

HANDHELD DENTAL X-RAY SYSTEM

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

House Bill 5647 as enacted
Public Act 544 of 2018
Sponsor: Rep. Ben Frederick
House Committee: Health Policy
Senate Committee: Health Policy
Complete to 3-15-19

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 0.5 millimeters of lead or lead equivalent shielding, as determined by LARA.
 - The shield is permanently affixed to the system.
- The system is calibrated by its manufacturer before its first use and is recalibrated at least every 24 months after the date of the last calibration.
- 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 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 if it is determined that the use of the system complies with state safety and health standards for radiation (or equivalent federal standards),² personal protective

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>

²According to Part 381 of the Michigan Occupational Safety and Health Administration (MIOSHA) Occupational Health Standards; http://dmbinternet.state.mi.us/DMB/ORRDocs/AdminCode/440_10415_AdminCode.pdf

equipment (or equivalent federal standards),³ occupational dose limits of radiation,⁴ and required surveys and monitoring of radiation dosage.⁵ However, a lead apron or other equipment must be available for use.)

- The equipment may not be used if the backscatter shield described above is broken, missing, or malfunctioning.

Under the bill, a handheld X-ray system that met these requirements could be used for routine dental radiography in a dental office or a situation where it was impractical to transfer a patient to a stationary radiation machine.

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

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.

³According to Part 33 of the MIOSHA General Industry Safety and Health Standards;
http://dmbinternet.state.mi.us/DMB/ORRDocs/AdminCode/1729_2017-053LR_AdminCode.pdf

⁴ According to Rule 57 of the Ionizing Radiation Rules Governing the Use of Radiation Machines;
http://dmbinternet.state.mi.us/DMB/ORRDocs/AdminCode/1305_2013-107LR_AdminCode.pdf

⁵ According to Rules 63 to 65 of the Ionizing Radiation Rules Governing the Use of Radiation Machines;
http://dmbinternet.state.mi.us/DMB/ORRDocs/AdminCode/1305_2013-107LR_AdminCode.pdf