

PROHIBITION OF THE OPERATION OF RADIOGRAPHIC X-RAY MACHINES WITH TUBE CURRENTS BELOW 100 mA IN DIAGNOSTIC RADIOLOGY

FDA CIRCULAR NO. 2014-005, February 20, 2014

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In 1993, the World Health Organization (WHO) convened a meeting to review the technical specifications of the WHO Basic Radiological System later renamed as the World Health Imaging System for Radiography (WHIS-RAD). Based on the report of the meeting, the WHO recommended in their publication entitled “Technical Specifications for the World Health Imaging System for Radiography (WHIS-RAD)” that “the x-ray tube current shall exceed 100 mA”.

Radiation Protection Survey and Evaluation (RPSE) data gathered by our health physics team from radiographic x-ray machines of selected chest x-ray clinics show that the guidance dose levels stated in the DOH Department Circular No. 323 s. 2004 entitled “Manual on the Basic Radiation Protection and Safety of X-ray Sources in the Philippines” had been exceeded.

In view of the above findings, the FDA through its Center for Device Regulation, Radiation Health, and Research (CDRRHR) and Regional Field Offices shall prohibit the operation of medical x-ray facilities using a radiographic x-ray machine with tube currents below 100 mA. Radiographic x-ray machines used in dental, veterinary, industrial, anti-crime, and research purposes as indicated in the facility’s license to operate (LTO) shall not be affected by this Circular. Mobile C-arm and specialized x-ray machines such as those used for mammography, bone densitometry, and lithotripsy shall also not be affected by this Circular.

The following procedures shall be observed by all concerned:

- Initial LTO applications of x-ray facilities using mA values below 100 mA radiographic x-ray machines shall not be received.
- Facilities previously licensed by the CDRRHR or by the DOH shall be given until 31 December 2014 to upgrade their x-ray machine to a tube current of at least 100mA. Upon application for the renewal of their LTO, the validity of their LTO shall be until 31 December 2014 only. No further application for the renewal of LTOs for the year 2015 shall be received by the FDA or by DOH unless the facility’s x-ray machine shall have been upgraded.
- X-ray facilities found to be operating the above mentioned x-ray machines beyond 31 December 2014 shall be meted the appropriate sanctions as provided by the Implementing Rules and Regulations of the Republic Act 9711.

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

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