

HANDHELD DENTAL X-RAY SYSTEM

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<http://www.house.mi.gov/hfa>

House Bill 5647 as introduced
Sponsor: Rep. Ben Frederick
Committee: Health Policy
Complete to 5-30-18

Analysis available at
<http://www.legislature.mi.gov>

SUMMARY:

House Bill 5647 would amend the Public Health Code to establish rules for the use of handheld dental X-ray systems.

Currently, under Part 135 (Radiation Control) of the Code, the Michigan Department of Licensing and Regulatory Affairs (LARA) regulates the use of radioactive materials and other sources of ionizing radiation.¹

The bill would prohibit use of a *handheld dental X-ray system* to perform dental radiography unless the machine is registered with LARA under applicable LARA rules and the system, personnel operating the system, and facility in which the system is being used meet all of the following requirements:

- The system has been approved for human use by the U.S. Food and Drug Administration (FDA) and is used consistently with that approval.
- The system has a backscatter shield that meets all of the following requirements:
 - The shield is composed of a leaded polymer or a lead-equivalent substance that has a substantially equivalent protective capacity.
 - The shield has at least 0.25 millimeters of lead or lead equivalent shielding, as determined by LARA.
 - The shield is permanently affixed to the system.
- The system is certified by its manufacturer before its first use and is recertified at least every 24 months after the date of the last certification.
- When not in use, the system is stored in a manner that restricts access to the system, such as by storing the system in a locked area of the facility.
- Each individual who operates the system is an individual who is authorized to operate a dental radiography machine as required in Part 166 of the Code, which governs dentistry. (An individual using the machine need not use a lead apron or other personal monitoring equipment, but that equipment must be available for use.)
- The equipment may not be used if the backscatter shield described above is broken.

The bill would define a *handheld dental X-ray system* as an X-ray system that is used to take radiographs, is designed to be handheld during its operation, and is portable.

The bill would take effect 90 days after enactment.

MCL 333.13521 and proposed MCL 333.13527

¹ Executive Reorganization Order 1996-1 transferred authority over the regulation of the radiation machine licensing and registration program from the Department of Health and Human Services (DHHS) to the Department of Commerce, the predecessor of LARA. <http://legislature.mi.gov/doc.aspx?mcl-330-3101>

FISCAL IMPACT:

House Bill 5647 would not have a fiscal impact on any unit of state or local government.

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■ This analysis was prepared by nonpartisan House Fiscal Agency staff for use by House members in their deliberations, and does not constitute an official statement of legislative intent.