FDA CIRCULAR
No. _____

SUBJECT : **AMENDMENT TO FDA CIRCULAR NO. 2017-013, ENTITLED, "GUIDELINES ON THE ISSUANCE OF CLEARANCE FOR CUSTOMS RELEASE (CFCR) OF RADIATION DEVICES BY THE FOOD AND DRUG ADMINISTRATION – CENTER FOR DEVICE REGULATION, RADIATION HEALTH, AND RESEARCH (FDA-CDRRHR)"**

I. BACKGROUND

FDA Circular No. 2017-013: "*Guidelines on the Issuance of Clearance for Customs Release (CFCR) of Radiation Devices by the Food and Drug Administration – Center for Device Regulation, Radiation Health, and Research (FDA-CDRRHR)*", was issued to rationalize the guidelines for the regulation of the importation of radiation devices used for both medical and non-medical applications. The issuance intended to provide regulatory action while the FDA is in the process of developing guidelines for medical device registration.

On January 2018, DOH Administrative Order No. 2018-0002 entitled, "*Guidelines Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements*" was issued to provide guidelines on the documentary requirements for the registration of medical devices based on the provisions of the ASEAN Medical Device Directive through a phased implementation specified through FDA Circular No. 2021-002 and its amendments.

As such, an amendment of the provisions of FDA Circular No. 2017-013 is needed to align with DOH AO No. 2018-0002. Specifically, all medical radiation devices shall also be classified in accordance with the agreed classification of the ASEAN Consultative Committee on Standards and Quality – Medical Device Product Working Group (ACCSQ-MDPWG). The registration of such devices shall also be covered and regulated by the specific and procedural guidelines of the AO.

In view thereof, this amendment aims to provide for the updated guidelines for the customs release of imported medical radiation devices harmonizing with current processes for other devices regulated by the FDA.

II. OBJECTIVES

This Circular aims to align and amend FDA Circular No. 2017-013 with provisions of DOH AO No. 2018-0002 and provide guidelines for medical radiation devices in line with the phased implementation of the AO specified through FDA Circular No. 2021-002 and its amendments.

III. SCOPE

This Circular shall apply to all importers of radiation devices used for medical and non-medical applications.

IV. GUIDELINES

To align with the full implementation of DOH AO No. 2018-0002 through FDA Circular No. 2021-002, the following Sections of FDA Circular No. 2017-013 are hereby amended:

A. Section V.A.6:

From	To
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.	For radiation devices used for medical applications, a **Certificate of Medical Device Registration (CMDR) / Certificate of Medical Device Notification (CMDN)** issued by the FDA-CDRRHR shall be submitted to the Bureau of Customs (BOC) for Class B, C, and D medical radiation devices prior to its release, in lieu of the Clearance for Customs Release (CFCR).

B. Sections V.C.1 and V.D.1 are amended and combined into a single provision with the inclusion of additional types of radiation devices :

From	To
Section V.C.1 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, Ophthalmology & Dental Purpose) h. Linear Accelerator i. Mammography X-ray Machine j. Medical CT X-ray Machine k. Mobile X-ray Machine l. Potable X-ray Machine m. Transportable X-ray Machine n. Tomotherapy Machine o. UV/Laser (for Dermatology **Section V.D.1** Radiation devices listed below are also regulated imports and are	Pursuant to Customs Memorandum Order No. 9-2015 dated 10 April 2015 entitled "*On the Strict Enforcement of Rules Concerning Regulated Imports*" and the updated List of BOC regulated imports, all importers, or Marketing Authorization Holder (MAH), as defined by FDA Circular No. 2021-002-A, shall be required to provide a CMDR or CMDN for medical radiation devices listed below when filing import entries with the BOC: a. Conventional X-ray Machines b. Dental Panoramic X-ray Machines c. Laser Pointers (Laser for Medical, Ophthalmological, & Dental Purposes) d. Medical Computed Tomography (CT) X-ray machines e. Electron Microscopes f. Computed Tomography (CT) Dental X-ray Machines g. Dental Conventional X-ray Machines h. Dental Panoramic X-ray Machines i. Digital Radiography X-ray Machines j. UV/Laser Devices (for Dermatology or Cosmetic Purposes) k. Linear Accelerators l. Mammography X-ray Machines m. Medical Computed Tomography (CT X-ray Machine)

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	n. Mobile X-ray Machines o. Portable X-ray Machines p. Tomotherapy Machines q. Transportable X-ray Machines r. Magnetic Resonance Imaging (MRI) s. Ultrasound Machines t. Bone Densitometers u. Interventional X-ray Machines v. Positron Emission Tomography machines w. Single photon emission computed tomography (SPECT) machines x. Stereotactic Radiosurgery Machines y. Gamma Camera Other types of medical radiation devices not included in the list provided, including new technologies or devices, shall also be required a CMDR or CMDN subject to the medical device classification and verification guidelines of DOH AO No. 2018-0002.

C. Section V.E:

From	To
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.	**Accessories and software** that are intended by the manufacturer to be used in combination with a medical radiation device to enable the latter to be used for its intended purpose, and as required by Section VI.1 of DOH AO No. 2018-0002, are required to have a **Certificate of Medical Device Notification (CMDN)** or **CMDR** prior to its release. Radiofrequency (RF) coils for MRI, x-ray tubes, (and other parts used for replacement of x-ray tube), and medical radiation device spare parts used to

	specifically generate radiation are still required to have a CFCR from CDRRHR.

D. Section V.F

From	To
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.	**Rescinded.**

E. Section V. Specific Guidelines additional provisions:

Addition
F. Medical radiation devices and accessories, regulated under this Circular, intended specifically and strictly for research, clinical studies, clinical investigations, exhibits, private use of health institutions, sample product for analysis/testing with ongoing CPR application, or donated brand new medical devices, shall apply for a **Certificate of Medical Device Listing (CMDL)** from CDRRHR prior to importation by the researcher, institution, and/or user of such devices. G. Medical radiation devices and accessories which is part of foreign donations to the health sector through the Bureau of International Health Cooperation (BIHC), as defined by DOH AO No. 2020-0001 or the "*Guidelines in the Importation, Facilitation, and Management of Foreign Donations involving Health and health-Related Products*" shall request for an FDA clearance for foreign donations.

V. TRANSITORY PROVISIONS

A. The CFCR and the License to Operate (LTO) of the medical device establishment shall still be submitted and honored for BOC release until **31 March 2023** pursuant to FDA Circular No. 2021-002-B.

B. Starting **1 April 2023**, all Marketing Authorization Holders (MAH) shall apply for a CMDN for Class B, C, and D medical radiation devices. While

applications for CMDN are ongoing, the CFCR and the License to Operate (LTO) of the medical device establishment shall still be submitted and honored for BOC release provided that a proof of application for CMDN shall be attached to the CFCR and LTO presented.

VI. SEPARABILITY CLAUSE

All other provisions of FC No. 2017-013 not affected by these changes shall remain valid and in effect. In case any section or provision of this Circular or any part thereof, or the application of such section, provision or portion shall be declared invalid, the validity of the remaining provisions of this Circular shall not in any way be affected or impaired thereby.

VII. EFFECTIVITY

This Circular shall take effect after fifteen (15) days following its publication in a newspaper of general circulation and upon filing three (3) certified copies to the University of the Philippines Law Center.

FRANCISCO T. DUQUE III, MD, MSc
Secretary of Health