Dental ConeBeam Computed Tomography (CBCT) X-ray Systems

PROPOSED REVISIONS TO 4732.XXXX, 1.0

4732.#### **DENTAL CONEBEAM COMPUTED TOMOGRAPHY (CBCT) X-RAY SYSTEMS; STATIONARY AND MOBILE.**

Subpart 1. **Applicability.** A registrant's x-ray system used for dental CBCT 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. Limit the x-ray field so that it does not exceed each dimension of the image receptor by more than two percent of source-to-image distance (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 2% of SID.

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

A. The tube housing assembly must remain stable during the exposure unless tube housing movement is a designed function of the dental CBCT 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 during the scan or series of scans of greater than 0.5 second duration.

B. after premature termination of x-ray exposure, require resetting of the CBCT condition of operation before initiating another scan.

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.

Commented [JC(1]: 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(2]: SSRCR F. 11. A vii (4) and 21cfr1020.33(f)(2)(ii)

Commented [JC(3]: Consistent with SSRCR, Part F, p. 50.

A. A visual indication that is observable at the CBCT x-ray control and gantry 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.

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 CBCT x-ray systems that have fixed technique factors.

C. An electronic or written protocol must be available at the control panel for each CBCT examination and the protocol must include:

(1) the anatomical regions to be imaged;

(2) all orientations and views that will be displayed;

(3) scanner settings including:

(a) field of view (FOV);

(b) resolution;

Commented [JC(4]: SSRCR F. 11. A v (1) and 21cfr1020.33(h)(1)

Commented [JC(5]: SSRCR, Part F, p. 50

Commented [JC(6]: From *SSRCR, Part F, p. 50* Item A is consistent with FDA 1020.31 (a) and Texas Administrative Code

(c) time;

(d) kVp;

(e) mA/mAs; and

(4) protocols for adult and pediatric.

Subp. 7. **Equipment performance evaluation; testing requirements; frequency.** A registrant using a dental CBCT x-ray system is responsible for the equipment performance evaluation testing requirements under subparts 7 and 8.

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:

(1) a qualified medical physicist for a dental CBCT x-ray system that operates at 20 mA or greater or 100kV or greater.

(2) a qualified service provider for a dental CBCT x-ray system that operates below 20 mA and below 100 kV.

C. Periodic equipment performance evaluation testing must be:

(1) performed by a qualified medical physicist at intervals not to exceed 12 months (365 calendar days) from the date of the previous equipment performance evaluation for a dental CBCT x-ray system that operates at 20 mA or 100kV or greater. 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.

(2) performed by a qualified service provider at intervals not to exceed 24 months (730 calendar days) from the date of the previous equipment performance evaluation for a dental CBCT x-ray system operates below 20 mA and below 100 kV. 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. If a registrant's dental CBCT x-ray system fails to meet any of the equipment performance evaluation testing under subpart 8, then a registrant must:

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

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

Commented [JC(7]: From 4732.0520, subp. 1, item E.

Subp. 8. **Equipment performance evaluation; dental CBCT x-ray system.** System performance measures must be evaluated using a phantom.

A. A registrant's dental CBCT x-ray system must meet manufacturer's specifications and tolerance limits for the following equipment performance tests:

(1) contrast scale;

(2) mean CT number of water and reference materials;

(3) linearity;

(4) slice thickness;

(5) image display and storage;

(6) safety analysis of audible and visual patient safety equipment; and

(7) daily quality control tests under subpart 9.

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

(1) use by a qualified service provider or a qualified medical physicist; and

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

C. When a manufacturer's equipment performance evaluation specifications are not available, a registrant must [**Placeholder: Seeking input on tolerance limits if not available.**]

Subp. 9. **Quality control.** A registrant using a dental CBCT x-ray system routine [daily and/or periodic] quality control tests must conduct equipment performance measurements

according to the manufacturer's recommendations, tolerance limits, and follow the requirements of this subpart.

A. A registrant and radiation safety officer must develop and comply with written warm-up procedures, quality control procedures, and tolerance limits to evaluate image quality based on the dental CBCT x-ray system manufacturer's specifications. Daily procedures must include quality control tests for:

(1) CT number accuracy for water and other reference material;

(2) image noise;

(3) artifact assessment; and

(4) proper function of audible and visual patient safety equipment.

Subitems (1) and (2) must be performed using a CT phantom by a qualified operator.

B. Periodic procedures must include quality control tests with the use of a CT phantom for:

(1) spatial resolution for high and low contrast objects;

(2) image uniformity;

(3) image display and storage devices; and

(4) air calibration, if required.

Commented [TP(8]: SSRCR: "The registrant [licensee] shall follow the QC recommendations provided by the CBCT manufacturer. In the absence of manufacturer provided QC recommendations, the registrant [licensee] shall implement and document QC guidelines established by a QMP [QE] in accordance to nationally recognized guidelines or those recognized by the Agency."

Commented [JC(9]: Consistent with IAC CBCT testing section 2 .3.2. IAC specifies periodic QA tests and does not define periodic.

C. A registrant must have a CT phantom for use with a dental CBCT x-ray system at the facility according to 21 CFR 1020.33.

D. A qualified operator must complete x-ray system warm-up procedures and daily quality control testing before first patient of the day using a CT phantom as specified by the dental CBCT x-ray system manufacturer.

E. When a manufacturer's specifications on quality control are not available, a registrant's periodic quality control tests must [**Placeholder: Seeking input on tolerance limits if not available.**]

Commented [JC(10]: Consistent with IAC CBCT testing section 2 .3.2. IAC specifies periodic QA tests and does not define periodic.

F. 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.

G. A registrant must maintain quality control procedures, tolerance limits, and manufacturer's recommendations for:

(1) use by a qualified operator; and

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

Shielding

Subp. 10. **Shielding requirements.** A registrant operating a stationary or a mobile dental CBCT x-ray system is responsible for the requirements of this subpart.

Commented [JC11]: 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.####;

B. A dental CBCT x-ray system that is installed on or after the effective date of this subpart must have the x-ray control permanently mounted behind a protective barrier so that a qualified operator remains behind the protective barrier during the entire exposure.

C. A dental CBCT x-ray system that is installed before the effective date of this subpart and does not incorporate structural shielding or a shielded position must have a radiation survey that identifies radiation levels at the operator position and the spaces surrounding the dental CBCT x-ray system room or area by December 31 of the year following the effective date of this subpart.

D. Corrective actions must be made when a radiation survey identifies that existing operating conditions may result in controlled (restricted) areas receiving a dose in excess of 0.1 mGy per week or uncontrolled (unrestricted) areas receiving a dose in excess of 0.02 mGy per week.

E. An evaluation must be performed to verify that corrective actions taken by the registrant resulted in controlled and uncontrolled areas receiving less than the restricted and unrestricted limits in subitem (1).

F. Placing a clear identified marked restricted area outlining a safe distance for qualified operators.

Commented [JC(12]: MDH intends to update the internal reference to the proposed equivalent of parts 4732.0410 – 47320.430 - **DOSE LEVELS**.

Commented [JC(13]: Design goals taken from NCRP 145, pg. 102 F.2.2
Controlled area is defined in 4731.0100 subp. 49 and uncontrolled area is not; however, restricted (subp.205) and unrestricted (subp.256) are defined in 4731.0100

Subp. 11. **Shielding plan.** A registrant with a dental CBCT x-ray system must comply with the shielding plan requirements under part 4732.####.

Commented [JC(14]: MDH intends to update the internal reference to the proposed equivalent of part 4732.0360 - **Shielding Requirements**.

Conditions of Operation

Subp. 12. **Qualified operators; dental CBCT x-ray systems.** Qualified operators of a dental CBCT 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. 13. **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:

Commented [JC(15]: 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.

A. training;

B. demonstration; or

C. other non-healing arts purposes.

Subp. 14. **Ordering of diagnostic radiographic examinations.** A registrant is exempt from the requirements of part 4732.#### if:

Commented [JC(16]: 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)**

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. 15. **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 underpart 4732.####.

Subp. 16. **Off-site use of a mobile dental CBCT x-ray system.** A registrant must document the date and location when a registrant's qualified operator uses a registrant's mobile dental CBCT x-ray system at a location that is not listed on the registrant's equipment registration.

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 remain outside clearly identified and marked restricted area;

B. At all times during an exposure, a qualified operator must be able to:

(1) view the patient; and

(2) monitor all entrances to the adjacent rooms or areas to prevent unauthorized access.

C. A qualified operator must limit the useful beam to the patient's area of clinical interest.

Subp. 18. **Records.**

Commented [JC(17]: There will be one Records provision applicable to all registrants.