

FDA CIRCULAR

No. _____

SUBJECT : Updated Guidelines for Payment of Applications with the Radiation Regulation Division of the Center for Device Regulation, Radiation Health, and Research (CDRRHR-RRD), repealing FDA Circular No. 2018-004

I. BACKGROUND

The issuance of the Department of Health (DOH) Administrative Order (AO) No. 2020-0035 or the “*Rules and Regulations on the Licensing and Registration of Radiation Facilities Involved in the Use of Radiation Devices and Issuance of Other related Authorizations*” established a more streamlined regulatory process for radiation facilities in accordance with Republic Act No. 11032, entitled, “*Ease of Doing Business and Efficient Government Service Delivery Act of 2018.*”

The new guideline includes online acceptance, processing, and release of authorizations through the FDA RRD Portal website. This includes the generation of Order of Payment (OP) and posting of payment as an integral part of the online system. As such, the previous guidelines for payment applications outlined in FDA Circular No. 2018-004, entitled “*Guidelines for Payment of Applications with the Radiation Regulation Division of the Center for Device Regulation, Radiation Health, and Research (CDRRHR-RRD)*” needs to be revised in view of the new established processes.

II. OBJECTIVES

This Circular aims to outline, harmonize, and consolidate the updated guidelines for payment of applications with the Radiation Regulation Division of the Center for Device Regulation, Radiation Health, and Research (CDRRHR-RRD), repealing FDA Circular No. 2018-004.

III. SCOPE

This Circular shall apply to all radiation facilities in the country under the jurisdiction of the FDA.

IV. GENERAL GUIDELINES

- A. The current FDA Payment Portal for radiation facilities and devices based on FDA Circular No. 2018-004 at <https://rrdpayment.fda.gov.ph/> shall be **shut**

down taking into account the new payment procedures provided for by FDA RRD Portal at <https://rrdportal.fda.gov.ph/>.

- B. Payment procedures provided for by FDA Circular No. 2020-026 shall apply to radiation facilities under the DOH One-Stop Shop (OSS) Licensing System, Certificate of Registration (COR) for Magnetic Resonance Imaging (MRI), and Clearance for Customs Release (CFCR).

V. SPECIFIC GUIDELINES

- A. Order of Payment for all radiation facilities shall be electronically generated through the FDA RRD Portal at <https://rrdportal.fda.gov.ph/>, except for radiation facilities under the DOH One-Stop Shop (OSS) Licensing System, Certificate of Registration (COR) for Magnetic Resonance Imaging (MRI), and Clearance for Customs Release (CFCR).
- B. Processing of payment for radiation facilities under the DOH One-Stop Shop (OSS) Licensing System, Certificate of Registration (COR) for Magnetic Resonance Imaging (MRI), and Clearance for Customs Release (CFCR) shall follow the following procedures:
 - i. Applications shall be received through the CDRRHR-RRD email at cdrhr.rrd@fda.gov.ph. It shall be subjected to pre-assessment and the notification of the result shall be sent through the applicant's email address.
 - ii. During pre-assessment, applications with complete documentary requirements shall be issued an Order of Payment to the applicant's registered email address.
 - iii. Oncoll payment using the details provided by the Order of Payment shall be done at any Land Bank of the Philippines (LBP) branch.
 - iv. The applicant shall email back the scanned copy of the **proof of payment** for the continuation of the process.
- C. Payment of fees is not a guarantee that the application will be approved. The application shall still be subjected to the evaluation of FDA and its compliance with pertinent laws, rules, and regulations.

VI. SEPARABILITY CLAUSE

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. REPEALING CLAUSE

The FDA Circular No. 2018-004 or the “*Guidelines for Payment of Applications with the Radiation Regulation Division of the Center for Device Regulation, Radiation Health, and Research (CDRRHR-RRD)*” is hereby repealed. Any other FDA issuances that are inconsistent with the provisions of this Circular are hereby modified or repealed accordingly.

VIII. 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.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

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REFERENCES

- Department of Health (DOH) Philippines. (2020). *Department of Health (DOH) Administrative Order (AO) No. 2020-0035 or the “Rules and Regulations on the Licensing and Registration of Radiation Facilities Involved in the Use of Radiation Devices and Issuance of Other related Authorizations”*. Manila.
- Food and Drug Administration Philippines. (2018). *Guidelines for Payment of Applications with the Radiation Regulation Division of the Center for Device Regulation, Radiation Health, and Research (CDRRHR-RRD)*. Muntinlupa City: FDA.
- Republic Act No. 11032. (2018). *Ease of Doing Business and Efficient Government Service Delivery Act of 2018*. Manila.