DEPARTMENT OF HEALTH

Hand-held Dental X-ray Systems Revision

4732.#### HAND-HELD DENTAL INTRAORAL X-RAY SYSTEMS.

Subpart 1. **Applicability**. A registrant's hand-held intraoral x-ray system must meet the requirements of Minnesota Statutes, section 144.1215, this chapter, and must:

A. meet nationally recognized standards such as Code of Federal Regulations, title 21, sections 1020, or successor requirements; or

B. meet the manufacturer's specifications; and

C. follow calibration testing under subpart 8.

X-ray Equipment

Subp. 2. **Beam quality; half-value layer.**

A. The half-value layer of the useful beam for a given kVp must not be less than the values shown in item C.

B. If it is necessary to determine a half-value layer at a kVp that is not listed under item C. then a service provider must:

(1) make a linear interpolation or extrapolation; and

(2) include the determination in the calibration report under part 4732.0280.

Commented [JC1]: Based on part 4732.0880.

Commented [JC(2]: *See* Laws 2017, Chapter 6, Article 10, Section 58

Commented [JC(3]: From: 4732.0800, subp. 6 **(GENERAL EQUIPMENT REQUIREMENTS FOR ALL DIAGNOSTIC RADIATION-PRODUCING SYSTEMS; Beam quality, half-value layer)**

Additional language from SSRCR that was not included:

Positive means shall be provided to ensure that at least the minimum filtration needed to achieve beam quality requirements is in the useful beam during each exposure. In the case of a system, which is to be operated with more than one thickness of filtration, this requirement can be met by a filter interlocked with the kilovoltage selector which will prevent x-ray emissions if the minimum required filtration is not in place. (21 CFR 1020.30)

Commented [JC(4]: MDH will update this internal reference to 4732.0280 - SERVICE PROVIVDER'S RESPONSIBILITY.

For purposes of this subpart, half-value layer means the thickness of a specified material that absorbs the beam of radiation to such an extent that the exposure rate is reduced to one-half of its original value. The contribution of all scattered radiation, other than any that might be present initially in the beam concerned, is considered excluded.

Commented [JC(5]: Defined term in Definitions is incorporated in rule part as discussed.

C. Values for half-value layer of useful beam for x-ray tube:

Design operating range (kVp)	Measured kVp	Half-value layer (millimeter of aluminum) Other x-ray Systems*	Specified Dental Systems
Below 50	30	0.3	1.5
	40	0.4	1.5
	50	0.5	1.5
51-70	51	1.2	1.5
	60	1.3	1.5
	70	1.5	1.5
Above 70	71	2.1 [2.5]	2.1
	80	2.3 [2.9]	2.3
	90	2.5 [3.2]	2.5
	100	2.7 [3.6]	2.7
	110	3.0 [3.9]	3.0
	120	3.2 [4.3]	3.2
	130	3.5 [4.7]	3.5
	140	3.8 [5.0]	3.8
	150	4.1 [5.4]	4.1

*Systems manufactured after June 10, 2006, are in brackets. All other systems were manufactured before June 10, 2006.

B. All hand-held dental intraoral x-ray systems must have a minimum half-value layer not less than 1.5 millimeters aluminum.

C. For capacitor energy storage equipment, compliance with the requirements of this subpart must be determined **[by a service provider]** with the capacitors fully charged and with a technique that discharges at least half of the energy stored in the capacitors, half of the maximum milliampere-second.

D. The half-value layer of the useful beam must be measured **[by a service provider]** with all the materials in the beam that normally are present between the source and the patient.

Subp. 3. **X-ray beam alignment.** A registrant is responsible for the x-ray beam alignment provisions of this subpart.

A. A hand-held x-ray system designed for use with an intraoral image receptor must limit the source-to-skin distance (SSD) to not less than 18 centimeters.

B. The x-ray field at the minimum source-to-skin distance must be contained in a circle in which the diameter does not exceed 7 centimeters.

Subp. 4. **Mechanical support of tube housing assembly and position-indicating device.** A registrant using a hand-held dental x-ray system is responsible for the requirements of this subpart. The tube housing assembly and the position-indicating device must be:

A. stable before the exposure is initiated and during the exposure;

B designed to operate while hand-held; and

C. may be held by the tube housing support or by the handle.

Commented [JC(6]: Items B, C, and D are from 21 CFR 1020 and taken directly from SSRCR.

MDH Note:
These equipment requirements are very technical and the responsibility of these provisions is more applicable to a service provider. MDH may move these provisions to a part that is specific to Service Provider requirements.

We are looking for feedback on: (1) the utility of these provisions; and (2) placement of these provisions within the chapter.

Commented [JC(7]: Service Provider focus group:
Is this relevant?

Commented [JC(8]: Replaces existing 4732.0800, subp. 5. **(GENERAL EQUIPMENT REQUIREMENTS FOR ALL DIAGNOSTIC RADIATION-PRODUCING SYSTEMS; Diagnostic radiographic systems designed for one image receptor size.)**
Consistent with *SSRCR, Part F, p. 51*.

Item A – 21 CFR 1020.31(i)(1)
Item B – 21 CFR 1020.31(f)(1)(i)

Commented [JC9]: From Proposed 4732.0880, subp. 2, item C

Adding "assembly" to "tube housing". Consistent with SSRCR and Definitions.

Commented [JC(10]: Definitions part because it was not used in the rule chapter. Recent legislation uses this term and so we are including it.

Commented [JC(11]: *See* Laws 2017, Chapter 6, Article 10, Section 58

Subp. 5. **Radiation exposure control.** A registrant is responsible for the radiation exposure control provisions of this subpart.

A. The x-ray control switch must:

(1) have a circuit-closing contact that requires a deliberate action and continuous pressure by an x-ray operator to complete the exposure; and

(2) be able to terminate the exposure at a preset time or interval.

B. The hand-held dental intraoral dental x-ray system must bear the warning statement which is legible and accessible to view: "WARNING This x-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions, and maintenance schedules are observed."

Subp. 6. **Beam-on indicators.** A registrant is responsible for the beam-on indicator provisions of this subpart.

A. A visual indication that is observable at or from the x-ray operator's protected position whenever x-rays are produced; and

B. a signal that is audible to the x-ray operator that the exposure has terminated.

Subp. 7. **Technique factors.** A registrant is responsible for the technique factor provisions of this subpart.

A. The technique factors on a hand-held x-ray system must be indicated55and visible to an x-ray operator before the exposure begins.

Commented [JC12]: 1. Adding "circuit-closing contact" to update and replace "dead-man type". *(Michigan provision – 333.5373 (12))*
2. Adding "a deliberate action". Consistent with SSRCR provision (*Part F, p. 49)*
3. Adding "by an x-ray operator". Specifies who is doing the action and consistent with both SSRCR and Michigan administrative code.
4. Adding subitem 2 – consistent with both SSRCR and Michigan administrative code.

Commented [JC13]: From 4732.0800, subp. 2, item D. (**GENERAL EQUIPMENT REQUIREMENTS FOR ALL DIAGNOSTIC RADIATION-PRODUCING SYSTEMS; Radiation exposure x-ray control.)**
No change.

Commented [JC(14]: From 4732.0800, subp. 2, Items C & F.
(**GENERAL EQUIPMENT REQUIREMENTS FOR ALL DIAGNOSTIC RADIATION-PRODUCING SYSTEMS; Radiation exposure x-ray control.)**
No changes – consistent with *SSRCR, Part F, p. 50.*

Commented [JC(15]: Specifying provisions for technique factors that were not part of 4732.0800, subp. 2.
(**GENERAL EQUIPMENT REQUIREMENTS FOR ALL DIAGNOSTIC RADIATION-PRODUCING SYSTEMS; Radiation exposure x-ray control.)**
From *SSRCR, Part F, p. 50*

B. If automatic exposure controls are used, the technique factors that are set before the exposure must be indicated and visible to an x-ray operator.

C. The requirements of items A and B may be met by permanent markings on intraoral dental x-ray systems that have fixed technique factors.

D. The technique chart used for all radiographic exposures must meet the requirements under part 4732.0550.

Subp. 8. **Calibrations.** A registrant using a handheld dental intraoral x-ray system is responsible for the calibration testing requirements of this subpart. Calibration testing must be performed:

A. at the time of installation before first use;

B. over all clinical ranges used by the registrant; and

C. at intervals not to exceed 24 months (730 calendar days) from the date of prior calibration testing.

D. A registrant may have a grace period of 30 calendar days to comply with calibration testing under this subpart. A registrant is in violation of item C if the calibration testing interval exceeds 760 calendar days.

E. CALIBRATION PERFORMANCE CRITERIA.

	TEST TYPE	MINIMUM PERFORMANCE CRITERIA
(1)	Filtration (HVL)	Meet requirements in subpart 2

Commented [JC(16]: From *SSRCR, Part F, p. 50*

Commented [JC(17]: From *SSRCR, Part F, p. 50*

Commented [JC(18]: MDH will update this internal reference to part 4732.0550 – RADIOGRAPHIC PRACTICE STANDARDS.

Commented [JC19]: Subp. 8 is comprised of 4732.1100, subparts 1, 2, and 11
INSTALLATION CALIBRATION TESTS AND EQUIPMENT PERFORMANCE TESTS FOR A QUALITY ASSURANCE PROGRAM.

Commented [JC(20]: This is based on existing 4732.1100, subpart 1, Item B, and combines subp. 2 (Frequency of tests.)

(2)	Timer reproducibility	± 10% of indicated timer setting
(3)	kVp accuracy	± 5% of indicated kVp for equipment manufactured before 1973. For equipment manufactured after 1973, follow manufacturer's specified limits
(4)	Exposure output reproducibility	Coefficient of variation < 5%
(5)	Dental mA linearity	± 10% over the clinical range

F. A service provider must make adjustments to the handheld dental intraoral x-ray system to meet the requirements under with subpart 1.

Commented [JC(21]: Based on existing 4732.1100, subpart 1, Item A

Shielding

Subp. 9. **Shielding requirements.** A registrant operating an intraoral hand-held dental x-ray system must:

Commented [JC22]: Proposed 4732.0365, subp. 1
Proposed 4732.0365, subp. 2, items A & B
Consistent with SSRCR

A. maintain the dose levels so that they do not exceed the limits under parts 4732.0410 to 4732.0430;

Commented [JC23]: MDH will update the internal references to these DOSE LEVELS provisions.

B. meet the requirements under Minnesota Statutes, section 144.1215, subdivision 2, paragraph (a)(2); and

Commented [JC24]: *See* Laws 2017, Chapter 6, Article 10, Section 58

C. provide protective barriers that are at least 2 meters (6.5 feet) in height or maintain at least 6 feet (1.8 meters) distance from adjacent room or area.

Commented [JC25]: Consistent with SSRCR

Subp. 10. **Shielding exemption.** A registrant with only an intraoral hand-held dental x-ray system and complies with subpart 9 is exempt from the requirements under part 4732.0000.

Commented [JC(26]: From: 4732.0220, subp. 4 (GENERAL REQUIREMENTS FOR ALL FACILITIES; Exemption.)

Commented [JC(27]: MDH will update internal reference to Shielding Requirements.

Conditions of Operation

Subp. 11. **Prohibited uses.** An individual must not be exposed to the useful beam except for healing arts purposes. Deliberate exposure is prohibited for:

Commented [JC(28]: Replaces 4732.0305, subp. 1, item A (Prohibited Uses).
Based on *SSRCR Part F, p. 18*
Will move this to General Requirements for all registrants.

A. training;

B. demonstration;

C. or other non-healing arts purposes.

Subp. 12. **Ordering of diagnostic radiographic examinations.** A registrant is exempt from the provisions of part 4732.0560 if the registrant has a written procedure for ordering dental examinations that:

Commented [JC(29]: This subpart contains revisions to part 4732.0560, subpart 3, that were provided by Board of Dentistry and agreed upon by the Dental Focus Group.

Commented [JC(30]: MDH will update this internal reference to 4732.0560 (**ORDERING OF DIAGNOSTIC RADIOGRAPHIC OR THERAPEUTIC PROCEDURE)**

A. is authorized and signed by a dentist who is licensed under Minnesota Statutes, chapter 150A; and

B. uses evidence-based radiological guidelines for patients that include one or more of the following:

(1) type and frequency of examination;

(2) risk for oral disease;

(3) age of patient; and

(4) stage of dental development.

Subp. 13. **Utilization data.** A registrant performing hand-held dental imaging examinations must maintain utilization data, in electronic or written form, including:

A. a patient identifier;

B. the type of examination;

C. the date the examination was performed;

D. the x-ray operator who is operating the x-ray system;

E. the name of all individuals who remain in the room during an x-ray examination; and

F. the name of all student externs if the registrant is an externship site under part 4732.0590.

Subp. 14. **Operator protection.** A registrant is responsible for the operator protection requirements in this subpart.

A. Occupational staff must not hold an image receptor in place by using their fingers.

B. An x-ray operator must:

(1) remain behind a protective barrier; or

Commented [JC(31]: Will move to General Requirements part.

Commented [JC32]: MDH will update this internal reference to 4732.0590 - **INDIVIDUALS OPERATING X-RAY EQUIPMENT DURING TRAINING.**

Commented [JC(33]: From - 4732.0880, subp. 2, item B (INTRAORAL DENTAL RADIOGRAPHIC SYSTEMS; Safety Controls)

(2) be at least six feet (or 1.8 meters) from the patient and the tube housing assembly; and

(3) not be in the path of the primary beam during an exposure.

C. Except for the patient, all individuals who remain in the room during an x-ray exposure must be protected by a minimum of 0.50 millimeter lead equivalent personal protective equipment.

Subp. 15. **Safety controls.** A registrant is responsible for the safety control provisions in this subpart.

A. The useful beam must be limited to the patient's area of clinical interest.

B. Intraoral film holders and bite blocks must be used except when endodontic procedures do not permit.

C. Occupational staff must not hold an image receptor in place by using their fingers.

D. A registrant must store an intraoral handheld dental x-ray system when not in use according to Minnesota Statutes, section 144.1215, subdivision 2, paragraph (d).

E. A registrant must notify the commissioner of the theft or loss of a dental hand-held intraoral x-ray system according to 4732.0600.

Subp. 16. **Quality control procedures.** A registrant using a digital imaging receptor must:

Commented [JC(34]: 1. 2m or 6.5 ft is SSRCR. We are staying with 6 feet.
2. Replacing "x-ray tube" with "tube housing assembly"

Commented [JC(35]: From - *Proposed 4732.0365, subp. 3, Item C.* No changes.

Commented [JC(36]: From - Proposed 4732.0365, subp. 1

Commented [JC(37]: From - *Proposed 4732.0365, subp. 3, Item C.* No changes.

From 4732.0880, subp. 2, item A (INTRAORAL DENTAL RADIOGRAPHIC SYSTEMS; Safety Controls)

Commented [JC(38]: From 4732.0880, subp. 2, item A (INTRAORAL DENTAL RADIOGRAPHIC SYSTEMS; Safety Controls)

Commented [JC(39]: From - 4732.0880, subp. 2, item B (INTRAORAL DENTAL RADIOGRAPHIC SYSTEMS; Safety Controls)

Commented [JC40]: *See* Laws 2017, Chapter 6, Article 10, Section 58

Commented [JC(41]: MDH will update the internal reference to 4732.0600 - **REPORTS OF THEFT OR LOSS OF RADIATION-PRODUCING EQUIPMENT.**

A. comply with the quality control recommendations provided by the digital imaging receptor manufacturer;

B. maintain quality control recommendations, tests, and evaluations for:

(1) use by an x-ray operator; and

(2) review by the commissioner at the time of inspection.

Subp. ##. **Records.**

Commented [JC(42]: There will one Records provision for all registrants.