FDA ADVISORY
No. 20232153

03 OCT 2023

TO: **ALL CONCERNED STAKEHOLDERS, MEDICAL DIAGNOSTIC X-RAY FACILITIES, HEALTHCARE PROFESSIONALS AND ALL OTHER CONCERNED LOCAL GOVERNMENT UNITS**

SUBJECT: **Use of Ultraportable / portable x-ray machines for TB Screening Programs.**

In line with the National TB Eradication Program of the Department of Health (DOH), the use of an ultraportable x-ray machine, as one of the tools for the conduct of Screening for Presumptive TB was allowed through Department Memorandum (DM) No. 2021-0518 dated 29 September 2021.

The Food and Drug Administration (FDA) allows the use of ultraportable/portable x-ray equipment for TB screening programs recognized by the local and national government, subject to the FDA licensing and regulatory requirements.

To reiterate and discuss the guidelines of the FDA for the issuance of authorization on the use of portable x-ray equipment in TB screening program.

1. The portable x-ray machine shall undergo performance testing and Radiation Protection Survey and Evaluation (RPSE) conducted by the FDA prior to use.
2. The portable x-ray machine shall not be held by the operator during chest x-ray procedures. The portable x- ray machine shall be equipped with tripod or stand holder during a procedure and the operators shall use the extendable hand switch and stand 2.5-3 m away from the X-ray tube.
3. Movable lead equivalent barriers or lead equivalent aprons shall be provided to protect the qualified and authorized personnel from radiation exposure.
4. A licensed radiologic/x-ray technologist of the Philippine Regulations Commission (PRC) shall operate the ultraportable x-ray machine.
5. For safekeeping and traceability, the x-ray equipment must be placed in a facility with existing License to Operate (LTO) for radiation services. A special permit shall be issued by the FDA in the form of an LTO for TB screening purposes for the type of application/use performed by the portable x-ray machine.
6. The identified facilities to use the UP-CXR shall be subjected to regular inspection and safety monitoring by the FDA.
7. Image interpretation shall be performed by a Diplomate or Fellow of the Philippine College of Radiology.

In view of the foregoing, it is reminded that, as per the provision in Section 5.3.23 of Administrative Order No. 35 s., 1994, which states that "Operation of portable x-ray equipment shall not be allowed", is still in effect.

For more information and inquiries, kindly contact the FDA Center for Device Regulation, Radiation Health, and Research through email at cdrrhr@fda.gov.ph or call (02) 857-1900 local 8301.

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