DEPARTMENT OF HEALTH

Intraoral Dental X-ray Systems Revision

4732.#### **INTRAORAL DENTAL 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 requirements of this chapter and must:

A. meet Code of Federal Regulations, title 21, section 1020, or successor requirements; or

B. meet 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 this determination in the calibration report under part 4732.0280.

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-

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

Commented [JC2]: From: part 4732.1100, subpart 11

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.

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

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.

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 x-ray systems were manufactured before June 10, 2006.

B. All intraoral dental x-ray systems installed on and after December 1, 1980, 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

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

MDH Note:
These equipment requirements are very technical and likely exceed the understanding of most dental registrants. 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 seeking input on the utility of these provisions and their placement within the chapter.

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?

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. 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. 4. **Mechanical support of the tube housing assembly and position-indicating device.** The tube housing assembly and the position-indicating device must:

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

B. remain stable before the exposure is initiated and during the exposure.

Subp. 5. **Radiation exposure control.** A registrant must comply with the radiation exposure control provisions of this subpart.

A. The x-ray control 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 interval or exposure limit.

B. The control panel containing the main power switch must bear the warning statement which is legible and accessible to view: "WARNING This x-ray unit may

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 - CFR 1020.31(i)(1)
Item B - 21CFR1020.31(f)(1)(i)

Commented [JC(9]: From Proposed 4732.0880, subp. 2, item C.
Adding "assembly" to "tube housing". Consistent with SSRCR and Definitions.

Commented [JC(10]: Tube housing assembly was proposed to be repealed but will remain in Definitions part.

Commented [JC(11]: MDH intended to repeal this term from the Definitions part because it was not used in the rule chapter. Recent legislation uses this term and so we are including it.

Commented [JC(12]: 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 (*SSRCR, 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 [JC(13]: From 4732.0800, subp. 2, item D. **(GENERAL EQUIPMENT REQUIREMENTS FOR ALL DIAGNOSTIC RADIATION-PRODUCING SYSTEMS; Radiation exposure x-ray control.)**
No change.

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 radiation exposure control 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 an intraoral x-ray system must be indicated and visible to an x-ray operator before the exposure begins.

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 examinations must meet the requirements under part 4732.0550.

Subp. 8. **Calibrations.** A registrant using a 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 patient 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.

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*

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

Commented [JC(17]: Is this needed and/or still relevant?
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.)

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
(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 dental intraoral x-ray system to meet the requirements under subpart 1.

Commented [JC(21]: Based on existing 4732.1100, subpart 1, Item A. May move to Service Provider requirements.

Shielding

Subp. 9. **Shielding requirements.** A registrant operating a stationary or a mobile dental intraoral 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 internal references to these DOSE LEVELS provisions.

B. 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 an adjacent room or area.

Commented [JC24]: Adding "at least 2 meters (6.5 ft) tall". Consistent with *SSRCR, Part F, p. 49*

Subp. 10. **Shielding exemption.** A registrant with only a dental intraoral x-ray system and complies with subpart 9 is exempt from the requirements under part 4732.0360.

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

Commented [JC(26]: 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:

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:

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 intraoral 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;

Commented [JC(27]: 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.

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

Commented [JC(29]: MDH will update this internal reference to 4732.0560 (**ORDERING OF DIAGNOSTIC RADIOGRAPHIC OR THERAPEUTIC PROCEDURE)**

Commented [JC(30]: Will move to General Requirements part.

D. the x-ray operator who is operating the intraoral 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.

Commented [JC31]: MDH will update this internal reference to 4732.0590 - **INDIVIDUALS OPERATING X-RAY EQUIPMENT DURING TRAINING.**

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.

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

B. An x-ray operator must:

(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

Commented [JC(33]: 1. 2m or 6.5 ft is SSRCR. We are staying with 6 feet.
2. Replacing "x-ray tube" with "tube housing assembly"

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

Commented [JC(34]: From - *Proposed 4732.0365, subp. 3, Item C.* No changes.

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.

Commented [JC(35]: From - Proposed 4732.0365, subp. 1

Subp. 15. **Film processing.** A registrant using an intraoral x-ray system with an analog image receptor must:

Commented [JC(36]: This is 4732.0555, Subp. 1. as amended by Dental Focus Group

A. use only E-speed or F-speed film;

B. have equipment for processing that meet the requirements of this subpart;

C. perform processing quality control testing each day before diagnostic films are processed; and

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

E. For manual processing, 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 Degrees	Thermometer Reading Fahrenheit Degrees	Minimum Developing Time (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
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:

(a) the date; and

(b) the developer temperature before first patient use.

(6) have a copy of the film or developer manufacturer's recommendations available for an x-ray operator; and

(7) have the recommendations under subitem (5) available at the time of inspection by the commissioner.

F. For automatic processing, 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 ~~s~~ 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-out or ready light.

(4) have a copy of the film and developer manufacturer's recommendations available for an x-ray operator; and

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

G. A registrant processing an intraoral image must 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 image.

Subp. 18. **Safety controls.** A registrant must comply with 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. A registrant using a film imaging receptor must:

(1) comply with subpart 17;

Commented [JC(37]: From – 4732.0880, subp. 3a (new)

SSRCR, p. 48-49
a. Quality Assurance. In addition to the general quality assurance provisions in Sec.F.3, the following requirements apply to a dental facility:
i. If using film, maintain a light-tight darkroom, use proper safelighting and safeguards, and evaluate darkroom integrity and daylight loading systems for film fog every six months and after a change that may impact film fog.

ii. If using a filmless system, maintain and operate PSP and DDR systems according to manufacturer specifications.

iii. Registrant [licensee] shall provide initial training and annual evaluations of x-ray operators to include but not limited to: positioning of the x-ray tube, image processing, operator location during x-ray exposure, source to skin distance, radiation protection, appropriate radiographic protocol, and applicable regulatory requirements. Records of training and annual evaluations shall be maintained for inspection by the Agency.

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

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

(2) maintain quality control recommendations, tests, and evaluations for:

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

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

D. A registrant using a digital imaging receptor must:

(1) comply with the quality control recommendations provided by the digital imaging receptor manufacturer;

(2) maintain quality control recommendations, tests, and evaluations for:

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

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

Subp. ##. **Records.**

Commented [JC(40]: There will one Records provision for all registrants.

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