GUIDELINE FOR THE EVALUATION OF
MOBILE C-ARM FLUOROSCOPIC X-RAY EQUIPMENT
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DRC Inspection Program Objective

The overall objective of the x-ray inspection program is to reduce the likelihood that individuals will be exposed to unnecessary radiation. In the case of registrants using x-ray equipment in the healing arts, patient exposure is of concern and proper equipment performance is essential. Registrants are required to demonstrate that the equipment satisfies the appropriate regulatory standards for calibration and performance.

Purpose of Guideline

The intent and purpose of this document is to provide users of mobile c-arm fluoroscopic x-ray equipment guidelines for the documentation required to demonstrate to the DRC that the x-ray equipment satisfies the regulatory standards under clinical use conditions.

X-ray Equipment Performance and Calibration

The registrant is to document that the following requirements are met.

1) Adequate total filtration is present.
2) The fluoroscopy timer terminates the exposure or produces an audible signal at the end of a five minute accumulative time interval.
3) During fluoroscopy, the x-ray field collimation and alignment with the image intensifier (II) is appropriate.
4) Fluoroscopic exposure rates do not exceed the regulatory standards.
5) Patient exposure information has been obtained for simulated clinical conditions and is posted where it is readily available to the physician during the fluoroscopic procedure.