

DEPARTMENT OF LABOR AND ECONOMIC OPPORTUNITY

DIRECTOR'S OFFICE

IONIZING RADIATION RULES GOVERNING THE USE OF RADIATION
MACHINES

Filed with the secretary of state on September 28, 2020

These rules take effect immediately upon filing with the secretary of state unless adopted under section 33, 44, or 45a(6) of the administrative procedures act of 1969, 1969 PA 306, MCL 24.233, 24.244, or 24.245a. Rules adopted under these sections become effective 7 days after filing with the secretary of state.

(By authority conferred on the director of the department of labor and economic opportunity by sections 13515, 13521, 13522, and 13527 of the public health code, 1978 PA 368, MCL 333.13515, 333.13521, 333.13522, and 333.13527 and Executive Reorganization Order Nos. 1996-1, 1996-2, 2003-1, 2011-4, and 2019-3, MCL 330.3101, 445.2001, 445.2011, 445.2030, and 125.1998)

R 333.5396 of the Michigan Administrative Code is amended, as follows:

HAND-HELD PORTABLE DENTAL X-RAY SYSTEMS

R 333.5396 Hand-held portable dental x-ray systems.

Rule 396. (1) 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.

(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) X-ray equipment designed to be hand-held must meet the requirements of R 333.5373, excluding subrules (9) and (13).

(4) The x-ray tube housing for tubes designed to be hand-held must be constructed so that the leakage radiation measured in air at a distance 5 centimeters from a point on the external surface does not exceed 0.02 mGy (2 milliroentgens) in 1 hour when operated under conditions of maximum radiation output permitted by the design or operating characteristics of the radiation machine.

(5) Operation of a hand-held portable x-ray system must meet the requirements of R 333.5376, excluding subrules (3) and (6).

(6) 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.

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- (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 of the act, MCL 333.16601 to 333.16659.
 - (f) 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 general industry safety and health standards, R 325.60601a to R 325.60618, 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, or equivalent federal occupational safety and health standards; R 333.5057; and R 333.5063 to R 333.5065. However, upon request, a registrant shall make a lead apron or other personal monitoring equipment available to an individual who operates the system.
 - (g) The system is not used if the backscatter shield described in subdivision (b) of this subrule is broken, missing, or malfunctioning.
- (7) An operator shall complete the training program supplied by the manufacturer and approved by the department before using the x-ray unit. Records of the training shall be maintained on file for examination by the department.