# Office of Radiological Health
# X-RAY BULLETIN

ORH-708: Guidance for Inspections at Mammography Facilities
Reissued Dec. 5, 2018

The Virginia Department of Health's Radiation Protection Regulations provide for the scheduled and random unannounced inspections of facilities and physicians' offices that provide mammography services to ensure compliance with laws, regulations or conditions specified by the Board (12VAC5-481-370).

Currently the Virginia Department of Health (VDH) has a contract with the U.S. Food and Drug Administration (FDA) for VDH Inspectors to conduct an annual inspection of fully certified mammography facilities to ensure compliance with the federal mammography regulations. The federal regulations require state inspectors to provide the facility a notification of at least five days prior to the inspection date.

The VDH also regulates mammography machines as part of its X-ray Protection Program, independent of the federal Mammography Quality Standards Act of 1994. This means that mammography facilities are regulated by both federal and state governments. Under state law (*Code of Virginia* § 32.1-25), VDH has the right of inspection during usual business hours with the owner's consent. If entry is denied, VDH may seek an inspection warrant to conduct the inspection. Although state regulations for X-ray equipment may be more restrictive than federal regulations, it is the intent of VDH to implement regulations identical to the federal standards.

Certified mammography facilities may continue to expect VDH Inspectors to conduct an annual scheduled inspection to fulfill FDA requirements. The VDH may initiate other inspections, scheduled or unannounced, and may include provisionally certified facilities to ensure compliance with state regulations. The VDH shall at its discretion initiate an inspection based upon a citizen's complaint. In those cases where the state initiated the inspection, the VDH State inspector shall inform the facility that the inspection is a state inspection conducted at state expense. Non-compliance with the federal standards will be forwarded to the FDA for enforcement.

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Questions and comments should be directed to the X-Ray Program at (804) 864-8150.
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