333.13527.added Use of handheld dental X-ray system; registration requirements; "handheld dental X-ray system" defined.

Sec. 13527. (1) A person shall not use a handheld dental X-ray system to perform dental radiography unless the machine is registered with the department under department rules for registration of radiation machines and the system, the personnel operating the system, and the facility in which the system is used meet all of the following requirements:

(a) The system has been approved for human use by the United States Food and Drug Administration and is used in a manner consistent with that approval.

(b) The system has a backscatter shield that meets all of the following requirements:

(i) The shield is composed of a leaded polymer or a lead-equivalent substance that has a substantially equivalent protective capacity.

(ii) The shield has at least 0.5 millimeters of lead or lead-equivalent shielding, as determined by the department.

(iii) The shield is permanently affixed to the system.

(c) 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.

(d) 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.

(e) Each individual who operates the system is an individual who is authorized to operate a dental radiography machine pursuant to rules promulgated under part 166. An individual operating the system is not required to wear a lead apron or other personal monitoring equipment while operating the system if it is determined that the use of the system is in compliance with part 381 of the Michigan occupational safety and health administration occupational health standards, R 325.60601a to R 325.60618 of the Michigan Administrative Code, or equivalent federal occupational safety and health standards; part 33 of the Michigan occupational safety and health administration general industry safety and health standard, R 408.13301 to R 408.13395g of the Michigan Administrative Code, or equivalent federal occupational safety and health standards; R 333.5057 of the Michigan Administrative Code; and R 333.5063 to R 333.5065 of the Michigan Administrative Code. Upon request, a registrant shall make a lead apron or other personal monitoring equipment available to an individual who operates the system.

(f) The system is not used if the backscatter shield described in subdivision (b) is broken, missing, or malfunctioning.

(2) A handheld dental X-ray system that meets the requirements described in this section may be used for routine dental radiography in a dental office or a situation in which it is impractical to transfer a patient to a radiation machine that is stationary.

(3) As used in this section, "handheld dental X-ray system" or "system" means an X-ray system that is used to take radiographs, is designed to be handheld during its operation, and is portable.