

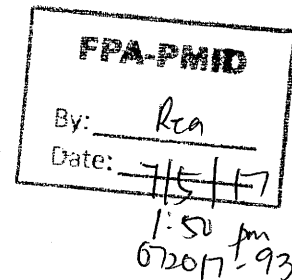


REPUBLIC OF THE PHILIPPINES
OFFICE OF THE PRESIDENT
FERTILIZER AND PESTICIDE AUTHORITY

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Memorandum Circular No. 05
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SUBJECT : GUIDELINES FOR THE IMPLEMENTATION OF THE FERTILIZER AND PESTICIDE AUTHORITY (FPA) LABORATORY RECOGNITION PROGRAM

1. RATIONALE

Pursuant to Section 9 of P.D. No. 1144, no pesticides, fertilizer, or other agricultural chemical shall be exported, imported, manufactured, formulated, stored, distributed, sold or offered for sale, transported, delivered for transportation or used unless it has been duly registered with FPA or covered by a numbered provisional permit issued by FPA for use in accordance with the conditions as stipulated in the permit. As part of FPA regulatory requirements in product registration, all fertilizer and pesticide products shall be subjected to laboratory analysis to determine if the products meet the required specifications.

In 2012, through the Department of Budget and Management (DBM) approved Rationalization Plan, the FPA has established its own laboratory, the Laboratory Services Division (LSD), to conduct laboratory analyses as support to its regulatory and monitoring activities on agricultural inputs. Samples analyzed in the LSD are for registration, new or renewal, and for monitoring activities of FPA. However, problems arise when transport of agrochemical samples from Luzon, Visayas and Mindanao are no longer allowed by the Freight Forwarders either by ship or plane because of issues on chemical hazards or danger in explosion. In order to address the issue and also to facilitate the agency's monitoring of fertilizer and pesticide products in remote areas in the country particularly in areas where there is difficulty in shipment/transport of samples, FPA shall recognize laboratories that has the capability to analyze the fertilizer and pesticide products either for renewal of registration and monitoring purposes only.

It is only through the process of the laboratory recognition program that FPA can ensure the reliability of fertilizer and pesticide laboratory results from participating laboratories that would be used by the agency in the regulatory decision making. It is a requisite that the laboratory analysis of all fertilizer and pesticide samples from the Fertilizer Regulations Division (FRD), Pesticide Regulations Division (PRD) and Regional Field Units (RFUs), submitted either for registration or monitoring purpose, shall be performed by LSD. Services of FPA recognized laboratories shall be utilized upon prior determination of LSD on the following grounds:

- 1) transportation issues; or
- 2) if LSD, for some valid technical reason, has determined that it cannot perform the analysis or can no longer accommodate the request for analysis.

The procedures and list of criteria in assessing the applicant shall be based on the internationally accepted standard by ISO 17025 for the general requirements for the competence of testing and calibration of laboratories and; the FPA's approved Laboratory Recognition principle found in Sections 4.5.6 and 4.5.7 of the FPA's Pesticide Regulatory Policies and Implementing Guidelines for the Implementation of FPA's Laboratory Recognition Program.

2. PURPOSE OF RECOGNITION

The FPA Laboratory Recognition Program is being established to support the agency's monitoring and regulatory activities on testing of fertilizer and pesticide formulations and residues both in agriculture and the environment mainly in remote areas and locations where shipment of samples to be submitted for analysis to LSD is not possible, thereby, enhancing the quality and safety of local and imported agricultural inputs and products while ensuring the protection of the environment.

This recognition program will also cover laboratories that can provide analytical services to stakeholders that cannot be accommodated by FPA laboratory but necessary for agency's regulatory decision making.

3. DEFINITION/SCOPE OF QUALITY

3.1 FPA Laboratory Recognition

FPA Laboratory Recognition is an official issuance acknowledging the technical competency of a laboratory to perform analytical testing of fertilizer and pesticide formulations and residues.

3.2 FPA Recognized Laboratories

FPA Recognized Laboratories refers to all competent laboratories in the Philippines that are approved by FPA to conduct fertilizer and pesticide analysis in support of the implementation of FPA Rules and Regulations. An FPA Laboratory Recognition Certificate shall be issued to the laboratories only if they comply with the FPA Laboratory Recognition requirements.

3.3 Scope of Laboratory Recognition

This Guidelines shall cover all participating laboratories that have the technical competence or capability to carry out specific analytical tests in fertilizers, pesticides and/or other agricultural chemicals. Moreover, LSD shall be the principal authorized laboratory to conduct analyses on all fertilizer, pesticides and other agricultural chemicals. All requests for laboratory analysis of fertilizers, pesticides and other agricultural chemicals from FRD, PRD and RFUs shall be submitted to and coordinated with LSD. FPA shall only tap the services of FPA recognized laboratories only when:

- 1) there are transportation issues; or
- 2) if LSD, for some valid technical reason, has determined that it cannot perform the analysis or can no longer accommodate the request for analysis.

Only specific tests on fertilizers, pesticides and other agricultural chemicals within the scope of the Laboratory Recognition for which the participating laboratory has been approved and recognized by FPA shall be considered as valid.

3.4 Types of Recognition Granted

3.4.1 Full recognition will be granted to the applicant laboratory that has satisfactorily completed all the requirements specified in this Guidelines. An FPA Laboratory Recognition Certificate will be issued to the qualified laboratory.

3.4.2 In case of emergency, as will be determined by FPA, a special recognition will be granted to a laboratory that can perform the required analysis.

3.5 Duration

The FPA Laboratory Recognition Certificate shall be effective for three (3) years from the date of issuance unless earlier revoked/cancelled.

4. REQUIREMENTS FOR LABORATORY RECOGNITION

4.1 Documentary requirements

Applicant laboratory shall provide to the FPA the following documents:

4.1.1 Application Documents

- a. Letter of Intent
- b. Duly accomplished and notarized FPA prescribed application form

4.1.2 Legal Documents

- a. Registration certificate from SEC for corporations or Department of Trade and Industry (DTI) for sole proprietorship
- b. Mayor's/Business permit issued by the city or municipality where the laboratory is located, or the equivalent document for Exclusive Economic Zones or Areas
- c. Tax clearance per E.O. 398, s. 2005, as finally reviewed and approved by the Bureau of Internal Revenue (BIR)

4.1.3 Technical Documents

- a. Organizational and functional chart of the laboratory including its position in its parent organization, if any, and job descriptions of its technical and support personnel
- b. Accreditation/Recognition record of the laboratory (if any)
- c. Laboratory test report forms
- d. List of reference literatures available in the laboratory
- e. Equipment calibration and maintenance program of the laboratory
- f. Quality assurance program of the laboratory
- g. Track record of the laboratory
- h. Validation report of test methods
- i. Results of proficiency testing participated or intra-laboratory exercise(s) conducted
- j. Floor plan of the laboratory and related facilities (scale=1:100)

4.2 Track Record of the Applicant Laboratory

Applicant laboratory shall be in operation for at least two (2) years and shall have analyzed a minimum of three hundred (300) fertilizer and/or pesticide samples.

4.3 Manpower Requirement

- 4.3.1 The Laboratory Head of the fertilizer and/or pesticide laboratory shall be a registered chemist holding a valid Professional Identification Card (PIC) issued by the Professional Regulatory Commission (PRC) and has at least five (5) years experience in laboratory analysis and management;
- 4.3.2 The laboratory shall have a minimum of one (1) registered chemist, having the necessary education, training, technical knowledge and experience to carry out the assigned function in the generation of test results. The said chemist shall have at least one (1) year experience in performing various fertilizer and/ or pesticide analyses;
- 4.3.3 The number of laboratory personnel shall be proportionate to the number of analysis and samples performed by the laboratory. In case the laboratory has chemical technician, the same shall have a valid PIC and must be supervised by a registered chemist.

4.4 Physical layout

- 4.4.1 The laboratory shall be housed in a permanent building constructed of strong materials.
- 4.4.2 The laboratory shall have adequate running water supply and regular electric power supply and provisions for emergency power source.
- 4.4.3 Workrooms shall be well ventilated with adequate provisions for either natural or artificial lighting.
- 4.4.4 The working space shall correlate with the volume and type of analysis to be undertaken, including provisions for periods of peak workload.
- 4.4.5 The laboratory shall include sufficient bench top area for processing samples, storage space for chemicals, glassware, portable and fixed equipment, and an adequate appropriate area for cleaning glassware and sterilizing materials
- 4.4.6 The laboratory shall ensure separation to incompatible laboratory activities (e.g. pesticide formulation area should be separated from pesticide residue area)
- 4.4.7 The laboratory shall have provisions for safety in the laboratory work area and its personnel by having emergency exits and egress, emergency eye wash, shower, medical kit, fire extinguishers, fume hoods and personal protective equipment (PPE).

4.5 Equipment and Apparatus

- 4.5.1 The laboratory shall be equipped with laboratory instrument, apparatus and other equipment required for the conduct of testing which include sampling, physical testing, sample preparation, extraction, clean-up, assay determination, processing and analysis of test data and storage as specified in their documented sampling and test procedure(s).

4.5.2 The laboratory shall ensure that all analytical instrument, equipment and apparatus used in the analysis of fertilizer and pesticide samples are calibrated and maintained. Maintenance and calibration records of these equipment shall be kept and updated and must be available upon request of the FPA.

4.6 Test Methods

4.6.1 The laboratory shall use only the test methods authorized by FPA which include but not limited to:

- a. The test methods prescribed and authorized by Codex Committee on Pesticide Residues (CCPR);
- b. Standard procedures and methods (e.g. AOAC, US EPA and FDA, ASTM, CIPAC or FAO); and
- c. In-house developed test methods or modified from standard methods for analysis of proprietary products provided these are properly documented and validated. Validation shall be done using analytical standards, through inter-laboratory calibration, or parallel runs with standard methods.

4.6.2 All test methods shall be properly documented.

4.7 Quality Control

4.7.1 The laboratory shall perform the adequate quality control for each batch of analysis which shall include:

- a. replicate test samples;
- b. replicate spike control samples;
- c. method blanks; and
- d. use of quality control chart for the analysis to evaluate the validity of the test results.

4.7.2 The laboratory shall satisfy the quality objectives for each test method set by FPA to suit the purpose for which the analysis is done.

4.7.3 The laboratory shall have a program to periodically validate the performance of the test methods.

4.8 Laboratory Procedures

4.8.1 The laboratory shall have documented standard operational procedures (SOP) and work instructions for the receipt of the samples, turnover of results, assignment of analysis, analyst reporting, checking of results, preparation of the laboratory test report, storage and filing of requests for analysis test reports, disposal of test solutions and samples. The SOPs shall include the pertinent forms used in the different processes involved. The SOPs shall also insure traceability of samples.

4.8.2 The laboratory shall have documented procedure in addressing clients' complaints on test reports.

5. PROCEDURE IN THE RECOGNITION PROCESS

5.1 Submission of Documentary Requirements

The applicant laboratory must submit all the documentary requirements listed in Section 4.1 and payment of FPA Laboratory Recognition fee.

5.2 Preliminary Assessment of the Laboratory

The FPA Laboratory Recognition Committee (FLRC) shall make preliminary assessment of the completeness of the documentary requirements. If complete, FLRC shall advise the applicant laboratory to submit one (1) hard copy and an electronic copy of the complete documentary requirements and pay the FPA approved laboratory recognition fee.

5.3 Laboratory Assessment

Upon the receipt of complete documentary requirements, FLRC Secretariat shall schedule the visits of FLRC to the laboratory for assessment. Each member of FLRC present as assessors shall be provided with the documentary requirements at least 1 week before the scheduled visit.

During the assessment visit, the FLRC assessors shall validate the data and information contained in the documentary requirements and evaluates the laboratory's compliance with FPA laboratory recognition guidelines.

5.4 Consolidation and Review of Data and Information

The FLRC Secretariat shall consolidate and make a summary of the Laboratory Assessment Reports by the FLRC assessors. Based on the reports and data or information available, the FLRC shall recommend to the FPA Executive Director the issuance/non-issuance of the FPA Laboratory Recognition Certificate to the applicant laboratory.

5.5 Re-assessment of Laboratory

5.5.1 If FLRC found the applicant laboratory not complying with the requirement(s) for recognition, the FLRC shall:

- a. Immediately inform the management of the applicant laboratory of its non-compliance(s) Make recommendations on how to correct the laboratory's non-compliance(s).
- b. Provide the Executive Director and the applicant laboratory with the Non-compliance Report that they prepared in accordance with the format prescribed by FPA.

5.5.2 The FPA shall require the applicant laboratory to correct its non-compliance(s).

5.5.3 Request for reassessment shall be entertained when the applicant laboratory provided the FLRC with a letter stating that they have already corrected their non-compliance(s) accompanied by supporting documents, if applicable, and paid the reassessment fee amounting to ten thousand pesos (P10,000).

5.6 Granting of Recognition

5.6.1 The FPA Laboratory Recognition Certificate shall be issued, signed and approved by the FPA Executive Director after the laboratory has been validated to comply with the appropriate requirements set by FPA.

The Certificate shall, among others, contain the following information: name and address of the recognized laboratory, recognition number, recognition status, names of the authorized signatories, effectivity of recognition, and signature of the Chair of FLRC and FPA Executive Director.

5.6.2 Scope of Recognition shall also be issued accompanying the FPA Laboratory Recognition Certificate listing those tests/analysis that FPA considers the recognized laboratory can perform effectively.

5.6.3 The FPA Laboratory Recognition Certificate shall not be transferable.

5.7 Extension of the Scope of Recognition

The FPA Recognized Laboratory requesting for the extension of its Scope of Recognition shall submit the prescribed FPA application form supported with the necessary data/information and pay the laboratory accreditation fee of ten thousand pesos (P10,000.00). This application shall undergo the same procedure as the application for laboratory recognition.

Upon the approval of the request for extension, the revised Scope of Recognition shall be issued to the Recognized Laboratory.

5.8 Directory of FPA Recognized Laboratories

All recognized laboratories shall be listed in a directory of official fertilizer and/or pesticide laboratories or another suitable publication or records maintained by Secretariat.

5.9 Monitoring and Surveillance of Recognized Laboratory

FPA shall institute monitoring mechanisms within the period of effectivity of Recognition to ensure that the recognized laboratories continuously comply with the requirements. The FLRC shall conduct periodic monitoring and surveillance of the Recognized laboratory. This includes but limited to the following:

- a. Scheduled/unscheduled laboratory inspection; and
- b. Provision of quality control/inter-comparison samples for analysis by the Recognized laboratory.

6. RESPONSIBILITIES OF THE RECOGNIZED LABORATORY

6.1 Compliance to Laboratory Recognition Requirements

6.1.1 The Recognized Laboratory shall continuously comply with the appropriate requirements in the FPA Guidelines and other requirements that may be specified by FPA.

6.1.2 The Recognized Laboratory shall pursue to comply or align with requirements of ISO 17025 “General Requirements for the Competence of Testing and Calibration Laboratories” and the “Guidelines on Good Laboratory Practice (GLP) in Pesticide Residue Analysis” set by Codex Alimentarius Commission.

6.2 Cooperation of Recognized Laboratory

6.2.1 The Recognized laboratory shall cooperate with the FLRC for the Laboratory Recognition Program to enable the latter to perform their duties conveniently during assessment and surveillance visits.

6.2.2 The Recognized Laboratory shall:

- a. Allow access of FPA assessors to the following: premises, records and analysis;
- b. Conduct tests required by the FPA; and
- c. Allow FPA assessors to interview the laboratory staff.

6.3 Proficiency Testing

6.3.1 The laboratory shall participate in inter-laboratory proficiency tests at least two (2) for residue and at least three (3) for formulation per year as part of the surveillance in the performance of the recognized laboratory.

6.3.2 Results of inter-laboratory exercises shall be submitted to FPA before it can renew its laboratory recognition. (Check guidelines of PAB on PT)

6.4 Payment of Fees

The applicant laboratory shall pay the laboratory recognition fee amounting to ten thousand pesos (P10,000.00) for new application, renewal, reassessment or extension of the scope of recognition.

6.5 Notification of Change

The Recognized Laboratory shall inform immediately the FLRC Secretariat (and in no case shall this be beyond one week) of significant changes in the laboratory that would affect the quality of its test results or compliance with laboratory recognition requirements. FPA may conduct reassessment, suspend, or withdraw recognition depending on the severity of effect of changes on quality of test results.

Significant changes that should be reported immediately include the following:

- a. the Recognized Laboratory’s technical staff, equipment, facilities, or laboratory location;
- b. the Recognized Laboratory’s organization, policies and procedures; and
- c. the Recognized laboratory’s authorized signatories.

6.6 Reference to FPA Laboratory Recognition

- 6.6.1 The Recognized Laboratory may cite in communication media such as brochures or any other advertising material its recognition by FPA. However, such reference shall be done only during the validity of recognition, and shall claim recognition to specific scope of tests for which it has been recognized.
- 6.6.2 The Recognized Laboratory shall not use the FPA Laboratory Recognition Certificate in such a manner as to bring FPA into disrepute, and shall not make any statement relevant to its recognition that FPA may reasonably consider to be misleading.
- 6.6.3 The Recognized Laboratory, in making reference to its recognition status, shall use the following phrase as appropriate: "FPA Recognized Laboratory for specific tests and identified by FPA Recognition Number(s).....".

6.7 Cooperation with FPA

- 6.7.1 The Recognized Laboratory shall perform tests (for fee) requested by FPA with respect to test data for registration or confirmation of test data submitted for registration and shall give priority to these tests.
- 6.7.2 The Recognized Laboratory shall participate in at least one (1) program of FPA on monitoring of fertilizer and pesticide formulations and residues under mutually agreed conditions (compensations, due dates, etc.).
- 6.7.3 The Recognized Laboratory shall participate in inter-laboratory tests programs run by FPA in its studies on sample handling, test procedures or other areas concerning fertilizer and pesticide residues or formulations.

7. MISCELLANEOUS REQUIREMENTS

- 7.1 Suspension, revocation of laboratory recognition certificate and reduction in the scope of recognition
 - 7.1.1 FPA may suspend or revoke the FPA Laboratory Recognition Certificate, reduce the scope of recognition, or require re-assessment, in the following grounds:
 - a. Changes in personnel, equipment, or scope of activity of an recognized laboratory that will render the laboratory to be non-compliant;
 - b. Non-submission/delay in the submission of annual reports;
 - c. Violation of the terms and conditions for the recognition;
 - d. Failure to provide reasonable cooperation to FPA and its assessment team; and
 - e. Deliberate falsification of documents and test results.

7.1.2 Should there be ground for suspension or revocation, the FPA shall issue a notice to the recognized laboratory requiring it to submit an explanation letter, within fifteen (15) calendar days from receipt, to show cause why the FPA Laboratory Recognition Certificate should not be suspended or revoked.

7.1.3 Upon receipt of the response of the show cause letter, the same shall be referred to the FLRC who shall evaluate and recommend to the FPA Executive Director the corresponding action.

7.2 Renewal

Application for renewal shall be filed at least three (3) months before the expiration of Certificate.

7.3 Handling of Complaints

7.4.1 FLRC shall act immediately on a complaint.

7.4.2 All complaints shall be recorded. The record shall include the name of complainant, nature of complaint, action taken, and the person who took charge of the complaint.

7.4.3 Complaints that are not resolved immediately shall be put in writing by the complainant. The letter of complaint shall be addressed to the FPA Executive Director. FLRC shall study or investigate and resolve the complaints. The complainant shall be provided with the resolution on their complaint(s).

7.5 Confidentiality

All information gained by FPA and its authorized agents in processing, granting, maintenance and renewal of laboratory recognition will be treated as confidential between FPA and the laboratory. Such information will be handled on a strict "need to know" basis and will not be divulged without written instructions from the FPA. The FLRC shall be made aware of and abide to this requirement of confidentiality. Moreover, the Recognized laboratory shall sign a contract or memorandum of agreement with FPA assuring that all laboratory information such as data and test reports shall not be disclosed or released to others without consent and approval from FPA.

8. REVOCATION CLAUSE

FPA reserves the right to amend, alter, add or delete any part of this guidelines, if in its assessment, such alterations, amendments, and additions are reasonable and necessary.

In the event of such alterations, amendments, and additions, all participating laboratories shall be notified and a reasonable time shall be given to them to fully adopt and comply with the altered terms and conditions of this guidelines.

9. SEPARABILITY CLAUSE

If any part or provision of this guideline is held invalid, other provisions not affected thereby shall remain in force and effect.

Recommending Approval:



MR. ERIC C. DIVINAGRACIA


Deputy Executive Director for Pesticide



ATTY. FRANCIS ROMULO I. BADILLA JR.

Chair of FPA Laboratory Recognition Program,
Acting Deputy Director for Fertilizer & Attorney IV

Approved:



WILFREDO C. ROLDAN

Executive Director

ANNEX D

SAMPLE TRANSMITTAL FORM

Name of Sample:	
Type of Sample:	
Analyte/Test Parameters to be Analyzed:	

Remarks:

Requested by:

Prepared & Reviewed by:

Client's Name &
Signature/Date

FRD/PRD Personnel/Date

ANNEX A

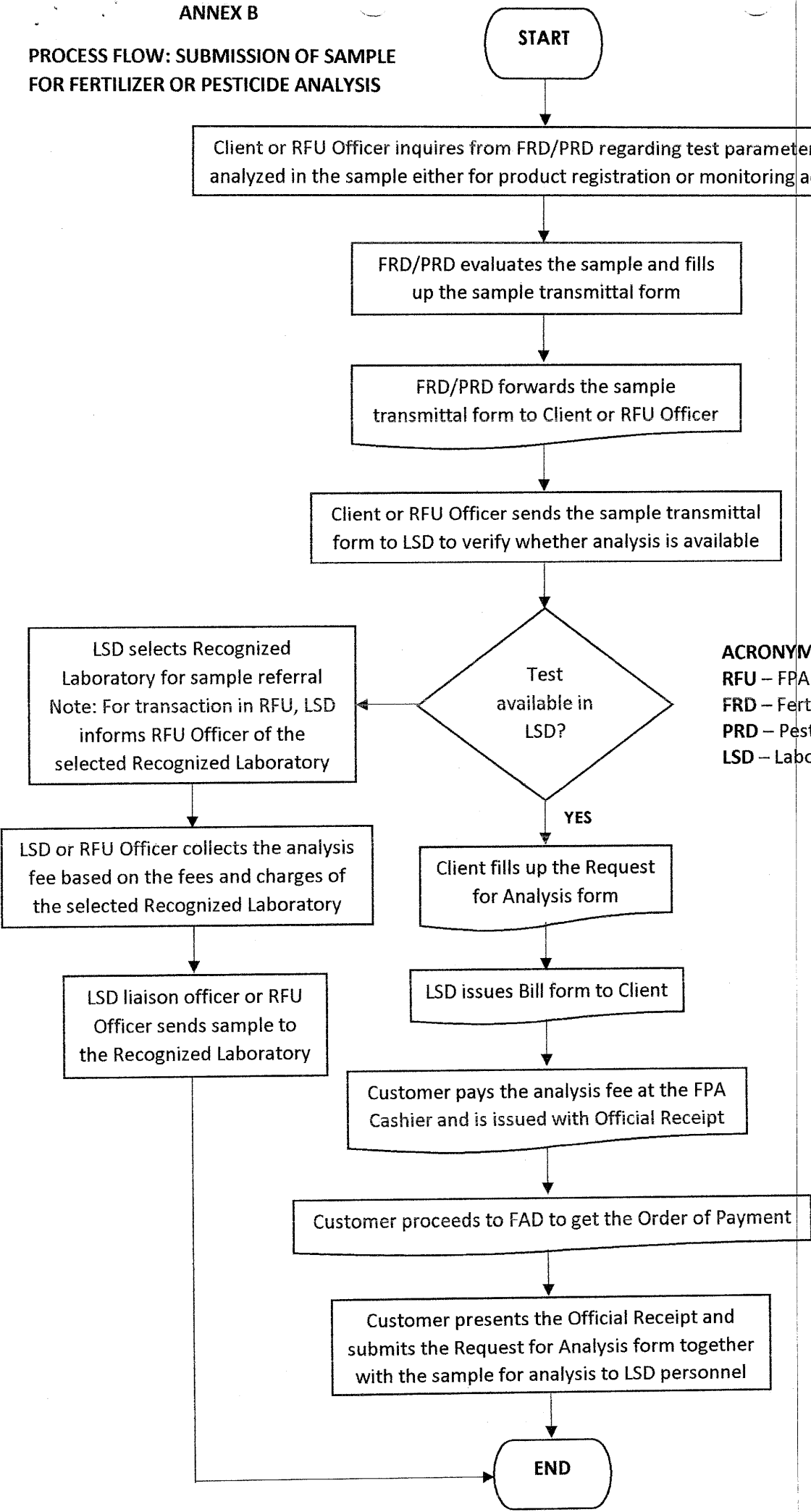
APPLICATION PROCEDURE FOR FPA LABORATORY RECOGNITION PROGRAM

To apply for FPA Laboratory Recognition Program, the applicant laboratory shall carry out the following:

1. Accomplish the FPA prescribed application form for laboratory recognition complete with notarization.
2. Prepare a Letter of Intent addressed to the FPA Executive Director stating interest to apply for recognition as testing laboratory for fertilizer and/or pesticide analysis.
3. Secure other documentary requirements:
 - A. Legal Documents
 - 1) Registration certificate from SEC for corporations or Department of Trade and Industry (DTI) for sole proprietorship
 - 2) Mayor's/Business permit issued by the city or municipality where the laboratory is located, or the equivalent document for Exclusive Economic Zones or Areas
 - 3) Tax clearance per E.O. 398, s. 2005, as finally reviewed and approved by the Bureau of Internal Revenue (BIR)
 - B. Technical Documents
 - 1) Organizational and functional chart of the laboratory including its position in its parent organization, if any, and job descriptions of its technical and support personnel
 - 2) Accreditation/Recognition record of the laboratory (if any)
 - 3) Laboratory test report forms
 - 4) List of reference literatures available in the laboratory
 - 5) Equipment calibration and maintenance program of the laboratory
 - 6) Quality assurance program of the laboratory
 - 7) Track record of the laboratory
 - 8) Validation report of test methods
 - 9) Results of proficiency testing participated or intra-laboratory exercise(s) conducted
 - 10) Floor plan of the laboratory and related facilities (scale=1:100)
4. Submit one (1) complete set of original copy of documentary requirements dossier in hard copy and one (1) in electronic copy to the FPA Laboratory Recognition Committee (FLRC) Secretariat.
5. Wait for confirmation from FLRC Secretariat if documentary requirements are complete.
6. If documentary requirements were determined to be complete after FLRC's preliminary assessment, obtain billing form from FLRC Secretariat.
7. Proceed to Finance and Administrative Division to get order of payment then pay the Laboratory Recognition Fee of P10,000.00 at FPA Cashier's office.
8. Present the official receipt to FLRC Secretariat.
9. Coordinate with FLRC Secretariat for scheduling of laboratory assessment visit.

ANNEX B

PROCESS FLOW: SUBMISSION OF SAMPLE
FOR FERTILIZER OR PESTICIDE ANALYSIS



ACRONYMS:
RFU – FPA Regional Field Unit
FRD – Fertilizer Regulations Division
PRD – Pesticide Regulations Division
LSD – Laboratory Services Division

ANNEX C

APPLICATION FOR FPA LABORATORY RECOGNITION

A. Name of Laboratory:

B. Address:

C. Tel./Fax. Nos.:

D. Email Address:

E. Name of Laboratory Head:

F. Scope of Recognition

TYPE OF ANALYSIS (FERTILIZER OR PESTICIDE)	TEST PARAMETER / ANALYTE	ANALYTICAL METHOD

I HEREBY CERTIFY that the foregoing data and information including the relevant attachments for this application are true and correct to the best of my knowledge.

IN WITNESS WHEREOF, I have hereunto set my hand this ____ day of _____, _____ at _____, Philippines.

Printed Name & Signature of
Authorized Representative

REPUBLIC OF THE PHILIPPINES
PROVINCE OF _____)S.S.
MUNICIPALITY/CITY OF _____)

SUBSCRIBED AND SWORN to before me this ____ day of _____, _____ at _____, Philippines. Affiant exhibited to me his/her Community
Tax Certificate No. _____, issued on _____, _____ at _____, Philippines.

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

NOTARY PUBLIC
Until December 31, 20____
PTR No. _____