

X-ray Unit Information Notice

HAND-HELD DENTAL X-RAY EQUIPMENT

Date:	July 1, 2017
То:	Dental Registrants in Minnesota
From:	Teresa Purrington, BS, RT (R) (CT), Supervisor, X-ray Program
Subject:	Hand-Held Dental X-ray Equipment

The Minnesota Department of Health (MDH) is issuing this Information Notice (IN) to inform dental registrants of recent law changes involving the use of hand-held dental x-ray equipment for human use. The 2017 Legislature authorized the use of hand-held dental x-ray equipment beginning July 1, 2017. See Laws 2017, 1st special session, Chapter 6, Article 10, Section 58.

Minnesota Statutes, section 144.1215 [new] specifies hand-held dental x-ray equipment requirements and operators who are authorized according to Minnesota Statutes, Chapter 150A. In addition to these statutory requirements, a registrant must also comply with applicable Minnesota Rules, Chapter 4732.

Minnesota Rules, Chapter 4732

Applicable rules required for hand-held dental x-ray equipment registrants.

- Registration requirements listed under part <u>4732.0200</u>. Hand-held dental x-ray equipment must be maintained at the registrant's facility with the person having administrative control of the x-ray equipment.
- Registration fees under part <u>4732.0210</u>.
- General requirements under part <u>4732.0220, Subp.1 & 2</u>.
- Reciprocity use outlined in part <u>4732.0250</u>.
- Exemptions listed in part <u>4732.0300</u>.
- Applicable prohibited uses listed in <u>4732.0305</u>.
- Unauthorized requirements listed in part <u>4732.0306, Items B, D, & E</u>.
- General administration requirements under parts <u>4732.0308</u>, <u>4732.0310</u>, <u>4732.0315</u>, and <u>4732.0320</u>.
- Record requirements under part <u>4732.0330</u>.

A registrant who currently has a variance to use hand-held dental x-ray equipment in Minnesota must complete records required under the variance through June 30, 2017 and must maintain the records for review at the registrant's next inspection.

- Inspection and enforcement requirements in parts <u>4732.0335</u> and <u>4732.0340</u>.
- Radiation dose levels and individuals monitoring requirements of parts <u>4732.0400</u> through parts <u>4732.0440</u>. Dosimetry is required for individuals who are likely to receive greater than 500 mRem occupational dose in a year.

- Safety and radiation safety officer responsibilities in parts <u>4732.0500</u> and <u>4732.0505</u>. A registrant must identify a radiation safety officer and the individual is responsible for the operation of the hand-held dental x-ray equipment under the registrant's administrative control.
- Procedures and safety instructions under part <u>4732.0510</u>.
- Quality assurance and ALARA program requirements under parts <u>4732.0520</u> and <u>4732.0530</u>.
- Annually review a registrant program with a program audit listed in part <u>4732.0540</u>.
- Requirements under parts <u>4732.0550</u> for radiographic practice standards, <u>4732.0555</u> for x-ray equipment processing, <u>4732.0560</u> for ordering of radiographic procedures, and <u>4732.0580</u>, Item C.
- A registrant must report and notify to MDH immediately after the theft of the hand-held dental x-ray equipment is known according to part <u>4732.0600</u>.
- Calibration requirements under parts <u>4732.0700, Subparts 1, 3, & 4</u>.
- General equipment requirements listed in part <u>4732.0800</u>, excluding Subpart 2, Item B.
- Requirements for intraoral dental radiographic systems listed in part <u>4732.0880</u>, excluding Subpart 2, Item C. An individual who is operating the hand-held dental x-ray equipment must be protected by a personal protective garment.
- Hand-held dental x-ray equipment must be calibrated according to parts <u>4732.1100</u>, <u>Subparts 1, 2 & 11</u>.

For specific questions related to hand-held dental x-ray equipment use, please contact Craig Verke at (651) 201-4533 or Teresa Purrington at (651) 201-4519.

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DEPARTMENT OF HEALTH

2017 Handheld Dental X-ray Legislation

Laws 2017, 1st special session, Chapter 6, Article 10, Section 58

Sec. 58. [144.1215] AUTHORIZATION TO USE HANDHELD DENTAL X-RAY EQUIPMENT.

Subdivision 1. Definition; handheld dental x-ray equipment. For purposes of this section, "handheld dental x-ray equipment" means x-ray equipment that is used to take dental radiographs, is designed to be handheld during operation, and is operated by an individual authorized to take dental radiographs under chapter 150A.

Subd. 2. Use authorized. (a) Handheld dental x-ray equipment may be used if the equipment:

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

(2) utilizes a backscatter shield that:

(i) is composed of a leaded polymer or a substance with a substantially equivalent protective capacity;

(ii) has at least 0.25 millimeters of lead or lead-shielding equivalent; and

(iii) is permanently affixed to the handheld dental x-ray equipment.

(b) The use of handheld dental x-ray equipment is prohibited if the equipment's backscatter shield is broken or not permanently affixed to the system.

(c) The use of handheld dental x-ray equipment shall not be limited to situations in which it is impractical to transfer the patient to a stationary x-ray system.

(d) Handheld dental x-ray equipment must be stored when not in use, by being secured in a restricted, locked area of the facility.

(e) Handheld dental x-ray equipment must be calibrated initially and at intervals that must not exceed 24 months. Calibration must include the test specified in Minnesota Rules, part 4732.1100, subpart 11. 2017 HANDHELD DENTAL X-RAY EQUIPMENT LEGISLATION

(f) Notwithstanding Minnesota Rules, part 4732.0880, subpart 2, item C, the tube housing and the position-indicating device of handheld dental x-ray equipment may be handheld during an exposure.

Subd. 3. Exemptions from certain shielding requirements. Handheld dental x-ray equipment used according to this section and according to manufacturer instructions is exempt from the following requirements for the equipment:

(1) shielding requirements in Minnesota Rules, part 4732.0365, item B; and

(2) requirements for the location of the x-ray control console or utilization of a protective barrier in Minnesota Rules, part 4732.0800, subpart 2, item B, subitems (2) and (3), provided the equipment utilizes a backscatter shield that satisfies the requirements in subdivision 2, paragraph (a), clause (2).

Subd. 4. Compliance with rules. A registrant using handheld dental x-ray equipment shall otherwise comply with Minnesota Rules, chapter 4732.

Effective July 1, 2017.

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