DEPARTMENT OF HEALTH

Dental Intraoral X-ray Systems

PROPOSED REVISIONS TO 4732.XXXX, 2.0

4732.#### **DENTAL INTRAORAL X-RAY SYSTEMS; STATIONARY AND MOBILE.**

Subpart 1. **Applicability.** A registrant's x-ray system used for stationary and mobile intraoral dental imaging must meet the applicable performance standards in Code of Federal Regulations, title 21, section 1020.30 to 1020.40, or successor requirements.

X-ray Equipment

Subp. 2. **X-ray beam alignment.** A registrant is responsible for the x-ray beam alignment provisions of this subpart.

A. An 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. 3. **Mechanical support of the tube housing assembly and position-indicating device.** A registrant using an intraoral dental x-ray system is responsible for the requirements of this subpart. The tube housing assembly and the position-indicating device must:

A. not be hand-held during an exposure; and

B. remain stable during the exposure.

Commented [JC(1]: Based on part 4732.0880.

Commented [JC(2]: 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 - CFR 1020.31(i)(1)
Item B - 21CFR1020.31(f)(1)(i)

Commented [JC(3]: From Proposed 4732.0880, subp. 2, item C.
Adding "assembly" to "tube housing". Consistent with SSRCR and Definitions.

Subp. 4. **Radiation exposure control.** A registrant is responsible for the radiation exposure control provisions of this subpart.

A. An x-ray control must:

(1) be incorporated into each x-ray system so that an exposure can be terminated by a qualified operator at any time.; and

(2) be of the continuous pressure type.

(3) bear the warning statement under 21 CFR 1020 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.", or successor requirements.

Subp. 5. **Beam-on indicators.** A registrant is responsible for the beam-on requirements of this subpart.

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

B. A signal that is audible to the qualified operator that the exposure has terminated.

Subp. 6. **Technique factors.** A registrant is responsible for the technique factor requirements of this subpart.

Commented [JC(4]: Based on Texas administrative code
3. Adding "by a qualified operator". Consistent with both SSRCR and Michigan administrative code.
4. Adding subitem 2 – consistent with both SSRCR and Michigan and Texas administrative code.

Commented [JC(5]: From 4732.0800, subp. 2, item D. (**GENERAL EQUIPMENT REQUIREMENTS FOR ALL DIAGNOSTIC RADIATION-PRODUCING SYSTEMS; Radiation exposure x-ray control.)** No change
Based on 21 CFR 1020

Commented [JC(6]: 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(7]: 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*

A. The technique factors on manual and automatic exposure control x-ray systems must be:

(1) indicated; and

(2) visible to a qualified operator before the exposure begins.

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

C. An electronic or written chart must be available at the control panel. The chart must identify the kVp, mA, time, and image receptor used for:

(1) anterior region, posterior region, and bitewing; and

(2) adult and pediatric.

Subp. 7. **Equipment performance evaluation; testing requirements; frequency.** A registrant using a dental intraoral x-ray system is responsible for the equipment performance evaluation testing requirements under subparts 7 to 11.

A. A registrant must have equipment performance evaluation testing performed over all clinical ranges used by the registrant.

B. Initial equipment performance evaluation testing must be performed at installation before first patient use by a qualified service provider.

Commented [JC(8]: From *SSRCR, Part F, p. 50* Item A is consistent with FDA 1020.31 (a) and Texas Administrative Code

Commented [JC(9]: From *SSRCR, Part F, p. 50* Item B is consistent with FDA, TX, and SSRCR, p. F 24.

Commented [JC(10]: Item C based on a sample technique chart in Texas guidance, Appendix C, and American Dental Association and FDA recommendations for Technique Chart/Protocols.

Commented [JC(11]: Subp. 7 comprised of 4732.1100, subparts 1, 2, and 11 - **INSTALLATION CALIBRATION TESTS AND EQUIPMENT PERFORMANCE TESTS FOR A QUALITY ASSURANCE PROGRAM.**

Commented [JC(12]: Based on existing 4732.1100, subpart 1, Item B, and combines subp. 2 (Frequency of tests.)

C. Periodic equipment performance evaluation testing must be performed at intervals not to exceed 24 months (730 calendar days) from the date of the previous equipment performance evaluation. A registrant may have a grace period of 30 calendar days to comply with the periodic equipment performance evaluation testing interval requirement under this item.

D. Equipment performance evaluation testing must be performed by a qualified service provider.

E. If a registrant's dental intraoral x-ray system fails to meet any of the equipment performance evaluation testing under subparts 8 to 11, then a registrant must:

(1) not use the dental intraoral x-ray system; and

(2) have a qualified service provider calibrate the dental intraoral x-ray system so that the operating parameter complies with this part.

Commented [JC(13]: Based on existing 4732.1100, subpart 1, Item A.

Based on existing 4732.1100, subpart 1, Item A. MDH intends to require a comparable qualified service provider requirement to calibrate equipment into proper working condition as specified in item F.

Commented [JC(14]: From 4732.0520, subp. 1, item E.

Subp. 8. **Equipment performance evaluation; filtration (half-value layer) test.**

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

Commented [JC(15]: Based on 4732.0800, subp. 6 (**GENERAL EQUIPMENT REQUIREMENTS FOR ALL DIAGNOSTIC RADIATION-PRODUCING SYSTEMS; Beam quality, half-value layer)**

B. 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

D. All dental intraoral x-ray systems installed on and after December 1, 1980, must have a minimum half-value layer not less than 1.5 millimeters of aluminum.

E. For capacitor energy storage equipment, compliance with the requirements of this subpart must be determined 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.

F. The half-value layer of the useful beam must be measured with all the materials in the beam that normally are present between the source and the patient.

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.

Subp. 9. **Equipment performance evaluation; timer test.**

A. The accuracy of the timer must meet the manufacturer's specifications.

B. The manufacturer specifications required under item A must be available for:

(1) use by a qualified service provider; and

Commented [JC(17]: MDH to ask Qualified Service Provider focus group if items E and F are relevant.

Commented [JC(18]: Defined term in Definitions is incorporated in rule part as discussed.
**HVL language is consistent with SSRCR.*

Commented [JC(19]: Reviewed UT, IN, FL, CO, NC, TX (232-61)
*Consistent with UT and NC.
Subp. 9 based on Texas §289.232(i)(6)(H) (p. 65). This also the same as FDA (21 CFR 1020.31(a)(2).

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

C. If the manufacturer specifications under item B are not available, then the timer accuracy must be ±10 percent of the indicated time with testing performed at 0.5 second.

D. Means must be provided to terminate the exposure at:

(1) a preset time interval;

(2) a preset product of current and time;

(3) a preset number of pulses; or

(4) a preset radiation exposure to the image receptor.

E. It must not be possible to make an exposure when the timer is set to a "zero" or "off" position, if either position is provided.

Subp. 10. **Equipment performance evaluation; kVp accuracy test.**

Commented [JC(20]: Based on Texas administrative code - §289.232(i)(6)(J) (p. 65).

A. A registrant's dental intraoral x-ray system must meet manufacturer's specifications for the kilovolt peak.

B. The manufacturer specifications required under items A and must be available for:

(1) use by a qualified service provider; and

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

C. If the manufacturer's specifications under item B are not available, then the indicated kilovolt peak of a registrant's dental intraoral x-ray system must be accurate to within ±10% of the indicated setting(s).

Subp. 11. **Equipment performance evaluation; exposure output reproducibility test.** When all technique factors are held constant, including control panel selections associated with automatic exposure control systems, the coefficient of variation of exposure for both manual and automatic exposure control systems must be less than or equal to 5%.

Commented [JC(21]: Reviewed comparable provisions from the following states: TX, IA, ME, NC. Craig prefers TX.

Shielding

Subp. 12. **Shielding requirements.** A registrant operating a stationary or a mobile dental intraoral x-ray system is responsible for the requirements of this subpart.

Commented [JC22]: Based on 4732.0365, subps. 1, 2 Consistent with SSRCR

A. maintain the dose levels so that they do not exceed the limits under parts 4732.#### to 4732.####;

Commented [JC(23]: MDH intends to update the internal reference to the proposed equivalent of parts 4732.0410 – 47320.430 - **DOSE LEVELS**.

B. provide protective barriers that are at least 6.5 feet (2 meters)in height or maintain at least 6 feet (1.8 meters) distance from the x-ray operator and the patient.

Commented [JC(24]: Consistent with SSRCR

Subp. 13. **Shielding plan exemption.** A registrant with only a dental intraoral x-ray system is exempt from the shielding plan requirements under part 4732.####.

Commented [JC(25]: From: 4732.0220, subp. 4 (GENERAL REQUIREMENTS FOR ALL FACILITIES; Exemption.)

Commented [JC(26]: MDH intends to update the internal reference to the proposed equivalent of part 4732.0360 - **Shielding Requirements**.

DEPARTMENT OF HEALTH

Conditions of Operation

Subp. 14. **Prohibited uses.** A registrant must not expose an individual to the useful beam except for healing arts purposes. [Deliberate] exposure to the useful beam is prohibited for:

A. training;

B. demonstration; or

C. other non-healing arts purposes.

Subp. 15. **Ordering of diagnostic radiographic examinations.** A registrant is exempt from the requirements of part 4732.#### if:

A. the registrant has a written procedure for ordering dental examinations;

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

C. the written procedure is available and on site for review by the commissioner.

Subp. 16. **Off-site use of mobile dental intraoral x-ray systems.** A registrant must document the date and location of a registrant's qualified operator's use of a mobile dental intraoral x-ray system when used off-site.

Subp. 17. **Qualified operator protection.** A registrant is responsible for the qualified operator protection requirements in this subpart.

A. A qualified operator must:

Commented [JC(27]: Replaces 4732.0305, subp. 1, item A (Prohibited Uses).
Based on SSRCR part F p. 18
MDH intends to move this to General Requirements for all registrants and add a comparable qualified service provider requirement.

Commented [JC(28]: Contains revisions to part 4732.0560, subpart 3, suggested by Board of Dentistry and agreed upon by Dental Focus Group.

MDH intends to update the internal reference to the proposed equivalent of part 4732.0560 (**ORDERING OF DIAGNOSTIC RADIOGRAPHIC OR THERAPEUTIC PROCEDURE)**

(1) remain behind a protective barrier; or

(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.

B. 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 apron.

Subp. 18. **Safety controls.** A registrant is responsible for the safety controls in this subpart.

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

B. Intraoral image receptor 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.

Subp. 19. **Film processing; dental registrants.**

A. A registrant using a dental intraoral x-ray system with an analog image receptor must:

(1) use only E-speed or F-speed film;

(2) have equipment for processing that meet the requirements of this subpart;

Commented [JC(29]: 6.5 ft. or 1.2m in SSRCR. MDH intends to stay with 6 ft (1.8m).
2. Replaced "x-ray tube" with "tube housing assembly"

Commented [JC(30]: From – 4732.0880, subp. 3a (new) Based on SSRCR, Part F, p. 48-49

Commented [JC(31]: From - 4732.0880, subp. 2 item D (INTRAORAL DENTAL RADIOGRAPHIC SYSTEMS; Safety Controls)

Commented [JC(32]: From 4732.0880, subp. 2, item A (INTRAORAL DENTAL RADIOGRAPHIC SYSTEMS; Safety Controls)

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

(3) use a dental radiographic normalizing and monitoring device, also referred to as a Crabtree device, when processing intraoral images. The film must be between 0.75 and 1.05 O.D. (optical density), or follow the Crabtree device manufacturer's recommendations;

(4) perform processing quality control testing daily before diagnostic films are processed; and

(5) document the results of processing quality control testing daily.

B. For manual processing of analog images, a registrant must:

(1) develop film according to the time-temperature relationships recommended by the film and chemistry manufacturers; or

(2) maintain the temperature of solutions in the tanks within the range of 60 degrees Fahrenheit to 80 degrees Fahrenheit (15.6 degrees Celsius to 26.7 degrees Celsius) according to the following time-temperature chart:

Time-Temperature Chart

Thermometer Reading Celsius	Thermometer Reading Degrees	Fahrenheit	Minimum Developing Time Degrees	(Minutes)
26.7		80		2
26.1		79		2
25.6		78		2-1/2
25.0		77		2-1/2
24.4		76		3
23.9		75		3

Thermometer Reading Celsius	Thermometer Reading Degrees	Reading Fahrenheit	Minimum Developing Time Degrees	(Minutes)
23.3		74		3-1/2
22.8		73		3-1/2
22.2		72		4
21.7		71		4
21.1		70		4-1/2
20.6		69		4-1/2
20.0		68		5
19.4		67		5-1/2
18.9		66		5-1/2
18.3		65		6
17.8		64		6-1/2
17.2		63		7
16.7		62		8
16.1		61		8-1/2
15.6		60		9-1/2

(3) use a thermometer to verify the actual temperature of the developer;

(4) use a timer for accurate development time;

(5) document daily the developer temperature before first patient use.

(6) maintain a copy of the film or developer manufacturer's recommendations for a qualified operator; and

(7) have the manufacturer's recommendations under subitem (6) available at the time of inspection by the commissioner.

C. For automatic processing of analog images, a registrant must:

(1) develop films according to the time-temperature relationship recommended by the film and chemistry manufacturer;

(2) use a thermometer to verify that the developer temperatures fall within manufacturer's specifications.

(3) document the developer temperature before first patient use:

(a) weekly when the processor has a digital read-out or ready light; or

(b) daily when the processor does not have a digital read-out or ready light.

(4) maintain a copy of the film and developer manufacturer's recommendations for a qualified operator; and

(5) have the manufacturer's recommendations under subitem (4) available at the time of inspection by the commissioner.

D. A registrant processing intraoral images with a manual or an automatic process must:

(1) verify that the amount of fog for a two-minute fog test does not allow visualization of the outline of a coin on the intraoral film; and

(2) perform a two-minute fog test at six month intervals.

Subp. 20. **Digital imaging.** A registrant using a digital imaging receptor must:

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

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

(1) use by a qualified operator; and

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

Subp. 21. **Records.**

Commented [JC(34]: There will be one Records provision applicable to all registrants.