



FDA ADVISORY
No. **2020-744**

22 APR 2020

TO: ALL MEDICAL RADIATION FACILITIES INCLUDING LOCAL GOVERNMENT UNITS, GOVERNMENT OWNED OR CONTROLLED CORPORATIONS AND OTHER GOVERNMENT INSTRUMENTALITIES

SUBJECT: ADVISORY FOR THE ISSUANCE OF SPECIAL PERMIT FOR MEDICAL RADIATION FACILITIES USING LOANED MOBILE X-RAY DEVICES DURING THE COVID-19 PANDEMIC

With the increasing Covid-19 cases in the country, there is also an increase in the demand of medical services including the use of mobile x-ray devices in the diagnosis of the disease. This prompted medical x-ray facilities to purchase mobile x-ray devices. But due to the delay in the delivery of the newly purchased mobile x-ray devices, suppliers provided service/loaner x-ray units for use until such time that the intended mobile x-ray devices are delivered to respective facilities. In response to pandemic, the Food and Drug Administration - Center for Device Regulation, Radiation, Health and Research (CDRRHR) thru the Radiation Regulation Division (RRD) shall be issuing a Special Permit for loaner unit mobile x-ray devices, intended for use in the diagnosis of Covid-19 patients in need of immediate imaging procedures and medical response.

The following requirements for special permit application shall be submitted:

1. Letter of intent for the issuance of Special Permit addressed to:
ENGR. BAYANI C. SAN JUAN, MSc, MNSA, CESE
Director IV
Center for Device Regulation Radiation Health and Research
2. Duly accomplished medical x-ray license application form.
3. Copy of On-Loan agreement between the user and the supplier.
4. Copy of the Official Receipt or certificate of subscription of the personal dose monitor (TLD or OSL) from the provider of personnel dose monitoring service.
5. Copy of the VALID Professional Regulation Commission (PRC) license of all the radiologic/x-ray technologist/s.
6. Calibration certificate of the loaned mobile x-ray machine.

Guidelines

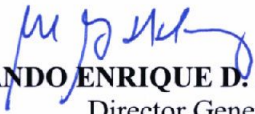
1. Applicants may email the scanned copy of their documentary requirements to cdrrhr.rrd@fda.gov.ph or cdrrhr@fda.gov.ph.
2. The processing of Special Permit that will be used for Covid-19 outbreak is exempted from payment.
3. The effectivity of the Special Permit shall be upon the complete and correct submission of requirements.



4. The validity of the Special Permit shall follow the duration of the use of equipment specified in the agreement.
5. The use of loaned mobile x-ray machines shall adhere with the radiation protection and safety standards prescribed by FDA.
6. In the event that the newly purchased mobile x-ray devices have been delivered and installed to respective facility, the facility shall submit an application for the issuance of appropriate authorization.
7. Scanned copy of approved Special Permit shall be sent to the registered email of the facility.

This shall take effect starting 14 April 2020.

For your guidance.


ROLANDO ENRIQUE D. DOMINGO, MD
Director General



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