Dental Extraoral X-ray Systems

PROPOSED REVISIONS TO 4732.XXXX, 1.0

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

Subpart 1. **Applicability.** A registrant's x-ray system used for dental extraoral 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 alignment for one image receptor size for a fixed source-to-image distance (SID).

Commented [JC(1]: 21 CFR 1020.31 (f)(4) and SSRCR part F.6 (g) (ii), p. 45.

A. Limit the x-ray field so that it does not exceed each dimension of the image receptor by more than two percent of SID, when the x-ray beam is perpendicular to the image receptor; and

B. Align the center of the x-ray field with the center of the image receptor to within two percent of SID; or

C. A qualified operator must be able to manually adjust both the size and alignment of the x-ray field to the dimensions of the image receptor so the x-ray field does not extend beyond the edge of the image receptor.

Subp. 3. **Mechanical support of the tube housing assembly.** A registrant using a dental extraoral x-ray system is responsible for the requirements of this subpart.

Commented [JC(2]: SSRCR Part F.7. (i) & (k), p. 50.

A. The tube housing assembly must remain stable during the exposure unless tube housing movement is a designed function of the dental extraoral x-ray system; and

B. All position locking, holding, and centering devices must function as intended.

Subp. 4. **Radiation exposure control.** A registrant is responsible for the radiation exposure control provisions of this subpart. An x-ray control must:

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

B. be of the continuous pressure type.

C. 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

Commented [JC(3]: Based on Texas administrative code

Commented [JC(4]: "by a qualified operator" - consistent with both SSRCR and Michigan administrative code

Commented [JC(5]: Consistent with both SSRCR and Michigan and Texas administrative code

Commented [JC(6]: Consistent with SSRCR, Part F.7 (g), p. 50.

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.

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 extraoral 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) patient size (small, medium, or large);

(2) adult or pediatric settings; and

(3) type of exam.

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

Commented [JC(7]: Consistent with SSRCR, Part F.7 (I), (i)(ii), p. 50.

Commented [JC(8]: 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(9]: Subp. 7 addresses 4732.1100, subparts 1, 2, and 11 - **INSTALLATION CALIBRATION TESTS AND EQUIPMENT PERFORMANCE TESTS FOR A QUALITY ASSURANCE PROGRAM.**

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.

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 extraoral 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 extraoral x-ray system; and

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

Commented [JC(10]: Based on existing 4732.1100, subpart 1

Commented [JC(11]: Based on existing 4732.1100, subpart 1
MDH intends to include a comparable requirement for qualified service providers to calibrate equipment into proper working condition as specified in item E.

Commented [JC(12]: 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.

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
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

*X-ray systems manufactured before June 10, 2006, are not in brackets. X-ray systems manufactured on or after this date are in brackets.

C. To determine a half-value layer at a kVp (x-ray tube potential) that is not listed under item C, a qualified service provider must:

(1) make a linear interpolation or extrapolation; and

(2)include this determination in the calibration report under part 4732.####.

Commented [JC(13]: MDH intends to update the internal reference to the proposed equivalent of part 4732.0280 – **SERVICE PROVIVDER'S RESPONSIBILITY**.

D. 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.

Commented [JC(14]: MDH to ask Qualified Service Provider focus group if items D and E are relevant.

E. 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.

Commented [JC(15]: Defined term from Definitions is incorporated in rule part as discussed.
HVL language is consistent with SSRCR.

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

(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.**

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

Commented [JC(16]: Reviewed UT, IN, FL, CO, NC, TX (232-61)
*Consistent with UT and NC.
Subp. 9 based on Texas §289.232(i)(6)(H)
Also the same as FDA 21 CFR 1020.31(a)(2)

Commented [JC(17]: Based on Texas administrative code §289.232(i)(6)(J)

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 extraoral 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(18]: Reviewed comparable provisions from the following states: TX, IA, ME, NC.

Subp. 12. **Equipment; quality control.** A registrant is responsible for the quality control of a dental extraoral x-ray system.

A. A registrant must develop and comply with written warm-up and quality control procedures based on the dental extraoral x-ray system manufacturer's recommendations;

B. A qualified operator must complete x-ray system warm-up and daily quality control testing before the first patient of the day; and

C. A qualified operator must complete periodic quality control testing at the frequency recommended by the manufacturer; and

D. If any quality control test results fail to meet the manufacturer's specifications, a registrant must:

(1) remedy any corrective actions; and

(2) conduct verification tests.

E. A registrant must maintain quality control recommendations from the dental extraoral x-ray system manufacturer for:

(1) use by a qualified operator; and

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

Shielding

Subp. 13. **Shielding plan.** A registrant with a dental extraoral x-ray system must comply with the shielding plan requirements under part 4732.####.

Commented [JC(19]: MDH intends to update the internal reference to the proposed equivalent of part 4732.0360 - **Shielding Requirements**.

Conditions of Operation

Subp. 14. **Qualified operators; dental extraoral x-ray systems.** Qualified operators of a dental extraoral x-ray system include:

A. a dentist licensed under Minnesota Statutes, section 150A.06;

B. a dental therapist licensed under Minnesota Statutes, section 150A.06

C. a dental hygienist licensed under Minnesota Statutes, section 150A.06; and

D. a dental assistant licensed under Minnesota Statutes, section 150A.06.

Subp. 15. **Prohibited uses.** A registrant must not expose an individual to the useful beam except for healing arts purposes. Exposure to the useful beam is prohibited for:

A. training;

B. demonstration; or

C. other non-healing arts purposes.

Subp. 16. **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. 17. **Qualified operator protection.** A registrant is responsible for the qualified operator protection requirements in this subpart.

A. A qualified operator must remain behind a protective barrier or be at least six feet (1.8 meters) from the patient and the tube housing assembly;

B. At all times during an exposure, an x-ray operator must be able to:

(1) view the patient;

Commented [JC(20]: Based on SSRCR part F.3 (xix), p. 18 MDH intends to move this to General Requirements for all registrants and add a comparable qualified requirement for qualified service providers.

Commented [JC(21]: Contains revisions to part 4732.0560, subpart 3, suggested by Board of Dentistry and agreed upon by Dental Focus Group.

Commented [JC(22]: MDH intends to update the internal reference to the proposed equivalent of part 4732.0560 (**ORDERING OF DIAGNOSTIC RADIOGRAPHIC OR THERAPEUTIC PROCEDURE)**

(2) monitor all entrances to the adjacent rooms or areas to prevent unauthorized access; 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 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. Use of fastest speed screen-film combinations must be consistent with the diagnostic objective of the examination.

C. Intensifying screens and film must be used according to the film manufacturer recommendations.

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

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

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

(2) use a medical 11-step aluminum step wedge when processing extraoral images. The reference step density on the daily evaluation must be ± one density of the reference step of the standard;

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

(4) 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	Thermometer Reading	Minimum Developing Time
Celsius Degrees	Fahrenheit 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	Thermometer Reading	Minimum Developing Time
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.

(8) If any parameters fail to meet performance criteria, a registrant must:

(a) remedy any corrective actions; and

(b) conduct verification tests.

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.

(6) If any parameters are outside of performance criteria, a registrant must:

(a) remedy any corrective actions; and

(b) conduct verification tests.

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

(1) verify that the amount of fog for a two-minute fog test does not exceed one step on either side of the designated step when using the step wedge for the fog test; and

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

(3) If any parameters are outside of performance criteria, a registrant must:

(a) remedy any corrective actions; and

(b) conduct verification tests.

Subp. 20. **Digital imaging.** A registrant using a digital imaging receptor is responsible for the requirements in this subpart.

A. A registrant must develop and comply with written quality control procedures based on the digital imaging receptor manufacturer's recommendations; and

B. A qualified operator must complete quality control image receptor testing before the first patient of the day; and

C. A qualified operator must complete periodic quality control image receptor testing at the frequency recommended by the manufacturer.

D. If any quality control test results fail to meet the manufacturer's specifications, a registrant must:

(1) remedy any corrective actions; and

(2) conduct verification tests.

E. A registrant must maintain quality control recommendations from image receptor manufacturer for:

(1) use by a qualified operator; and

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

Subp. 22. **Records.**

Commented [JC(23]: There will be one Records provision applicable to all registrants.