X-ray Unit Information Notice
HAND-HELD DENTAL X-RAY EQUIPMENT

Date: July 1, 2017
To: 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 4732.0200. 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 4732.0210.
- General requirements under part 4732.0220, Subp.1 & 2.
- Reciprocity use outlined in part 4732.0250.
- Exemptions listed in part 4732.0300.
- Applicable prohibited uses listed in 4732.0305.
- Unauthorized requirements listed in part 4732.0306, Items B, D, & E.
- General administration requirements under parts 4732.0308, 4732.0310, 4732.0315, and 4732.0320.
- Record requirements under part 4732.0330.

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 4732.0335 and 4732.0340.
- Radiation dose levels and individuals monitoring requirements of parts 4732.0400 through parts 4732.0440. 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 4732.0500 and 4732.0505. 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 4732.0510.

Quality assurance and ALARA program requirements under parts 4732.0520 and 4732.0530.

Annually review a registrant program with a program audit listed in part 4732.0540.

Requirements under parts 4732.0550 for radiographic practice standards, 4732.0555 for x-ray equipment processing, 4732.0560 for ordering of radiographic procedures, and 4732.0580, 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 4732.0600.

Calibration requirements under parts 4732.0700, Subparts 1, 3, & 4.

General equipment requirements listed in part 4732.0800, excluding Subpart 2, Item B.

Requirements for intraoral dental radiographic systems listed in part 4732.0880, 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 4732.1100, Subparts 1, 2 & 11.

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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To obtain this information in a different format, call: 651-201-4545.
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.
(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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