



Republic of the Philippines  
Department of Health  
**FOOD AND DRUG ADMINISTRATION**



10 April 2015

**FDA CIRCULAR**  
No. 2015-007

**SUBJECT: Rules and Regulations on the Licensing of Hospitals and Other Health Facilities Involved in the Manufacture of Medical Gases**

**I. BACKGROUND/RATIONALE**

Section 15, Article II of the 1987 Philippine Constitution declares it a policy of the State to protect and promote the right to health of the people and instill health consciousness among them. Further, Section 11 of Article XIII mandates the State to adopt an integrated and comprehensive approach to health development which shall endeavor to make essential goods, health and other social services available to all the people at affordable cost.

Republic Act No. 9711, otherwise known as the “Food and Drug Administration (FDA) Act of 2009”, and its Implementing Rules and Regulations, empowers FDA to develop and issue policies, standards, regulations, and guidelines that would cover establishments, facilities and health products, including drug products.

In Republic Act No. 9502 (Universally Accessible Cheaper and Quality Medicines Act of 2008), “Drugs and medicines” are referred to as any article recognized in the current official United States Pharmacopeia-National Formulary (USP-NF) and other specified national compendium or any supplement to any of them, which is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals.

Oxygen, Nitrous Oxide, Carbon Dioxide, and other medical gases recognized in different pharmacopeias have diverse indications for use and are therefore classified as drugs under the regulatory jurisdiction of FDA.

Presently, manufacturers of medical oxygen in cylinder tanks are required to be licensed as drug manufacturers. Their products are also required to be registered with FDA.

With the recent increase in the number of hospitals and other health facilities setting-up their own medical gas generating machines and



subsequent engagement in the manufacture of medical gas both for inpatient use and other consumers, FDA, as the drug regulatory authority of the Philippines responsible for ensuring the safety, efficacy, and quality of drug products, hereby promulgates the following rules and regulations on the licensing of these establishments. This Circular is issued following the provisions of Administrative Order No. 2014-0034 (Rules and Regulations on the Licensing of Establishments Engaged in the Manufacture, Conduct of Clinical trial, Distribution, Importation, Exportation, and Retailing of Drug Products, and Issuance of Other Related Authorizations), dated 13 October 2014.

## **II. OBJECTIVES**

The objective of this Circular is to promulgate the rules and regulations on the licensing of hospitals and other health facilities involved in the manufacture of medical gases as drug manufacturers.

## **III. SCOPE**

These rules and regulations shall apply to all government and private hospitals and other health facilities engaged in the manufacture of medical gases. For the purpose of this Circular, "medical gases" shall refer to any gas or mixture of gases intended for administration to patients for anesthetic, therapeutic, diagnostic or prophylactic purposes, which may be manufactured in a liquefied, non-liquefied, or cryogenic state and administered as a gas. These gases may be stored in cylinders, pressurized storage tanks, or in low pressure collecting tanks.

## **IV. IMPLEMENTING DETAILS**

### *A. Establishments Required Licensing*

All government and private hospitals and other health facilities engaged in the manufacture of medical gases are required to secure a License to Operate (LTO) as drug manufacturer. For the purpose of this Circular, a "manufacturer" refers to any establishment engaged in any or all operations involved in the production of drug products, including preparatory processing, compounding, formulating, filling, packaging, repackaging, altering, ornamenting, finishing, and labeling with the end in view of its storage, sale or distribution; provided, that the term shall not apply to the compounding and filling of prescriptions in drugstores and hospital pharmacies.

An LTO is required for abovementioned establishments regardless of the following:

- 1) Method of medical gas manufacturing (e.g., concentrator, chemical synthesis, purifier)
- 2) Scale of manufacturing (e.g., small, medium, large)
- 3) Mode of gas delivery (e.g., from cylinders, from a medical gas pipeline system)

- 4) End users of the manufactured medical gas (e.g., inpatients of hospitals and other health facilities, other consumers)
- 5) Type of ownership [e.g., Department of Health (DOH)-retained, Local Government Unit (LGU)-owned, privately-owned]

*B. Documentary Requirements*

1) Application Form

A completely filled-out and notarized application form signed by the pharmacist and owner/authorized representative must be submitted.

2) Proof of Business Name Registration

A valid proof of business name registration must be submitted:

- (a) For single proprietorship - Certificate of Business Registration issued by the Department of Trade and Industry (DTI)
- (b) For corporation, partnership and other juridical person - Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation
- (c) For cooperative - Certificate of Registration issued by the Cooperative Development Authority and the approved by-laws
- (d) For government-owned or controlled corporation - the law highlighting the provision creating such establishment

The proof of business name registration must specify the exact and complete address, e.g. unit number, floor, building, lot, block, phase, street, barangay, city/ municipality, province, where applicable.

3) Credentials of the Pharmacist-in-Charge

The credentials of the identified pharmacist-in-charge must be submitted, which include:

- (a) Valid Professional Regulation Commission (PRC) ID
- (b) Certificate of Attendance to appropriate FDA Licensing Seminar
- (c) Resignation letter of the pharmacist from previous employer (if previously employed)

The other qualified personnel shall be listed, which include the (1) hospital engineer or equally qualified person responsible for overseeing the operations of the manufacturing facility and (2) personnel responsible for maintenance. The credentials will not be submitted during application but may be verified during inspection.

4) Risk Management Plan

A general Risk Management Plan (RMP) for the establishment must be submitted. The RMP shall contain details on how to identify, characterize, prevent or minimize risks relating to the medical gas they engage in. These shall include pharmacovigilance activities and interventions of the establishment to manage the risks.

5) Location Plan

A sketch of the location of the establishment must be submitted which shall be used for inspection purposes. This sketch must indicate clear directions with identified landmarks to locate the establishment.

In addition, the Global Positioning System (GPS) Coordinates in decimal degrees (DD) [Latitude and Longitude] must be indicated in the submission.

6) Site Master File

The Site Master File (SMF) must be submitted, in accordance with the latest edition of the Pharmaceutical Inspection Cooperation Scheme (PIC/S) – Good Manufacturing Practice (GMP).

7) Proof of Payment

Proof of payment (e.g., official receipt or authorized bank payment slip) must be included as proof of filing of application.

8) Self-Assessment Toolkit

To guide and facilitate the submission, a Self-Assessment Toolkit (SATK) must be submitted, which shall also serve as the worksheet during evaluation of FDA.

The list of documentary requirements for initial and renewal applications of LTO, reissuance of lost or destroyed LTO, as well as voluntary cancellation of LTO is attached as Annex A.

*C. Evaluation of Application*

1) Desktop Evaluation

All applications shall be initially reviewed by the respective FDA Regional Field Offices to determine compliance with the administrative and technical requirements.

The FDA, in the course of its evaluation may require additional or supplemental documents as proof of compliance to the existing regulations.

2) Pre-opening Inspection

After evaluation of the LTO application, the establishment shall be subjected to pre-opening inspection to determine compliance with the existing guidelines on PIC/S-GMP.

In addition to the documentary requirements submitted during application (Section IV, B of this Circular), the following documents related to the manufacturing of medical gas shall be verified during inspection:

- Quality Management System of the establishment, incorporating the medical gas manufacturing facility;
- Quality Manual and Standard Operating Procedures of the medical gas manufacturing facility;
- Contract Agreement between the supplier/installer of the medical gas manufacturing machine and the establishment
- Qualification and Validation Documents
- Master and/or Batch Production Records
- Specifications
- Credentials of other qualified personnel
- Relevant reference materials (e.g. Republic Acts, PIC/S-GMP Guide, standard practice guidelines)
- Other procedures, protocols, records, and reports as required by PIC/S-GMP

The abovementioned additional documents will serve as proof of compliance by the establishment with the existing regulations on licensing.

A report shall be issued to the drug establishment after inspection, which shall be the basis for further decision/action of FDA (e.g., approval/disapproval of an application for LTO, and/or for such other purposes).

### 3) Post-licensing Inspection

All establishments with approved LTO shall be subjected to routine inspection for their compliance to GMP and other relevant and applicable practices. In addition, major variation applications may require post-licensing inspection prior to the approval of such variation. Establishments which are subject to regulatory action due to different triggers (e.g., violation of any of the provisions of FDA laws, rules and regulations, and any other laws related thereto, occurrence of adverse drug reactions, as well as other quality, safety, and/or efficacy issues) shall also be inspected.

#### D. *Application for Variation*

The following are the applicable variations to an approved LTO:

- 1) Major Variation
  - (a) Change of Ownership
  - (b) Transfer of Location
- 2) Minor Variation – Prior Approval
  - (a) Expansion of Establishment
  - (b) Change of Business Name
  - (c) Zonal Change in Address
- 3) Minor Variation – Notification
  - (a) Change of Pharmacist-in-Charge or Other Qualified Personnel

FDA should be duly informed of any changes to the approved LTO, whether or not these are classified as variations described above. Other changes may also be added to the variations mentioned, which shall be subject of an appropriate regulation.

The list of documentary requirements for the abovementioned variations is attached as Annex B.

All variations are subject to the existing variation/amendment fee except for transfer of location which is subject to initial payment for two (2) years validity of LTO.

Hospitals and other health facilities applying for minor variations may continue business operations provided that an application for such variation has already been filed.

#### *E. Accessibility*

All electronic fillable forms shall be made accessible at the FDA Website.

### **V. RESPONSIBILITIES OF OTHER IMPLEMENTING OFFICES**

Consistent with the regulatory powers provided under (3), c, Sec. 2, Article III, Book I of the implementing rules and regulations of Republic Act No. 9711, FDA and its Regional Field Offices through the Director General may call on the assistance of any department office and/or government agency for the effective implementation of its rules and regulations.

In addition, Local Government Units (LGUs) are enjoined in monitoring licensed hospitals and other health facilities in their localities for their compliance to the existing laws and their respective rules and regulations. Any violation found by the LGU inconsistent with the FDA rules and regulations shall be reported to FDA for regulatory action.

### **VI. TRANSITORY PROVISIONS**

Hospitals and other health facilities are given until 30 June 2015 to file their application for LTO following the existing documentary requirements. Hospitals and other health facilities that continue to engage in the activities described herein without any application shall be a ground for the filing of administrative charges pursuant to the existing rules and regulations of FDA and the Health Facilities and Services Regulatory Bureau.

Hospitals and other health facilities with existing medical gas manufacturing facilities which have filed the LTO application before the aforementioned deadline may continue operations until issuance of LTO. An intensive inspection transition phasing shall be employed by FDA using a risk based approach.

Table 1. Inspection Transition Phasing

Phase	Classification of Hospitals and Other Health Facilities*	
1	General Hospital	Level 3
2		Level 2
3		Level 1
4	Specialty Hospital	
5	Other Health Facilities	Category A
		Category B
		Category C
		Category D

\*as per Administrative Order No. 2012-0012

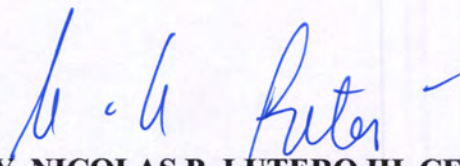
Incoming applications after 30 June 2015 shall need to secure an LTO prior to operations; FDA will inspect these establishments once all the transition phasing for previously submitted applications have been completed.

**VII. REPEALING CLAUSE/SEPARABILITY CLAUSE**

Provisions of previous FDA circulars and memoranda that are inconsistent with this issuance are hereby withdrawn, repealed, and/or revoked accordingly. In case any part, term or provision of this FDA Circular is declared contrary to law or unconstitutional, other provisions which are not affected remain in force and effect.

**VIII. EFFECTIVITY**

This Circular shall take effect immediately upon approval and signature by the FDA Director General.



**ATTY. NICOLAS B. LUTERO III, CESO III**  
 OIC-Director IV  
 Food and Drug Administration

## ANNEX A

### **LIST OF DOCUMENTARY REQUIREMENTS FOR HOSPITALS AND OTHER HEALTH FACILITIES AS MANUFACTURERS OF MEDICAL GASES LTO APPLICATIONS**

- A. Initial LTO Application
  - 1) Application Form
  - 2) Proof of Business Name Registration
  - 3) Credentials of the Pharmacist-in-Charge
  - 4) Risk Management Plan
  - 5) Location Plan
  - 6) Site Master File
  - 7) Proof of Payment
  - 8) Self-Assessment Toolkit
  
- B. Renewal LTO Application
  - 1) Application Form
  - 2) Copy of Certifications issued as a result of LTO Variation
  - 3) Proof of Payment (e.g. official receipt or authorized bank payment slip)
  - 4) Self-Assessment Toolkit
  
- C. Reissuance of Lost or Destroyed LTO
  - 1) Letter of Request
  - 2) Affidavit of Loss or Destruction
  - 3) Proof of Payment (e.g. official receipt or authorized bank payment slip)
  
- D. Voluntary Cancellation of LTO
  - 1) Letter of Request
  - 2) Original LTO



## ANNEX B

### LIST OF REQUIREMENTS FOR VARIATION APPLICATIONS FOR HOSPITALS AND OTHER HEALTH FACILITIES AS MANUFACTURERS OF MEDICAL GASES

#### A. Major Variations

Change of Ownership	
C	There is a change of ownership of the hospital and other health facility licensed.
D	<ol style="list-style-type: none"><li>1. Application Form</li><li>2. Proof of business name registration reflecting the name of new owner</li><li>3. Deed of sale or transfer of rights/ownership</li><li>4. Proof of payment</li><li>5. Self-Assessment Toolkit</li></ol>

Transfer of Location	
C	<ol style="list-style-type: none"><li>1. Physical transfer of the medical gas manufacturing facility within the hospital or other health facility</li><li>2. Other variations (e.g. change of identified pharmacist-in-charge and/or business name) may also be included as long as the variation is noted in the application and the corresponding requirements for such changes are included. The payment remains as initial fee, regardless of the additional variation.</li></ol>
D	<ol style="list-style-type: none"><li>1. Application Form</li><li>2. Proof of business name registration reflecting the new address</li><li>3. New Location Plan</li><li>4. Updated Site Master File</li><li>5. Proof of payment</li><li>6. Self-Assessment Toolkit</li></ol>

## B. Minor Variations – Prior Approval

Expansion of Establishment	
C	<ol style="list-style-type: none"><li>1. Shall refer only to the expansion of the adjacent physical space of the medical gas manufacturing facility, not necessarily the hospital or other health facility</li><li>2. Expansion shall include additional floors where the building is occupied</li></ol>
D	<ol style="list-style-type: none"><li>1. Application Form</li><li>2. Updated Site Master File</li><li>3. Proof of payment</li><li>4. Self-Assessment Toolkit</li></ol>

Change of Business Name	
C	<ol style="list-style-type: none"><li>1. Change only in the business name</li><li>2. No transfer of location or change of ownership</li></ol>
D	<ol style="list-style-type: none"><li>1. Application Form</li><li>2. Proof of business name registration reflecting the new name of the hospital or other health facility</li><li>3. Proof of payment</li><li>4. Self-Assessment Toolkit</li></ol>

Zonal Change in Address	
C	Shall refer to the change of the name/number of the street/building without physical transfer of the hospital or other health facility.
D	<ol style="list-style-type: none"><li>1. Application Form</li><li>2. Document issued by the local municipality as proof of zonal change</li><li>3. Proof of payment</li><li>4. Self-Assessment Toolkit</li></ol>

### C. Minor Variations – Notification

Change of Pharmacist-in-Charge or other Qualified Personnel	
C	<ol style="list-style-type: none"><li>1. There is a change of the pharmacist-in-charge or other qualified personnel registered with FDA.</li><li>2. For other pharmacists and qualified personnel employed but not registered with FDA, changes on such shall not be required to apply for variation.</li></ol>
D	<ol style="list-style-type: none"><li>1. Application Form</li><li>2. Credentials(for change of pharmacist only)</li><li>3. Proof of payment</li><li>4. Self-Assessment Toolkit</li></ol>

\*C – Condition

\*D – Documents required