Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA CIRCULAR
No. 2017 - 013

16 NOV 2017

SUBJECT : **Guidelines on the Issuance of Clearance for Customs Release of Radiation Devices by the Food and Drug Administration – Center for Device Regulation, Radiation Health, and Research**

I. RATIONALE / BACKGROUND

Pursuant to Section 1(a) of Presidential Decree (PD) No. 480 entitled *"Creating a Radiation Health Office in the Department of Health"* dated 06 June 1974 as amended by PD No. 1372 and under Republic Act No. 9711 also known as *"The Food and Drug Administration Act of 2009"*, the Center for Device Regulation, Radiation Health, and Research (CDRRHR) of the Food and Drug Administration (FDA) is empowered to regulate the import and export of radiation devices that can be ionizing such as x-ray devices and non-ionizing such as laser, ultrasound, scanners and infrared radiation devices and others.

The above-mentioned devices shall not be allowed to enter the country unless a Clearance for Customs Release (CFCR) has been issued by the CDRRHR. This is to ensure control on the said devices entering the country, and that persons importing and receiving the said devices are identified.

Bureau Order (B.O.) No. 020 s. 2007 entitled *"Revocation of Bureau Order No. 032 s. 2006 and Promulgation of Guidelines on Issuance of Clearances for Release of Radiation Emitting Device by the Bureau of Customs"* covers guidelines for the issuance of CFCR for both emitting and non-emitting radiation devices. The B.O. No. 020 is hereby revoked and replaced by this Circular.

This Circular is focused on devices which emit radiation and is issued to promulgate complete requirements in securing a CFCR of radiation device.

II. OBJECTIVES

This Circular is issued to streamline the process of issuance of a CFCR for radiation devices. This rationalization will guarantee the identification, distribution and inventory for traceability of all radiation devices to their importer establishments and their end-users in the country.

III. SCOPE AND COVERAGE

This Circular shall apply to all importers of all radiation devices used for medical and non-medical applications that will be entering the country.

All devices not listed in this Circular, as well as the non-emitting radiation devices, shall not be required to secure a CFCR from the CDRRHR.

IV. DEFINITION OF TERMS

For purposes of this Circular, the terms below are defined as follows:

A. ***Bureau of Customs (BOC)*** is the national agency under the Department of Finance in charge of imports, exports, and foreign trade.

B. ***Center for Device Regulation, Radiation Health, and Research (CDRRHR)*** is the national agency under the Food and Drug Administration of the Department of Health that regulates the production, import, export, distribution, sale, promotion, and use of electrical/electronic devices capable of emitting radiation. Its former name is the Bureau of Health Devices and Technology.

C. ***Clearance for Customs Release (CFCR)*** refers to a document issued upon approval of the CDRRHR allowing and informing the release of regulated imports by the BOC.

D. ***Certificate of Product Registration*** is an authorization issued to an approved application for a device registration.

E. ***Device*** means medical devices and radiation devices.

1. ***Medical Device*** shall mean any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent and calibrator, software, material or other similar or related article intended by the product owner to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation for an injury; investigation, replacement, modification, or support of the anatomy or of a physiological process; supporting or sustaining life; control of conception; disinfection of medical devices; and providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body. This device does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

2. ***Radiation Device*** means an electrical or electronic apparatus emitting any ionizing or non-ionizing electromagnetic or particulate radiation; or any sonic, infrasonic, or ultrasonic wave. It includes ionizing radiation emitting device which is not intentionally designed to produce radioactive materials.

F. ***Device Accessories*** are parts of a device intended to supplement, support or augment the performance of radiation device for a useful purpose, but such parts are not designed by it to produce radiation.

G. ***Importer*** refers to any person or establishment that imports devices for its own use or for distribution to other establishments.

H. ***Non-emitting Radiation Devices*** are devices not capable of producing radiation.

V. SPECIFIC GUIDELINES

A. The client shall submit a written request for issuance of a CFCR addressed to the Director of the CDRRHR containing the following information and documents:

1. Number of units to be imported;
2. Intended use of unit;
3. Name and address of importer/supplier;
4. Name of owner and address of the facility where the unit will be installed (if available);
5. A duly notarized letter guaranteeing submission to the CDRRHR of the name and address of the buyer of the device within fifteen (15) days of the sale/transfer of ownership of the device (if name of buyer is unavailable upon application);
6. For a radiation device item to be used for medical applications, a Certificate of Product Registration (CPR) or any equivalent document certifying that the product is safe and allowed to be sold in the country of origin issued by the Ministry of Health of the country of origin;
    a. This document shall be duly authenticated by the Philippine Consulate in the country of origin.
    b. If the CPR is unavailable immediately, a duly notarized letter guaranteeing submission of this document to the CDRRHR, within sixty (60) days from receipt by the CDRRHR of the written request, shall be allowed in lieu of the CPR.
7. For a radiation device item to be used for non-medical applications, a document certifying that the product is safe and allowed to be sold in the country of origin issued by the Ministry of Health of the country of origin, or international certification for safety for a particular device (i.e., standards issued by the International Electrotechnical Commission);
    a. This document shall be duly authenticated by the Philippine Consulate in the country of origin.
    b. A duly notarized letter guaranteeing submission of this document to the CDRRHR, within sixty (60) days from receipt by the CDRRHR of the written request, shall be allowed.
8. Brochure/Literature of the device/device;
9. Copy of importer's permit (from the local government where the office of the importer is located); and

10. Copy of proforma invoice.

B. Upon submission of all the requirements, an evaluation within three (3) working days shall be done by the CDRRHR – Radiation Regulation Division to determine whether the device is capable of emitting radiation or not. If the device is radiation-emitting, a CFCR shall be required.

C. Pursuant to Customs Memorandum Order No. 9-2015 dated 10 April 2015 entitled *"On the Strict Enforcement of Rules Concerning Regulated Imports"*, all importers shall be required to provide a CFCR for radiation devices listed below when filing import entries with the BOC:

1. Radiation Devices used for Medical Applications

    a) Computed Tomography (CT) Dental X-ray Machine
    b) Conventional X-ray Machine
    c) Dental Conventional X-ray Machine
    d) Dental panoramic X-ray Machine
    e) Dental Radiography X-ray Machine
    f) Electron Microscope
    g) Laser Pointer (Laser for Medical, Opthalmology & Dental Purpose)
    h) Linear Accelerator
    i) Mammography X-ray Machine
    j) Medical CT X-ray Machine
    k) Mobile X-ray Machine
    l) Portable X-ray Machine
    m) Transportable X-ray Machine
    n) Tomotherapy Machine
    o) UV/Laser (for Dermatology)

2. Radiation Devices used for Non-Medical Applications

    a) Anti-Crime X-ray Machine
    b) Cabinet Type X-ray Machine
    c) Industrial X-ray Machine
    d) Laser Device
    e) X-ray Diffractometer
    f) X-ray Fluorescence Analyzer

D. Radiation devices listed below are also regulated imports and are required to have a CFCR from the CDRRHR:

1. Radiation Devices used for Medical Applications

    a) Magnetic Resonance Imaging (MRI)
    b) Ultrasound Machine
    c) Bone Densitometer
    d) Interventional X-ray Machine

2. Radiation Devices used for Non-Medical Applications

    a) X-ray Machines used in:
        1) Research X-ray Facility
        2) Veterinary X-ray Facility
        3) Education and Training X-ray Facility
    b) Laser
    c) UV
    d) Infrared

E. RF coils for MRI, ultrasound probes or transducers, x-ray tubes (and other parts or device accessories used for replacement of x-ray tube) are required to have a CFCR from the CDRRHR prior to release of the said regulated imports. However, radiation device parts and device accessories such as cassettes, printers, software, and/or of the same kind shall not be required to have a CFCR from the CDRRHR.

F. For medical devices listed in the FDA Memorandum Circular No. 2014-005 and its amendments, a CPR is required prior to release by the BOC. For exempted products, a Certificate of Exemption shall be required.

VI. FEES AND PAYMENT

In accordance with the Administrative Order No. 50 s. 2001 entitled "Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drug Drugs" dated 17 September 2001 and its amendments, an amount of ***THREE HUNDRED PESOS*** *(P300.00)* per device payable to the Food and Drug Administration shall be required prior to the processing of the application for a CFCR.

VII. APPLICATION PROCESSING TIME

The application for the issuance of a CFCR shall be processed within three (3) working days from the time the client has made the corresponding payment thereon.

VIII. REPEALING CLAUSE

Provisions of Bureau Order No. 020 s. 2007 *"Revocation of Bureau Order No. 032 s. 2006 and Promulgation of Guidelines on Issuance of Clearances for Release of Radiation-Emitting Device by the Bureau of Customs"* and all other issuances inconsistent with the provisions of this Circular are hereby repealed/rescinded and modified accordingly.

IX. SEPARABILITY CLAUSE

In case any section or provision of these regulations or any part thereof, or the application of such section, provision or portion shall be declared invalid or unconstitutional, the validity of the remaining provisions shall not in any way be affected or impaired thereby.

X. EFFECTIVITY

This Circular shall be made of record and shall take effect immediately.

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Keywords	*Radiation Device, CDRRHR, Clearance for Customs Release, CFCR*
Related issuances, laws, directives from other government agencies	*Bureau Order No. 020 s. 2007, Administrative Order No. 50 s. 2001, Customs Memorandum Order No. 9-2015*