Department of Health (DOH)
DIVISION OF PUBLIC HEALTH
State Public Health Laboratory
Radiological Health Program5455
Dr. Martin Luther King Jr. Ave.
Anchorage, Alaska 99507
Main: 907.334.2101
Fax: 907.334.2161

CHECKLIST: DENTAL

Purpose: Checklist for use in the compliance process. (7 AAC19.010-.030 & CRCPD Part F).
The purpose of the inspection is to determine that facility, x-ray equipment, and procedures are compliant with state regulations to minimize or eliminate any condition(s) which cause(s) re-exposure, higher than necessary exposures, unwarranted exposure to clinically unimportant anatomy, or reduced diagnostic quality of the radiographic image(s) which increase(s) risk to patients, operators, unborn fetuses, or the general public.

Note: This checklist is provided as a courtesy to the facility to reference the applicable regulations. State inspectors will follow this checklist in reviewing and determining compliance activities of a facility. The checklist is comprehensive and applies to all types of dental practices. Each section has an item #, regulation identification and description (in black), and the required documentation section (in blue) to address each rule/regulation for compliance. **Items on this checklist may not be applicable to all facilities**. For example, if your facility does not have a Cone Beam Computed Tomography (CBCT) device then those rules do not apply to your facility. If you have any questions concerning this checklist or submittal of documents, please contact your inspector as indicated on the inspection documents or email us at doh.radiation.control@alaska.gov.

Inspection timeframes: Dental facilities are inspected once every six years. The inspection period begins on the day of inspection and closes 30 calendar days later. Any noted deficiencies will be listed on an *Action Item* list provided at the inspection exit debriefing by the inspector. Response to action items is due within 30 days. Once 30 days have passed, any unresolved items will be listed in a Notice of Deficiency Letter and will continue to follow the DOH policy of Due Process of Compliance. A copy of the Due Process policy is available through our office, if needed. After 180 days, penalties may occur. *However, during the implementation phase of dental facility inspections, we are increasing this to 1 year from the initial dental inspection date to provide sufficient acclimation time to understand and comply with state laws*. If dental clinics are found to be unresponsive during this 1st year, they will be reported to the Alaska Board of Dentistry to coordinate penalties under the statutory authority of the Department of Health.

Evidence submission: Submit documents via email unless otherwise arranged with your inspector. You may need to "zip" or compress larger files. Indicate on your document(s) the item number it satisfies on the checklist. For example: #1, Operating Policy (OP). When an Operating policy satisfies multiple sections, state each item number such as #1, #2, #3, Operating Policy. The OP must address each section of the rules.

Facility: _____ **Registration #:** _____

Location: _____, _____ **AK, 99** _____

Point of Contact; Name and Email: _____

DOCUMENTS ARE DUE WITHIN 30 DAYS OF INSPECTION DATE*

All dental facilities must be compliant with 7 AAC 19.010-030 and the Conference of Radiation Control Program Directors (CRCPD) suggested state regulations (Part F, Part D, and the rules they reference). **During the implementation phase of dental facility inspections, we are increasing this to 1 year from the initial dental inspection date to provide sufficient acclimation time to understand and comply with state laws.*

Checklist key

Item #	Reference	Regulation Title (in black) – **Focus of the regulation (emboldened black)**
	Documentation	**Types of evidence required to demonstrate compliance (in blue)**

1	Part F Sec. F.3 Part D Sec. D.1101	Medical Diagnostic and Interventional X-Ray and Imaging Systems **General and Administrative Requirements.** Standards For Protection Against Radiation **Radiation Protection Programs**
	Documentation ☐ Compliant ☐ Non-compliant	1. **Provide the written Operating Policy (OP) for your radiology section, including cover page & table of contents.** 2. **Provide a section detailing how ALARA is practiced. The policy must have a statement and definition.** 3. **Provide evidence that the Radiation Safety Program is reviewed at least annually.**

2	Part D Sec. D.1201	Standards For Protection Against Radiation **Occupational Dose Limits for Adults (5 rem per year)**
	Documentation ☐ Compliant ☐ Non-compliant	1. **Provide the section of your Operating Policy/Procedure that covers the radiation safety with aspects of minimizing dose to the employee or worker.** 2. **Provide the document or justification if no monitoring is being used and provide evidence that this is reviewed annually.** 3. **Provide the document stating or showing dose record results were provided to the employee.**

3	Part D Sec. D.1208	Standards For Protection Against Radiation **Occupational Dose Equivalent to an Embryo/Fetus (0.5 rem per pregnancy)**
	Documentation ☐ Compliant ☐ Non-compliant	1. **Provide the section of your Operating Policy/Procedure that covers the radiation safety with aspects of minimizing dose to the embryo/fetus of a declared pregnant employee.** 2. **Provide your section of your Operating Policy/Procedure that states this limit and how it's controlled.**

4	Part D Part D.1301 Part D.1302	Standards for Protection Against Radiation **Radiation Dose Limits for Individual Members of the Public (0.1 rem/year)** **Compliance with Dose Limits for Individual Members of the Public**
	Documentation ☐ Compliant ☐ Non-compliant	1. **Provide the section of your Operating Policy/Procedure that covers the radiation safety with aspects to minimizing dose to the public. The Policy/Procedure must state the limit and how it's controlled.** 2. **Provide Operating Policy/Procedure for protecting patients who are pregnant. Include any pictures of signs that address this concern to patients.**

5	Part D Sec. D.1502 Sec. D.1503	Standards for Protection Against Radiation Surveys and Monitoring, **Conditions Requiring Individual Monitoring for Occupational Dose** Surveys and Monitoring, **Location of Individual Monitoring Devices**
	Documentation ☐ Compliant ☐ Non-compliant ☐ N/A	**Provide the section of your Operating Policy/Procedure that covers radiation safety when using monitoring devices. *This item only applies for those facilities using monitoring devices.***

6	Part D Sec. D.2101 Sec. D.2102 Sec. D.2110	Standards for Protection Against Radiation Records, **General Provisions** **Records of Radiation Protection Programs** **Form of Records**
	Documentation ☐ **Compliant** ☐ **Non-compliant**	**1. Each registrant must maintain records of radiation protection program for three years after the record is created.** **2. Each registrant must maintain records of each equipment service or calibration for the life of the device.** **3. Each registrant must maintain a record of state inspection for twelve years (or two required state inspections).**

7	Part D.2202	**Notification of Incidents** Each registrant shall immediately report each event involving a source of radiation that may have caused any of the following: a. Total dose of ≥ 25 rem b. Lense dose of ≥ 75 rem c. Shallow dose to the skin/extremities or organ dose of ≥ 250 rad
	Documentation ☐ **Compliant** ☐ **Non-compliant**	**Provide policy/procedures stating actions taken following documented incidents. Outline reporting information and actions used to mitigate future incidents.**

8	7 AAC 19.020(b) Inspection	Inspection by the State of Alaska, Department of Health, Radiological Health Program **Inspection frequency** Radiological Health Program inspections of dental radiological equipment occurs at least once every six years.
	Documentation ☐ **Compliant** ☐ **Non-compliant**	**Provide the last inspection date or record completed by a state inspector. This inspection is the inspection of the facility, not just the device.**

9	7 AAC 19.010	Registration with the State of Alaska, Department of Health, Radiological Health Program **Review all facility registration details.**
	Documentation ☐ **Compliant** ☐ **Non-compliant**	**1. Provide the registration number assigned to your facility by the Radiological Health Program.** **2. Provide a copy of your business license issued by the Department of Commerce, Community, and Economic Development, https://www.commerce.alaska.gov/cbp/businesslicense/search/License** **3. Provide the name of the Owner, Radiation Safety Officer (RSO), responsible person, manager, and billing contacts for your facility. These may all be the same person for a sole propriety business.** **4. Provide the email address and telephone number for each person above in #3.** **5. Provide an inventory of your in-use and in-storage devices. Facilities should maintain inventory of their devices, including completion dates documenting maintenance completed on each device.**

10	7 AAC 19.020(a)	Inspection by the State of Alaska, Department of Health, Radiological Health Program **Review of device evaluation records - installations and/or repairs** All devices are required to be calibrated after installation. Records should demonstrate that the machine was checked for operational accuracy and safety prior use following installation or repair. Devices must be serviced (calibrated) by a qualified technician if the unit is over ≥3 years old. An invoice does not suffice for this documentation.
	Documentation ☐ **Compliant** ☐ **Non-compliant**	**1. Provide device installation records including records of calibration, linearity, and image resolution/contrast quality.** **2. Provide date of installation, installer's name, and contact information.** **3. Provide the current service record showing service and/or calibration.**

11	7 AAC 19.030(a)	Review completed forms by the State of Alaska, Department of Health, Radiological Health Program **Review all device types and conditions.**
	Documentation ☐ **Compliant** ☐ **Non-compliant**	**1. Provide the device manual (only cover page and contents pages) for each type of device.** **2. Provide a photo of the device. If you have several identical devices, one representative picture suffices. For larger units, such as a CT, cone beam or panoramic, please provide a picture of the control panel and unit.**

12	7 AAC 19.030(a)	Review completed forms by the State of Alaska, Department of Health, Radiological Health Program **Review timeliness of notification of sale, relocation, or discontinuation of registered devices.** Device registrations must be updated within 30 days of status change.
	Documentation ☐ **Compliant** ☐ **Non-compliant**	**Provide documentation for each registered device that was sold, relocated, or discontinued.**

13	Part F Sec. F.3 (a)	Medical Diagnostic and Interventional X-Ray and Imaging Systems **Radiation Safety Requirements** All facilities must have a safety program manual. An example SOP is available. Key features must include, but are not limited to, statements addressing: 1. Notification to the DOH's Radiological Health Program within 1 day of a medical event. 2. Ceasing use of non-compliant x-ray systems and correcting within 30 days to ensure image quality. 3. Routine compliance evaluations for the device, device operator, and quality testing. 4. How the device is evaluated routinely to meet manufacturer's recommendations. 5. Operator qualification and training documentation requirements. 6. The provision of sufficient protective apparel is on site and evaluated, including records of testing leaded garments. 7. Documentation of annual evaluations of protective apparel and auxiliary shields. Reference details such as who inspected the item, which item(s) were inspected, description of repairs, if needed. 8. The use of nationally recognized diagnostic reference levels in the facility's policies. 9. How auxiliary equipment is used to minimize patient and personnel exposure commensurate with needed diagnostic information. 10. The use of portable x-ray equipment shall only be used when stationary x-ray devices are impractical. If you are using portable devices, you must state your justification for their use in your practice. 11. The restriction of holding the x-ray tube housing or collimating device during an exposure, unless specifically designed to be hand-held. 12. How the operator must use collimation to localize the beam. 13. How appropriate techniques are used for all patient sizes and clinical indications. 14. How patients are to be verified and identified. 15. What is included in operator protocols including adult vs pediatric considerations, technique factors, type of image receptor used, source to image receptor distance used (except for dental intraoral radiography), and type of grid, if any. 16. How safety procedures are communicated to operators including acknowledgement form for trainings and direct observations documented to assure proper operation. 17. How your facility manages persons in the room besides the patient. How do you ensure they are not receiving scatter radiation while the patient is being imaged? 18. Prohibition of deliberate exposure for training, demonstration, or healing arts screening. 19. The safe use of any auxiliary support and/or another person, if needed, to hold the patient. 20. All individuals who are associated with the operation of an x-ray system are subject to Part D (See checklist items #1-7). 21. How you maintain equipment records. 22. How you maintain patient records.
	Documentation ☐ **Compliant** ☐ **Non-compliant**	**Provide the facility's radiation safety program manual.**

14	Part F Sec. F.3 (b)	Medical Diagnostic and Interventional X-Ray and Imaging Systems **Quality Assurance** Each facility must have a quality assurance (QA) manual. An example SOP is available. See also Item#15 describing requirement in Sec. F.7 (a). Key features must include, but are not limited to, statements addressing: 1. Minimum qualifications for x-ray equipment operators. 2. Maintenance of a list of individuals in the facility and identify the responsible person for the QA program. 3. Need for written QA and or QC procedures to include evaluation frequencies and tolerances using the device manual and recommendations for QA/QC and/or calibration. 4. Any image that has an artifact, must be investigated and corrected. Document findings/corrections. 5. Dental must avoid excessive repeat imaging. *Dental facilities are exempt from quarterly repeat/reject analysis of images if performing only intra-oral, panoramic, cephalometric or volumetric dental imaging.* 6. Equipment preventative maintenance must be completed within 12 months after installation and documented. 7. Equipment servicing must be completed with appropriate testing instruments which are calibrated by a qualified service technician or physicist. 8. Responsible person or RSO must document the annual review of the QA/QC program. 9. QA/QC records must be kept for no less than six years, or until a second inspection by the state. 10. For X-Ray film processing facilities, facilities must address separate QA/QC procedures for image processing. a) Any registrant using analog image receptors (radiographic film) must have suitable equipment and procedures in place to process and develop films. See original regulations on all those requirements for solutions, developing times, temperatures, etc. b) Automatic processors and other closed processing systems shall be operated and maintained following manufacturer's instructions within the films developing time temperature relationships. Any deviations from manufacturer's recommendations must be documented. 11. Additional requirements for facilities using X-ray film include using light-excluded pass boxes, restrictions to reduce accidents in dark rooms, proper film storage, film cassette inspections, rejection of outdated film, appropriate spectral compatibility between film and intensifying screen, use of proper safelighting and safeguards, and evaluating dark room integrity for film fog every 6 months and after a change that my impact film fog.
	Documentation ☐ **Compliant** ☐ **Non-compliant**	**Provide the facility's QA program manual.**

15	Part F Sec. F.7 (a)	Medical Diagnostic and Interventional X-Ray and Imaging Systems Dental Facilities, **Quality Assurance** If using film, maintenance of a light-tight darkroom, evaluations performed, and use of fog tests must all to be documented. If using a filmless system, maintain and operate PSP and DDR systems in accordance with manufacturer's recommendations, and document procedures in your operations policy and documents. Documented training records and annual evaluations are required for state inspections. Training of operator(s) must include, but is not limited to: • Positioning of the x-ray tube, image processing, operator location during x-ray exposure, skin to source distance, radiation protection, radiographic protocol, and available regulations.
	Documentation ☐ **Compliant** ☐ **Non-compliant**	**1. If using film, provide documents describing quality measures taken to maintain and assess film development environment.** **2. If not using film, provide procedures describing how the facility complies with manufacturer recommendations in terms of maintaining and operating PSP and DDR systems.** **3. Provide training records and annual evaluations for all operators.**

16	Part F Sec. F.4 a. Sec. F.7 b.	Medical Diagnostic and Interventional X-Ray and Imaging Systems Requirements for All Diagnostic and Interventional X-Ray Systems Dental Facilities, **Warning Label** For systems manufactured on or before June 10, 2006, the control panel containing the main power switch shall bear the following viewable warning statement: "WARNING: this x-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions are observed". After June 10, 2006, the control panel containing the main power switch shall bear the following viewable warning statement: "WARNING: this x-ray unit maybe dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed".
	Documentation ☐ **Compliant** ☐ **Non-compliant**	**1. Provide a picture of the device with the appropriate label attached.** **2. Provide documentation of how warning labels are viewed on devices.**

17	Part F Sec. F.7 c.	Medical Diagnostic and Interventional X-Ray and Imaging Systems Dental Facilities, **Radiation Exposure Control** Each device must have means to initiate the radiation exposure by a deliberate action on the part of the operator, such as a dead man switch or timer.
	Documentation ☐ **Compliant** ☐ **Non-compliant**	**Provide the device manual describing the type of initiation switch for each type of device.**

18	Part F Sec. F.7 d.	Medical Diagnostic and Interventional X-Ray and Imaging Systems Dental Facilities, **Exposure Control Location and Operator Protection** Operators should be behind a protective barrier at least 2 meters tall or at least 6.5 feet from the tube housing assembly, outside the path of the useful beam, while making exposures.
	Documentation ☐ **Compliant** ☐ **Non-compliant**	**Provide picture(s) of operator position while taking exposures.**

19	Part F Sec. F.7 e.	Medical Diagnostic and Interventional X-Ray and Imaging Systems Dental Facilities, **Administrative Controls** The tube housing and position indicating device (PID) shall not be hand-held during an exposure, except for units designed to be hand-held. Dental fluoroscopy without image intensification shall not be used. No handheld shall be used without the proper shield for the device.
	Documentation ☐ **Compliant** ☐ **Non-compliant**	**Provide photo documentation of patients and image receptor holding devices that are used, when techniques permit.**

20	Part F Sec. F.7 f.	Medical Diagnostic and Interventional X-Ray and Imaging Systems Dental Facilities, **Hand-Held Intraoral Equipment** For hand-held devices, the shield must be not less than 0.25mm lead equivalent and 15.2 cm (6 inches) in diameter located on the distal end of device. *Note*: Procedures for hand-held devices are the same as those for stationary devices and, therefore, must also address these items as well: (a) When operating a hand-held device, the operator must wear a lead apron. (b) If the operator cannot physically hold the device, a stand to immobilize the device must be used. This shall secure the handheld device to prevent unauthorized removal or use.
	Documentation ☐ **Compliant** ☐ **Non-compliant** ☐ **N/A**	**1. Provide a picture of the hand-held device with a backscatter shield.** **2. Provide your Operating Procedure for each type of hand-held device.**

21	Part F Sec. F.7 g.	Medical Diagnostic and Interventional X-Ray and Imaging Systems Dental Facilities, **Beam-on Indicators**
	Documentation ☐ **Compliant** ☐ **Non-compliant**	**Provide the sections of the device manual demonstrating that the X-ray control panel has visual indication when x-rays are being produced and a signal audible to the operator shall indicate that the exposure has terminated.**

22	Part F Sec. F.7 h.	Medical Diagnostic and Interventional X-Ray and Imaging Systems Dental Facilities, **Multiple Tubes**
	Documentation ☐ **Compliant** ☐ **Non-compliant** ☐ **N/A**	**Provide the sections of the device manual where two or more radiographic tubes are controlled by one exposure switch, and the tube which has been selected shall be clearly indicated prior to initiation of the exposure.**

23	Part F Sec. F.7 i.	Medical Diagnostic and Interventional X-Ray and Imaging Systems Dental Facilities, **Mechanical Support of Tube Head** The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the x-ray system. If it has drift during exposure it, must be repaired.
	Documentation ☐ **Compliant** ☐ **Non-compliant** ☐ **N/A**	**Provide record of evaluation, adjustment, check, or repair to the device, if applicable.**

24	Part F Sec. F.7 j. Sec. F.4 g.	Medical Diagnostic and Interventional X-Ray and Imaging Systems Dental Facilities, **Battery charge indicator** Requirements for All Diagnostic and Interventional X-Ray Systems
	Documentation ☐ **Compliant** ☐ **Non-compliant** ☐ **N/A**	**Provide the device manual section that demonstrates that battery-powered generators have a visual means on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.**

25	Part F Sec. F.7 k.	Medical Diagnostic and Interventional X-Ray and Imaging Systems Dental Facilities, **Locks** All position locking, holding, and centering devices on x-ray system components and systems shall function as intended. If not, the device must be repaired.
	Documentation ☐ **Compliant** ☐ **Non-compliant** ☐ **N/A**	**Provide record of checks or repairs to the device, if applicable.**

26	Part F Sec. F.7 l. Sec. F.4 d.	Medical Diagnostic and Interventional X-Ray and Imaging Systems Dental Facilities, **Technique Indicators** Requirements for All Diagnostic and Interventional X-Ray Systems For x-ray equipment capable of displaying technique factors, the technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated. This requirement may be met by permanent markings on equipment having fixed technique factors.
	Documentation ☐ **Compliant** ☐ **Non-compliant**	**Provide your operating procedures that address displaying technique factors.**

27	Part F Sec. F.7 m.	Medical Diagnostic and Interventional X-Ray and Imaging Systems Dental Facilities, **Exposure Reproducibility** For any specific combination of selected technique factors, the estimated coefficient of variation of the air kerma shall be no greater than 0.05.
	Documentation ☐ **Compliant** ☐ **Non-compliant**	**Provide your annual calibration record that demonstrates that the exposure reproducibility is < 0.05.**

28	Part F Sec. F.7 n.	Medical Diagnostic and Interventional X-Ray and Imaging Systems Dental Facilities, **Timers (See also Sec. F.7 c., dead man switch)** If the device does not have a dead man switch, it must have a timer that will terminate the exposure at a preset time interval, a preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.
	Documentation ☐ **Compliant** ☐ **Non-compliant** ☐ **N/A**	**Provide the section of the device manual regarding the timer.**

29	Part F Sec. F.7 o.	Medical Diagnostic and Interventional X-Ray and Imaging Systems Dental Facilities, **Kilovolt Peak (kVp)** Deviation of technique factors from indicated values must not exceed the limits provided by the manufacturer. At a minimum, the kVp on variable kVp units shall be accurate to within 10% and within 20% on fixed kVp units.
	Documentation ☐ **Compliant** ☐ **Non-compliant**	**Provide the calibration report showing the accuracy of the kVp.**

30	Part F Sec. F.7 p.	Medical Diagnostic and Interventional X-Ray and Imaging Systems Dental Facilities, **X-ray Beam Alignment** Intraoral Dental Units: X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit the source-to-skin distance (SSD) to not less than 18 cm. The x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 7 cm. Extraoral, Panoramic and Cephalometric Units: X-ray systems designed for use with extraoral image receptors and when used with an extraoral image receptor, shall be provided with means to limit the x- ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2 percent of the SID, when the axis of the x-ray beam is perpendicular to the plane of the image receptor. In addition, means shall be provided to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or means shall be provided to both size and alignment the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.
	Documentation ☐ **Compliant** ☐ **Non-compliant**	**Provide the calibration report showing the light field collimation. The useful x-ray beam must be limited to the area of clinical interest.**

31	Part F Sec. F.7 q. Sec. F.4 e.	Medical Diagnostic and Interventional X-Ray and Imaging Systems Dental Facilities, **Beam Quality** Requirements for All Diagnostic and Interventional X-Ray Systems The Half Value Layer (HVL) of the useful beam for a given x-ray tube potential shall not be less than the values shown in 21 CFR 1020.30 (m) Table 1. For fluoroscopic systems manufactured on or after June 10, 2006, incorporating an x-ray tube(s) with a continuous output of 1 kilowatt or more and an anode heat storage capacity of 1 million heat units or more shall provide the option of adding x-ray filtration to the diagnostic source assembly in addition to the amount needed to meet the HVL provision of this subsection. Refer to 21 CFR 1020.30 (m)(2)).
	Documentation ☐ **Compliant** ☐ **Non-compliant**	**Provide the calibration report showing the half value layer at the measured operating potential. Refer to 21 CFR 1020.30 (m) Table 1.**

32	Part F Sec. F.7 r.	Medical Diagnostic and Interventional X-Ray and Imaging Systems Dental Facilities, **Intraoral dental x-ray machines and operational kVp** Intraoral dental x-ray machines shall not be operated at less than a measured 51 kVp.
	Documentation ☐ **Compliant** ☐ **Non-compliant** ☐ **N/A**	**1. Provide the value at which your device is operated.** **2. Provide a record that shows the kVp during operation.**

33	Part F Sec. F.7 s.	Medical Diagnostic and Interventional X-Ray and Imaging Systems Dental Facilities, **Modification of certified x-ray components/systems** Diagnostic x-ray components and systems certified in accordance with 21 CFR Part 1020 shall not be modified.
	Documentation ☐ **Compliant** ☐ **Non-compliant** ☐ **N/A**	**If your system was modified, please provide the reasons and documented information detailing the modification.**

34	Part F Sec. F.7 t. Sec. F.4 b.	Medical Diagnostic and Interventional X-Ray and Imaging Systems Dental Facilities, **Leakage Radiation from the Diagnostic Source Assembly** Requirements for All Diagnostic and Interventional X-Ray Systems The leakage radiation from the diagnostic source assembly measured at 1 meter in any direction from the source shall not exceed 0.88 milligray (mGy) air kerma (vice 100 milliroentgen (mR) exposure) in 1 hour when the x-ray tube is operated at its leakage technique factors.
	Documentation ☐ **Compliant** ☐ **Non-compliant**	**Provide the leakage evaluation completed during annual calibration of device.**

35	Part F Sec. F.7 u. Sec. F.4 c.	Medical Diagnostic and Interventional X-Ray and Imaging Systems Dental Facilities, **Radiation from Components Other than the Diagnostic Source Assembly** Requirements for All Diagnostic and Interventional X-Ray Systems The radiation emitted by a component other than the diagnostic source assembly shall not exceed an air kerma of 18 microgray (vice 2 milliroentgens exposure) in 1 hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters (See 21CFR1020.30(l)).
	Documentation ☐ **Compliant** ☐ **Non-compliant**	**Provide the leakage evaluation completed during annual calibration of device.**

36	Part F Sec. F.7 v.	Medical Diagnostic and Interventional X-Ray and Imaging Systems Dental Facilities, **Maintaining Compliance** Diagnostic x-ray systems and their associated components used on humans and certified pursuant to the Federal X-Ray Equipment Performance Standard (21 CFR Part 1020) shall be maintained in compliance with applicable requirements of that standard.
	Documentation ☐ **Compliant** ☐ **Non-compliant**	**Provide the calibration or service record for the device.**

If your facility uses Computed Tomography Equipment, please proceed to the remaining items. If not, skip to item #48.

Computed Tomography Equipment
Cone Beam Computed Tomography Dental Systems shall meet Part F Sec.F.4, Part F Sec. F.6 i. and k., F11h, and F.11a.ii through F.11a.vii., as applicable. Provide documentation as described in each item described below.

37	Part F Sec. F.11 Sec. F.11 a(i)	Medical Diagnostic and Interventional X-Ray and Imaging Systems Dental Facilities, Computed Tomography Equipment **Accreditation** All diagnostic CT x-ray systems for human use shall be accredited by an accrediting organization recognized by the Agency unless otherwise authorized by the Agency.
	Documentation ☐ **Compliant** ☐ **Non-compliant**	**Provide the accreditation documents for all devices.**

38	Part F Sec. F.11 Sec. F.11 a(ii)	Medical Diagnostic and Interventional X-Ray and Imaging Systems Dental Facilities, Computed Tomography Equipment **Technical and Safety Information** The technical and safety information relating to the conditions of operation, dose information and imaging performance provided by the CT manufacturer shall be maintained by the facility.
	Documentation ☐ **Compliant** ☐ **Non-compliant** ☐ **N/A**	**Provide CT manufacturer technical and safety information.**

39	Part F Sec. F.11 Sec. F. 11 a(iii)	Medical Diagnostic and Interventional X-Ray and Imaging Systems Dental Facilities, Computed Tomography Equipment **Termination of Exposure** (1) Means shall be provided to terminate the x-ray exposure automatically by either de-energizing the x-ray source or shuttering the x-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110 % of its preset value with either a backup timer or devices which monitor equipment function. (2) A visible signal shall indicate when the x-ray exposure has been terminated through the means required by Subsection F.11a.iii. (1). (3) The operator shall be able to terminate the x-ray exposure at any time during a scan, or series of scans under CT x-ray system control, of greater than one-half second duration. (first part of 21CFR1020.33(f)(2)(ii)).
	Documentation ☐ **Compliant** ☐ **Non-compliant**	**Provide the CT device manual sections and or calibration records that address termination of exposure, including visible signals.**

40	Part F Sec. F.11 Sec. F.11 a(iv)	Medical Diagnostic and Interventional X-Ray and Imaging Systems Dental Facilities, Computed Tomography Equipment **Tomographic Plane Indication and Alignment** (1) For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane. (2) For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic planes. (3) If a mechanism using a light source is used to satisfy the requirements of Subsections F.11a.iv. (1) or F.11a.iv.(2), the light source shall allow visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.
	Documentation ☐ **Compliant** ☐ **Non-compliant**	**Provide the CT device manual sections and or calibration records that address visual determination of the tomographic plan and/or reference plane.**

41	Part F Sec. F.11 Sec. F.11 a(v)	Medical Diagnostic and Interventional X-Ray and Imaging Systems Dental Facilities, Computed Tomography Equipment **Beam-On and Shutter Status Indicators and Control Switches** (1) The CT x-ray control and gantry shall provide visual indication whenever x- rays are produced and, if applicable, whether the shutter is open or closed. (First part of 21CFR1020.33(h)(1)) (2) Each emergency button or switch shall be clearly labeled as to its function.
	Documentation ☐ **Compliant** ☐ **Non-compliant**	**Provide the CT device manual sections and or calibration records that address visual indicators whether the shutter is open or closed and the location and function of emergency buttons or switches.**

42	Part F Sec. F.11 Sec. F.11 a(vi)	Medical Diagnostic and Interventional X-Ray and Imaging Systems Dental Facilities, Computed Tomography Equipment **Indication of CT Conditions of Operation** The CT x-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.
	Documentation ☐ **Compliant** ☐ **Non-compliant**	**Provide the CT device manual sections and or calibration records that address visibility of operation conditions.**

43	Part F Sec. F.11 Sec. F.11 a(vii) *Item 43 applies mainly to dental facilities using CT equipment in surgery centers*	Medical Diagnostic and Interventional X-Ray and Imaging Systems Dental Facilities, Computed Tomography Equipment **Additional Requirements Applicable to CT X-Ray Systems Containing a Gantry Manufactured After September 3, 1985.** (1) The total error in the indicated location of the tomographic plane or reference plane shall not exceed 5 millimeters. (2) If the x-ray production period is less than one-half second, the indication of x- ray production shall be actuated for at least one-half second. Indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible. (3) The deviation of indicated scan increment versus actual increment shall not exceed ±1 mm with any mass from 0 to 100 kgs resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel. (4) Premature termination of the x-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.
	Documentation ☐ **Compliant** ☐ **Non-compliant** ☐ **N/A**	**Provide the CT device manual sections and or calibration records that address the use of gantry and 1) tomographic plane and/or reference plane errors, 2) visibility of indicators, 3) measurements of actual versus indicated scan increment, and 4) procedures following premature termination of exposures.**

44	Part F Sec. F.11 Sec. F.11 b	Medical Diagnostic and Interventional X-Ray and Imaging Systems Dental Facilities, Computed Tomography Equipment **CT Facility Design Requirements** (1) The facility operating CT equipment must have provision for two-way aural communication between the patient and the operator at the control panel. (2) Windows, mirrors, closed-circuit television, or an equivalent must be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel. (3) When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) must be available for use in the event of failure of the primary viewing system.
	Documentation ☐ **Compliant** ☐ **Non-compliant**	**Provide floor plan or other documentation that demonstrates positioning of audio and visual permissions between the patient and the operator, as well as downtime plans in case of failure.**

45	Part F Sec. F.11 Sec. F.11 c	Medical Diagnostic and Interventional X-Ray and Imaging Systems Dental Facilities, Computed Tomography Equipment **CT Surveys, Performance Evaluations, Routine QC, and Operating Procedures** Satisfying item #45 on the checklist is dependent on consistent service from a Qualified Medical Physicist (QMP). A QMP must have a graduate-level degree in physics and be certified by an appropriate national certifying body that requires continuing education.
	Sec. F.11 c (i)	**Radiation Protection Surveys** All facilities must commit to having their CT x-ray devices surveyed by a QMP within 30-days of installation. Existing systems that have never been surveyed must be done by July 1, 2024. Surveys should also be done after any change in the facility or equipment which might cause a significant increase in radiation hazard. These records must be available to the state inspectors as evidence of compliance.
	Sec. F.11 c (ii)	**System Performance Evaluations** The annual testing of the CT x-ray system shall be performed by, or under the personal supervision of, a QMP who assumes the responsibility and signs the final performance evaluation report. The QMP sets tolerances that reflect nationally recognized standards. System performance should be done within 30 days of installation or after any change or replacement of components that may change radiation output or image quality. The measurement of the radiation output of a CT x-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding 2 years. The evaluation shall include, but not be limited to: • Geometric factors and alignment (alignment light and table increment accuracy) • Image localization from scanned projection radiograph (localization image) • Radiation beam width • Image quality (high contrast (spatial) resolution, low contrast resolution, uniformity, noise, and artifact evaluation) • CT number accuracy • Image quality for acquisition workstation display devices • A review of the results of the routine QC required under F.11a.iii. • A safety evaluation of audible and visual signals, posting requirements • Dosimetry
	Sec. F.11 c (iii)	**Routine Quality Control** All facilities require a quality control (QC) plan. The QC plan describes metrics you intend to measure at a frequency acceptable to the person designated as the QMP. At a minimum, noise, CT number, and artifacts should be routinely monitored and documented. Additional metrics are encouraged. Your own internal policies dictate frequency of measurement; however, whatever is chosen (i.e., daily, weekly, monthly) cannot be exceeded by one week.
	Sec. F.11 c (iv)	**Operating Procedures**. All operators of x-ray devices should be trained by a QMP. Operators must have access to protocols on performing routine QC, allowable tolerances set by the QMP, and results of the most recent routine QC completed on the system. If the QMP evaluation or routine QC of the CT x-ray system identifies that a system operating parameter has exceeded a tolerance established by the QMP, use of the CT x-ray system on patients shall be limited to those uses permitted by established written instructions of the QMP.
	Documentation ☐ **Compliant** ☐ **Non-compliant**	1. **Provide documentation related to all radiation protection surveys done by a QMP** 2. **Provide documentation related to all performance evaluations done by a QMP.** 3. **Provide QC plan for review and recommendation.** 4. **Provide operator training records, including who trained them.** 5. **Provide the device operating procedure addressing routine QC, allowable tolerances, and limitations of the system when tolerances are exceeded.**

46	Part F Sec. F.11 Sec. F.11 d	Medical Diagnostic and Interventional X-Ray and Imaging Systems Dental Facilities, Computed Tomography Equipment **CT Radiation Protocol Committee (RPC)** Each facility must participate in an RPC consisting of Lead CT radiologists and technologists, the QMP, and other individuals deemed necessary such as safety officers, medical officers, administration, etc. Cooperative RPCs (i.e., more than one registered facility working together) are acceptable if each site has their own representative. The committee must meet at least annually and address issues surrounding the use of CT equipment, such as: • Establishing operating procedures to minimize patient and occupational radiation exposure • Establish and implement written protocols including methods to monitor CT radiation output, a standard method of naming, a DRL, notification value, and alert value for CT procedures, actions to be taken with alert values are exceeded, authorization process for making changes to policies and procedures. • reviewing existing CT protocols along with evaluate and implement new technologies that improve image quality and/or lower patient dose. • reviewing protocols that are used frequently or could result in significant doses. • reviewing acquisition and reconstruction parameters, image quality, and radiation dose. • reviewing the clinical protocols annually, if performed, such as pediatric head, adult head, dental techniques, and brain perfusion. • Preparing an annual report describing key accomplishments and findings Records of each RPC meeting must be maintained. The record shall include the date, names of individuals in attendance, minutes of the meeting, and any action(s) taken. The RPC must also have a record of their own policies and procedures. Facilities also need to maintain a record of radiation output information so the radiation dose may be estimated in accordance with established protocols (e.g., SSDE). The record shall include patient identification, type and date of examination, identification of the CT system used; and the dose values the CT system provides (e.g., CTDIvol, DLP, SSDE).
	Documentation ☐ **Compliant** ☐ **Non-compliant**	**1. Provide documentation of your facility's RBC activities including participants and their roles, meeting minutes, and policies and procedures.** **2. Provide record of radiation output to track use of CT systems on patients.**

47	**Part F** **Sec. F.11** **Sec. F.11 h**	Medical Diagnostic and Interventional X-Ray and Imaging Systems Dental Facilities, Computed Tomography Equipment **Cone Beam Computed Tomography Systems** *Beam Alignment:* The x-ray field in the plane of the image receptor shall not exceed beyond the edge of the image receptor by more than 2 percent of the SID, when the axis of the x-ray beam is perpendicular to the plane of the image receptor. In addition, the center of the x-ray field shall be aligned with the center of the image receptor to within 2 percent of the SID. *Performance Evaluations:* Like all CT equipment described in F.11.c (item #45), CBCT systems must also have performance evaluations performed by, or under the direct supervision of, a QMP. The evaluation shall follow nationally recognized standards and tolerances or those recognized by the Agency. The evaluation shall be performed within 30 days of initial installation, at intervals not to exceed 12 months, and within 30 days after any change or replacement of components which, in the opinion of the QMP, could cause a change in the radiation output or image quality. The facility shall maintain documentation of the established standards and tolerances and testing results. *Quality Control*: Facilities should be following the QC recommendations provided by the CBCT manufacturer. In the absence of manufacturer's provided QC recommendations, the facility shall implement, and document QC guidelines established by a QMP in accordance to nationally recognized guidelines or those recognized by the DOH. If deviating from established protocols, the facility must have a policy document addressing it. *Operator training and support*: The CBCT x-ray system shall only be operated by an individual who has been specifically trained in its operation. The CBCT operator must have available the instructions on performing routine QC, including the use of the CBCT phantom(s), a schedule of routine QC appropriate for the system, allowable variations set by the QMP, if required, for the indicated parameters, and the results of at least the most recent routine QC completed on the system.
	Documentation ☐ **Compliant** ☐ **Non-compliant**	1. **Provide records of beam alignment for CBCT equipment.** 2. **Provide documentation of performance evaluations.** 3. **Provide documentation of QC records and related policy and procedures.** 4. **Provide evidence of training for each operator. Operators may be asked to demonstrate feasibility of obtaining related policy and procedures, allowable variations, and where they record QC.**

48	**Part F** **Sec. F.4** **Sec. F.4. f** *This item does not apply to CT x-ray systems.*	Medical Diagnostic and Interventional X-Ray and Imaging Systems Requirements for All Diagnostic and Interventional X-Ray Systems **Aluminum equivalent of material between patient and image receptor** Except when used in a CT x-ray system, the aluminum equivalent of each of the items listed in Table 2 (inserted below), which are used between the patient and the image receptor, may not exceed the indicated limits. Compliance shall be determined by x-ray measurements made at a potential of 100 kilovolts peak and with an x-ray beam that has an HVL specified in Table 1 (inserted below) for the potential. This requirement applies to front panel(s) of image receptors and film changers provided by the manufacturer for patient support or for prevention of foreign object intrusions. It does not apply to screens and their associated mechanical support panels or grids. TABLE 1 (21CFR1020.30(m)) X-Ray Tube Voltage (kilovolt peak) Design Operating Range / Measured Operating Potential / Minimum HVL (mm in Aluminum) Specified Dental Systems \1\ / Other X-Ray Systems\2\ / Other X-Ray Systems\3\ Below 51: 30: 1.5, 0.3, 0.3; 40: 1.5, 0.4, 0.4; 50: 1.5, 0.5, 0.5 51 to 70: 51: 1.5, 1.2, 1.3; 60: 1.5, 1.3, 1.5; 70: 1.5, 1.5, 1.8 Above 70: 71: 2.1, 2.1, 2.5; 80: 2.3, 2.3, 2.9; 90: 2.5, 2.5, 3.2; 100: 2.7, 2.7, 3.6; 110: 3.0, 3.0, 3.9; 120: 3.2, 3.2, 4.3; 130: 3.5, 3.5, 4.7; 140: 3.8, 3.8, 5.0; 150: 4.1, 4.1, 5.4 \1\ Dental x-ray systems designed for use with intraoral image receptors and manufactured after December 1, 1980. \2\ Dental x-ray systems designed for use with intraoral image receptors and manufactured before or on December 1, 1980, and all other x-ray systems subject to this section and manufactured before June 10, 2006. \3\ All x-ray systems, except dental x-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after June 10, 2006. TABLE 2 Item / Maximum Aluminum Equivalent (millimeters) 1. Front panel(s) of image receptor (total of all) — 1.2 2. Film panel(s) of film changer (total of all) — 1.2 3. Cradle — 2.3 4. Tabletop, stationary, without articulated joints — 1.2 5. Tabletop, movable, without articulated joint(s) (including stationary subtop) — 1.7 6. Tabletop, with radiolucent panel having one articulated joint — 1.7 7. Tabletop, with radiolucent panel having two or more articulated joints — 2.3 8. Tabletop, cantilevered — 2.3 9. Tabletop, radiation therapy simulator — 5.0
	Documentation ☐ **Compliant** ☐ **Non-compliant**	**Provide records that demonstrate that the aluminum equivalent of material between the patient and the image receptor meets the guidelines.**

49	**Part F** **Sec. F.5** *This item only applies to facilities operating fluoroscopic imaging or for recording images from the fluoroscopic image receptor.*	Medical Diagnostic and Interventional X-Ray and Imaging Systems **Fluoroscopy Equipment.** Only image-intensified or direct-digital receptor fluoroscopic equipment shall be used for fluoroscopy. There are many components to this regulation. Please refer to https://www.ecfr.gov/current/title-21/chapter-I/subchapter-J/part-1020/section-1020.32 for details.
	Documentation ☐ **Compliant** ☐ **Non-compliant** ☐ **N/A**	**1. Provide device manual sections that describe safety features.** **2. Provide calibration documentation that addressed AKR compliance measurements, field limitations, conformity of the image receptor, and alignment error.** **3. Provide documentation that source-skin distance is acceptable for the model used.** **4. Provide documentation that fluoroscopic irradiation time, display, and signal are operable and within regulation.** **5. Provide evidence that the fluoroscopic equipment is equipped with display of LIH (last-image-hold).** 6. **Provide evidence that the fluoroscopic equipment is capable of displaying the fluoroscopist's working position, the AKR, and cumulative air kerma.**

50	Part F Sec. F.6 *Only certain parts of Sec F.6 apply to dental offices.*	Medical Diagnostic and Interventional X-Ray and Imaging Systems **Radiographic Equipment** Sec. F.6 i. **Source-skin distance.** The minimum source-skin distance must not be less than 30 cm, except intraoral dental equipment covered under F.6i.ii. Sec, F.6 k. **Radiation Exposure Control**. Sec. F.6 k. (i) **Exposure Initiation.** Means must be provided, such as the depression of a switch to initiate the radiation exposure by a deliberate action on the part of the operator. Radiation exposure must not be initiated without such an action. In addition, it must not be possible to initiate an exposure when the timer is set to a "zero" or "off" position if either position is provided. Sec. F.6 k. (ii) **Exposure Indication.** Visual indication means observable at or from the operator's protected position must be provided whenever X-rays are produced. In addition, a signal audible to the operator must be available to indicate that the exposure has terminated. Sec. F.6 k. (iii). **Operator Protection, Except Veterinary Systems.** (1) **Stationary Radiographic Systems**. The X-ray control, including the exposure switch must be permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure for stationary radiographic systems. (2) **Mobile and Portable Systems**. Mobile and portable X-ray systems which are: (a) Used continuously for greater than one week in the same location, i.e., a room or suite, must meet the requirements of F.6k.iii. (1); (b) Used for less than one week at the same location must be provided with either a protective barrier at least 2 meters (6.5 feet) high for operator protection during exposures or means must be provided to allow the operator to be at least 2.7 meters (9 feet) from the tube housing assembly during the exposure.
	Documentation ☐ **Compliant** ☐ **Non-compliant** ☐ **N/A**	**1. Provide records to demonstrate adequate source to skin distance.** **2. Provide photos to demonstrate how exposures are initiated in compliance with Sec. F.6 k. (i).** **3. Provide evidence of exposure indication.** **4. Provide evidence of operator protection in compliance with Sec. F.6 K. (iii)**

----------End of checklist----------

Resources:

1. Alaska State Legislature, 7 AAC 18.990, Article 6, Definitions
2. Conference of Radiation Control Program Directors (CRCPD) suggested state regulations adopted by reference (Part D and F and its referenced regulations) https://www.crcpd.org/page/ssrcrs_flipbook
3. Alaska State Legislature website: http://www.akleg.gov/basis/aac.asp