




Arkansas Department of Health

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Governor Asa Hutchinson

Nathaniel Smith, MD, MPH, Director and State Health Officer

ARKANSAS INFORMATION NOTICE 19-01

To: Registrants Performing Fluoroscopic Examinations. 

From: Bernard Bevill, Section Chief, Radiation Control, Arkansas Department of Health

Date: February 11, 2019

Subject: Hand-held Fluoroscopic Equipment

The following information is in regard to product marketing being circulated by Radiographic Equipment Vendors as to the sales and use of hand-held fluoroscopic equipment. As yet, the Department has no indication that these devices have received pre-market approval from the Food and Drug Administration (FDA). Once that approval is received by the manufacturer and an FDA premarket approval number is assigned, a waiver or exception must be requested of the Arkansas Board of Health and approved before the equipment can be registered with the Department and utilized in your facility.

Currently there is no provision in the Arkansas Board of Health's *Rules and Regulations for Control of Sources of Ionizing Radiation* for any hand-held device other than those that are typically used in dental practice or general radiography utilizing low kilovoltage x-ray such as that for extremities.

As is always the case, the Arkansas Board of Health will only approve devices which have FDA clearance to be sold within the United States.

Prior to purchase of this type of equipment it would be in your best interest to contact the X-ray Program office at the contact information below.

If you should have any question regarding this information notice, please do not hesitate to contact: Sherry Davidson, X-ray/Mammography Program Supervisor, 501-661-2922 or sheryl.davidson@arkansas.gov