



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA CIRCULAR
No. 2016-021

28 OCT 2016

TO : **ALL RADIATION FACILITIES/ESTABLISHMENTS REGULATED BY THE FOOD AND DRUG ADMINISTRATION SEEKING LICENSE TO OPERATE**

SUBJECT : **New Procedure for Filing an Application for a License to Operate thru the Food and Drug Administration (FDA) Public Assistance, Information, and Receiving (PAIR), Department of Health Regional Field Offices and FDA Regional Field Office**

I. BACKGROUND

Due to the transfer of the Radiation Regulation Division (RRD) of the Center for Device Regulation Radiation Health and Research (CDRRHR) from the Department of Health (DOH) – Sta. Cruz Manila to the Food and Drug Administration – Alabang, Muntinlupa, the new procedure for filing an application for a License to Operate is hereby adopted. The new procedures for filing of application for license to operate shall be implemented starting November 07, 2016, until such time that the on line application process of application for radiation facilities thru the electronic portal (e portal) of the FDA becomes fully operational and implemented. Covered by this Circular are LTO applications for initial, renewal, amendment and compliance.

All Food and Drug Regulatory Officers of the designated region are directed to disseminate this information and assist client applicants in the new procedure for LTO application.

II. SPECIFIC GUIDELINES

1. For hospital and non-hospital based x-ray facilities, the applicant facility shall submit the hard copy of their application documents at the FDA Public Assistance, Information, and Receiving (PAIR) Unit during Monday, Thursday and Friday only from 8:00 AM to 5:00 PM. However, the payment of fees and charges at the cashier is from 7:00 AM to 3:00 PM, no noon break.
2. For the submission of compliance documents during the conduct of Radiation Protection Survey and Evaluation and Facility Compliance Monitoring, the applicant facility shall submit the said documents to the FDA PAIR Unit during



Monday to Friday from 8:00 AM to 5:00 PM.

3. Applications received at the DOH Regional Field Offices / FDA Regional Field offices shall be forwarded to the FDA PAIR Unit, Alabang Muntinlupa.

III. PROCESS FLOW

The following process flow shall be followed in receiving the applications at the FDA PAIR UNIT during the transition process :

1. The applicant facility shall secure a queue number from the guard-on-duty.
2. The officer of the day (OD) reviews the application as to the completeness and correctness and in accordance with the checklist of requirements.
3. If the application is complete and correct, an Order of Payment and Document Tracking Number (DTN) shall be issued to the applicant facility.
4. The applicant facility shall proceed to the cashier for the payment.
5. The applicant facility shall then proceed to the person-in-charge in receiving the evaluated and paid application.

IV. EFFECTIVITY

This Order shall take effect on November 07, 2016.


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FDA Director General



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