.7.4 The application requirements or post-licensing inspections
42 show that the PCO establishment does not meet the required
43 technical requirements and appropriate standards;

44 1.7.5 Such other analogous grounds or causes as determined by FDA.
45

46 2. *Standards Applicable for PCO Establishments, SPH and PH*
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48 The FDA shall continuously develop, issue and update the standards
49 applicable for PCO establishments, SPH and PH.
50

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

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

14 15 *3. Postmarketing Surveillance*

16
17 PCO establishments, SPH and PH shall be subject to postmarketing
18 surveillance activities of the FDA. Appropriate regulatory actions shall be
19 imposed upon erring establishments, or individuals.

20 21 *4. Responsibilities of PCO Establishments*

- 22
23 4.1 PCO establishments shall be responsible for ensuring the safe conduct
24 and execution of their pest control activities.
- 25 4.2 PCO establishments shall not permit SPH and PH that are not FDA-
26 certified to carry out pest control activities.
- 27 4.3 PCO establishments shall ensure use of FDA-registered household
28 pesticides for the intended purpose in their pest control activities.
- 29 4.4 PCO establishments shall ensure that integrated vector management
30 principles are applied in the management of pest.
- 31 4.5 PCO establishments shall provide accurate pest control advice,
32 disclose chemicals to be used, inform re-entry interval, and provide
33 pest control report to their clients.
- 34 4.6 PCO establishments shall keep records of their pest control activities
35 and made them readily available upon audit by FDA.
- 36 4.7 PCO establishments shall keep inventory of pesticides, and pest control
37 equipment including number and type of equipment
- 38 4.8 PCO establishments shall provide suitable storage facility, vehicle,
39 personal protective equipment (PPE), application equipment, signage
40 on PCO, and disposal of waste and empty containers. Specific
41 conditions and requirements are prescribed in *Annex C* of this Circular.
- 42 4.9 PCO establishments shall report and coordinate with FDA on matters
43 of PMS including but not limited to: (a) serious adverse events such as
44 serious injury/illness resulting to hospitalization or death that can
45 reasonably be attributed to the conduct of their pest control activities;
46 (b) pesticide resistance; (c) and/or other related health issues arising
47 from their pest control activities.

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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


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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: \ ? / : * “ > < |.”

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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 _____

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Annex A.2 Online User's Registration Form

Request for ePortal 2.0 User Account

First Name * JB

Last Name * Dela Cruz

Region * NCR

City * Manila

eMail Address of the Authorized Representative * jdelacruz@gmail.com

Position in the Company * Owner

Contact Number * 7891234

Company Name * JB Vape Philippines

Authorization Letter * Choose Files

Authorization Letter.pdf

Submit

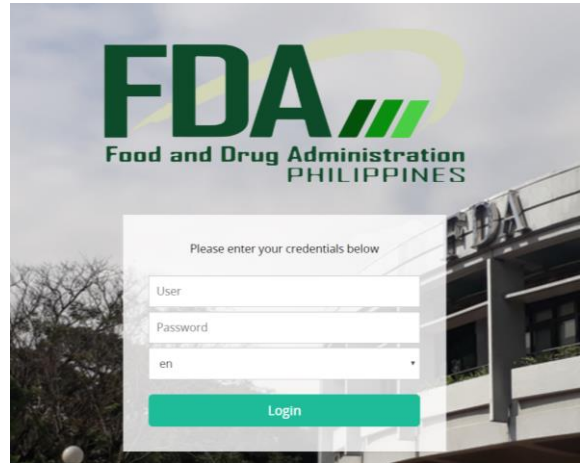
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The Form can be accessed thru the link below:
bit.ly/ePortal2

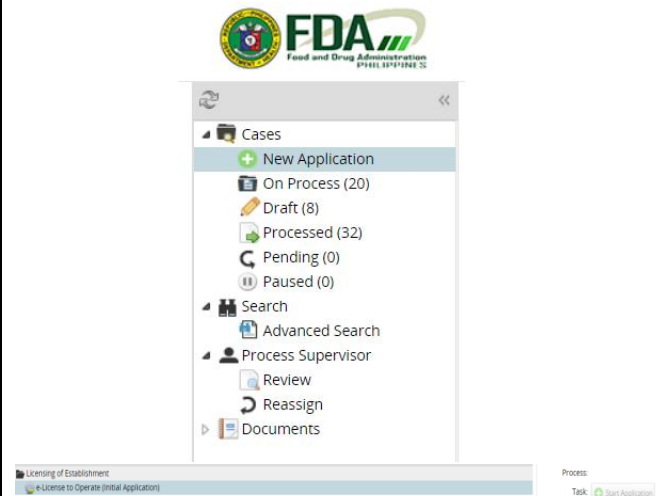
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Annex B Submission of LTO Application Thru the FDA e-Portal V.2

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'.

Declaration of Undertaking

I, (duly authorized officer/s or representative/s) of the Establishment hereby voluntarily and categorically declare, undertake, and agree that all data and information contained and provided in the attached application, together with all other submissions, including amendments, are true and correct based on my knowledge and are based on existing records, legal documents and available information.

I, (licensee declares, undertakes and agree that:

- I. The said establishment shall be open during business hours under the supervision of a PIC registered professional (e.g. Pharmacist) or authorized personnel at all times;
- II. The pharmacist/s and the other appropriate allied health professional/s, upon and during employment in the establishment, to live and will not in any way be connected, employed by or engaged with any other FDA-regulated establishment;
- III. The approved and valid License to Operate shall be displayed in a conspicuous place in the establishment visible to my customer/s;
- IV. The establishment will change to business name and/or brand name in the case of products, in the event that there is a similar, same, or confusingly similar name registered with the Food and Drug Administration, or if the FDA has later that such name is misleading, offensive, against the law, customs, public morals, public policy or otherwise violative of relevant rules and regulations;
- V. The electronic copy of the files, documents, or information submitted in relation to this application are the exact duplicate or scanned copy of the same and, any discrepancy, prejudicial contents, false claims or misrepresentation on any of the data therein shall be a ground for the disapproval of application, or if discovered post-approval shall be a ground for the appropriate sanctions including the revocation of the license or, and/or the filing of the appropriate legal action against me, the owner, its officers or the establishment whenever possible;
- VI. If applying for automatic renewal, the establishment has filed the application, and have paid the complete appropriate renewal fee before expiry date and in which case there are no changes or variations in the establishment since last renewal of DO, specifically but not limited to a change of location, change of ownership, change of business name, change of registered pharmacist, change in warehouse site, additional supplier and product lines, change in activity, change in key personnel;
- VII. The products that my establishment manufacture, distribute and/or sell are registered or to be registered with FDA prior to distribution or sale, and that we assume primary responsibility and/or reworking over the product in case of liability, adverse events, and/or other public health & safety issues;
- VIII. The establishment whether for initial, renewal or automatic renewal, is still subject to inspection by FDA's authorized representatives at any reasonable time and the establishment and its personnel and officers undertake to respond and cooperate fully with the FDA in regards any subsequent post-renewal activity;
- IX. Non-compliance with the requirements and/or failure to give notice to the FDA of the change in business address, business name, ownership, or any other circumstances in relation to the approval of this application is a ground for the revocation of the License to Operate;
- X. The above declarations and undertakings which are based on existing regulations are deemed conditions for the approval of the DO and therefore non-compliance or defiance after approval can be a cause for SUSPENSION, CANCELLATION, REVOCATION of the License to Operate which shall be guided by the provisions of Republic Act 3720 as amended by Republic Act 9711 and other relevant laws, rules and regulations;
- XI. This document is executed in full knowledge and awareness of Republic Act 3720, as amended by Republic Act 9711, otherwise known as the Food and Drug Administration Act of 2000, other relevant laws and their implementing rules and regulations; and
- XII. I and the establishment herein registered grants authority to the Food and Drug Administration to verify through government and private resources the veracity of the information provided in all submissions and the authenticity of all the documents attached or submitted.

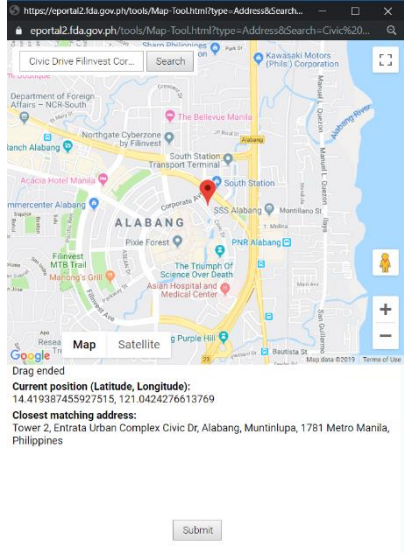
Yes, I agree

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'.

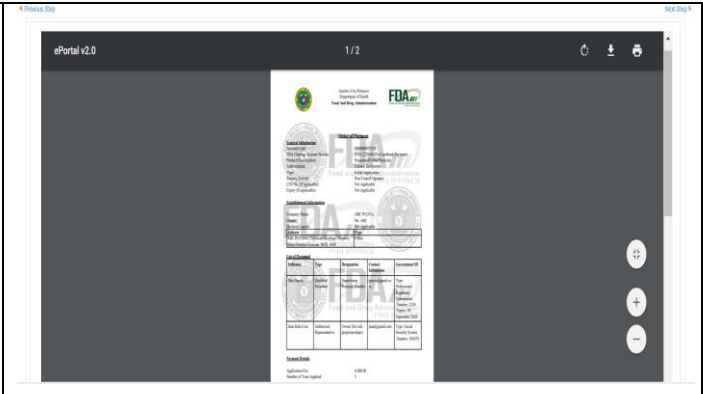


- List of Personnel – Declare the Authorized and Qualified personnel. Select the Type of Personnel and provide the required information. An establishment may add only one (1) Authorized Representative and one (1) or more Qualified Personnel. The Authorized Representative should be the owner of the establishment 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’.

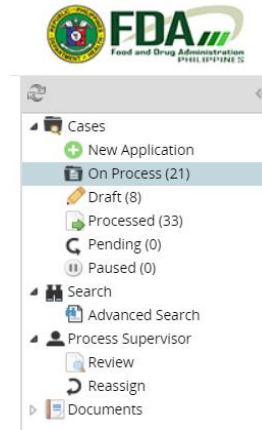
- Upload Documents – Upload the required document/s in PDF format. Tick the box to certify all information is true and correct, then ‘Next’. Applicants may upload documents simultaneously.

- 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.



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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 and 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.

1 4. Personal protective equipment (PPE)

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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.