

# Department of Health

DIVISION OF PUBLIC HEALTH State Public Health Laboratory 5455 Dr. Martin Luther King Jr. Ave.

Anchorage, Alaska 99507 Main: 907.334.2101 Fax: 907.334.2161

DENTAL FACILITY
ALL DENTAL
PRACTICES ALASKA
STATEWIDE NOTICE

DOH.Radiation.Control@alaska.gov

#### RE: Welcome letter and resources for new Radiological Health Program dental registrants

Dear Dental Facility Representative:

On behalf of the State of Alaska's Radiological Health Program, we would like to welcome you as a new registrant! We understand that there will be many questions as we build a relationship with your facility. To assist and establish effective communication, we are reaching out to provide you with valuable information that can serve as a helpful resource.

The Alaska Administrative Code followed by the Board of Dental Examiners, in collaboration with Department of Commerce, Community, and Economic Development (DCCED), have transferred authority of duties for registering and inspecting dental radiological devices to the Department of Health's (DOH) Radiological Health Program. Like DCCED, DOH will continue to rely on the suggested state regulations of the Conference of Radiation Control Program Directors (CRCPD), specifically Part F and any associated referenced regulations in Part F, to evaluate facility compliance.

#### The following appendixes are attached to this letter to serve as resources for new registrants:

Appendix A: Instructions for using Smartsheet (online registration system)

Appendix B: Narrative of legislative timeline

Appendix C: Repealed legislation related to dental x-ray devices

Appendix D: New legislation related to dental x-ray devices

Appendix E: Evaluation of Radiological Health Equipment Form (adopted by reference) v01.05.2024

Appendix F: Key differences between DCCED and DOH dental x-ray device program execution

Appendix G: Additional resources for dental registrants

Appendix H: Definitions and Acronyms

We trust that you will find the information provided herein valuable, and we extend an invitation for any inquiries or feedback you may have. We would like to invite members of the Board of Dental Examiners to the following meeting opportunities to speak directly with the Radiological Health Program. These meetings will serve as educational opportunities, offering clarification on how our program may impact your practice. Please note, the purpose of these meetings is not to debate the health affects of radiation but to address concerns about the delivery of the Radiological Health Program to dental providers.

• April 18: 12:00 - 1:00 pm: [Zoom Link]

• April 22: 4:00 – 5:00 pm: [Zoom Link]

If you have any questions or concerns, please contact our office through email at <a href="mailto:doh.radiation.control@alaska.gov">doh.radiation.control@alaska.gov</a>. We reply to all emails in the order received and our goal is to reply within 48 hours of receipt of concern or question. Your inquiries are important to us, and we appreciate your patience.

Sincerely,

/s/Irene Easares

Irene Casares, Radiological Health Physicist 2

Department of Health, Division of Public Health, Section of Laboratories

#### **Appendix A- Instructions for using Smartsheet (online registration system)**

DOH maintains a registration database of all radiological equipment on the platform 'Smartsheet' and requires your participation in verifying your information. All facilities are required to have a login email to view and/or correct any information regarding their facility and/or device(s). *Please note: These instructions are generic and may not work for every facility.* Please contact us for tailored assistance if you have any questions or issues with this process and we can help you.

#### **New Registrations**

#### Step 1. Create a Smartsheet email login (If you have already completed this step, continue to Step 2.)

- a. Create a Smartsheet email login at <a href="https://app.smartsheet.com/b/home">https://app.smartsheet.com/b/home</a>
- b. At the top of the page, you will see "Don't have an account? Click "Create one".
- c. A pop-up window will appear stating "Get started with your work account. 30-day free trial. No credit card required". Enter a login email in the box. Click "Continue"
  - Note: The email address used to log in to Smartsheet provides access to your facility files. It is recommended that facilities avoid using an individual's email address since the login email will be used in subsequent years to review, update, and submit correspondence regarding your facility. Instead, alias emails that represent a "contact group" (formerly called "distribution lists") are preferred. This ensures that a single person at the facility isn't responsible for all communication due to personal leave, illness, staff turnover, etc. For example, the contact email for the Radiological Health Program, doh.radiation.control@alaska.gov, is an alias email accessed by numerous employees to provide adequate coverage of service.
- d. Enter your first and last name, then click "Try Smartsheet for Free."
- e. A "Welcome" box will appear instructing you to check your inbox to activate your trial. Follow the instructions.
- f. When you have finished the process of creating your Smartsheet login email, please notify our office with your Smartsheet login email. You can do this by emailing us at <a href="mailto:doh.radiation.control@alaska.gov">doh.radiation.control@alaska.gov</a> notating your facility name and Smartsheet login email in the body of the email.
- g. Shortly after we receive your Smartsheet login email, you will receive an invitation email from Smartsheet to view our facility and device management dashboard. You will then move on to Step 2.

#### **Step 2. Setup a Smartsheet Account**

- a. Create an account by visiting the web address below: <a href="https://app.smartsheet.com/dashboards/Gmpv7QcfMX63MVMhRCFp5RCVhxqMJcwjpjPjgjQ1">https://app.smartsheet.com/dashboards/Gmpv7QcfMX63MVMhRCFp5RCVhxqMJcwjpjPjgjQ1</a>
- b. Under Part One: Facility Information, click on the "Don't see your facility? Click here to register" button. \*\*IMPORTANT\*\*If your facility has a registration number, please do not re-register by clicking on "Don't see your facility? Click here to register". If you don't see your facility in the window under Step 1, please contact our office at doh.radiation.control@alaska.gov.
- c. Complete the New Facility Registration Intake Form. You must hit "Enter" after entering information in each field before moving on to the next field. If a field does not apply to your facility or you are uncertain of entry, please type "NA" or "Unknown".
- d. Once all information is complete, click Submit.
- e. Wait to receive the "Your Registration Number" confirmation email.

  Note: You will need your facility registration number before moving on to Step 3.

# Step 3. Add Devices to your Smartsheet account (you will need your facility registration number to add devices).

- a. Under Part Two: Device Information, click "Don't see your device? Click here to add device" button.
- b. Complete the X-ray Device Registration Form making sure all fields are completed. You must hit "Enter" after entering information in each field before moving on to the next field. If a field does not apply to the device or you are uncertain of entry, please type "NA" or "Unknown".
- c. Once all information is complete, click Submit.
- d. Repeat steps a c for each device at your facility.
- e. Your devices should be visible in your Smartsheet account within 24 hours.
- f. If further action is required, you will be notified through email.

#### Appendix A (cont.):

#### **Existing Registrations**

#### Step 1. Update Facility Information

- a. Login to the system using the following link:
- https://app.smartsheet.com/dashboards/Gmpv7QcfMX63MVMhRCFp5RCVhxqMJcwjpjPjgjQ1
- b. Under Part One: Facility Information, click on your registration number in the facility information window. A pop-up box will appear on the right.
  - **Note:** For agencies with multiple locations, please click the "Click here to expand facility information view".
- c. Verify ALL information is correct, making any necessary changes. You must hit "Enter" after entering information in each field before moving on to the next field.
- d. Ensure all required fields are completed. If a field does not apply to your facility or you are uncertain of entry, please type "NA" or "Unknown". Click Save.
- e. Repeat steps a d for each registration number.
- f. Your changes should be visible in your Smartsheet account within 24 hours.
- g. If further action is required, you will be notified through email.

#### Step 2. Update Device Information for Each Registration Number

- a. Under Part Two: Device Information, click "Click here to expand device information View". Click on device row. A pop-up box will appear on the right.
  - **Note:** If there are no devices listed, this is because your devices did not transfer properly from our files to Smartsheet. You will need to complete Step 3 under "New Registrations" to add your devices.
- b. Verify all device information is correct, making any necessary changes. You must hit "Enter" after entering information in each field before moving on to the next field.
- c. If the status of device changes from "Active", please be sure to complete the Public Comment box with all details of the status of the device. For example, state where the device was transferred to, or the storage location. If the status of the device is disposed, be sure to select the appropriate disposal option in the disposal drop-down box.
- d. Ensure all required fields are completed. If a field does not apply to your device or you are uncertain of entry, please type "NA" or "Unknown". Click Save.
- e. Repeat steps a d for each device at your facility.
- f. Your changes should be visible in your Smartsheet account within 24 hours.
- g. If further action is required, you will be notified through email.

#### **Appendix B: Narrative of legislative timeline**

During the thirty-second legislative session in 2022, two Acts, <u>House Bill 295</u> and <u>Senate Bill 173</u>, were signed into law, transitioning authority and charge of duties for the registration and inspection of dental radiological devices from the Board of Dental Examiners with the Department of Commerce, Community, and Economic Development (DCCED), to the Department of Health (DOH) Radiological Health Program.

Both Acts relating to dental radiological equipment provided for an effective date under AS 44.62.020 (Administrative Procedure Act), but not before the effective date of the law implemented by the regulation. This Act took effect immediately under AS 01.10.070(c) and the DOH radiological equipment section of this Act took effect July 1, 2023. New regulations surrounding this statute change (7 AAC 19 Registration and Inspection of Dental Radiological Equipment) were drafted by the DOH and underwent public comment in November of 2023. These new regulations have been signed and made effective as of 3/22/2024.

In the new regulations, the DOH established standards that comply with federal law for the registration, use, and inspection of dental radiological equipment, including standards for record keeping relating to the control panels and the use of the equipment. In this subsection "dental radiological equipment" means equipment for use in the practice of dentistry, consisting of a control panel and associated tube heads producing x-ray radiation, as defined in AS 18.60.545, or uses radionuclides, as defined in AS 18.60.545.

The DOH shall establish fee levels so that the total amount of fees collected by the DOH approximately equals the total regulatory costs of the department to include the cost of inspecting dental radiological equipment under AS 44.29.020(d). DOH operates the non-dental program in the same manner and strives to make the process as efficient as possible. For dental equipment, we are proposing a fee of \$100 for intraoral devices and \$200 for extraoral devices to cover annual registration and certification. Facilities will be inspected every 6 years by DOH at no extra cost.

Link to public comments to adopted legislation and DOH replies: <a href="https://aws.state.ak.us/OnlinePublicNotices/Notices/Attachment.aspx?id=145267">https://aws.state.ak.us/OnlinePublicNotices/Notices/Attachment.aspx?id=145267</a>

#### Appendix C: Repealed legislation related to dental x-ray devices

#### 12 AAC 28.960. REGISTRATION OF DENTAL RADIOLOGICAL EQUIPMENT.

- (a) Dental radiological equipment with a valid registration from the Department of Health and Social Services under AS 18.60.475 as of September 6, 1998, is considered registered with the board under AS 08.36.075 and this section.
- (b) Repealed 3/11/2016.
- (c) Repealed 3/11/2016.
- (d) The owner or lessee of dental radiological equipment that is registered under this section shall notify the board in writing within 60 days after the equipment is sold, relocated, or no longer in use.
- (e) To register dental radiological equipment, the owner or lessee of the equipment shall submit a completed registration form, adopted by reference in 12 AAC 28.970(b).
- (f) Upon receipt of a completed registration form, the board will issue a registration seal to the owner or lessee of the equipment if it meets the requirements of AS 08.36.075, this section, and 12 AAC 28.965. The owner or lessee of the equipment shall ensure that the registration seal is attached to the equipment that is registered under this section.

#### 12 AAC 28.965. INSPECTION OF DENTAL RADIOLOGICAL EQUIPMENT.

- (a) The owner or lessee of dental radiological equipment must have that equipment inspected within six years from the date that the equipment was first registered with the board under 12 AAC 28.960. The owner or lessee of dental radiological equipment must have that equipment inspected again at least once during every six-year period following the initial inspection.
- (b) The inspection of dental radiological equipment must
  - (1) repealed 9/26/2018;
  - (2) be documented by the inspector on the form adopted by reference in 12 AAC 28.970(c); and
  - (3) meet or exceed, and must determine whether the equipment meets or exceeds, the standards applicable dental radiological equipment in the *Suggested State Regulations for the Control of Radiation*, Part F, published by the Conference of Radiation Control Program Directors, Inc., May, 2009 edition, adopted by reference.
- (c) Repealed 3/11/2016.
- (d) Repealed 3/11/2016.
- (e) Upon receipt of a form documenting an inspection that meets the requirements of AS 08.36.075 and section, this inspector shall issue to the owner or lessee of the dental radiological equipment, an inspection seal indicating the date by when the equipment must be inspected again. The owner or lessee shall ensure that the inspection seal is placed on the equipment in a location visible to persons operating the equipment.
- (f) Owners or lessees of dental radiological equipment shall maintain records that document compliance with the requirements of AS 08.36.075, 12 AAC 28.960, and this section. The records shall be made available to the board or its designee for inspection.
- (g) Repealed 3/11/2016.
- (h) An inspector who performs an inspection of dental radiological equipment shall complete and submit the form titled "Inspection of Dental Radiological Equipment," adopted by reference in 12 AAC 28.970(c), to the owner or lessee of the equipment after the inspection.

#### 12 AAC 28.970. REGISTRATION AND INSPECTION FORMS; REVIEW OF COMPLETED FORMS.

- (a) A registration seal or inspection seal may not be issued unless the information on the completed form meets the requirements of AS 08.36.075, and of 12 AAC 28.960 and 12 AAC 28.965, as applicable.
- (b) The form titled *Radiological Equipment Registration Form*, dated February 2014, is adopted by reference. This form is established by the board for review by staff of the registration of dental radiological equipment under 12 AAC 28.960.
- (c) The form titled *Inspection of Dental Radiological Equipment*, dated February 2014, is adopted by reference. This form is established by the board for use by inspectors of dental radiological equipment, and for review by staff of the documentation of the inspection of that equipment, under 12 AAC 28.965.

#### Appendix D: New legislation related to dental x-ray devices

\*New\*Chapter 19. Registration and Inspection of Dental Radiological Equipment.

#### 7 AAC 19.010. Registration of dental radiological equipment.

- (a) To register dental radiological equipment, an owner or lessee of the equipment shall submit a request to the department's radiological health program.
- (b) Upon receiving this request, the department will register the equipment and issue applicable fees if the equipment meets the requirements of AS 44.29.020(d), this section, and 7 AAC 19.020. Once the department reconciles applicable fees, it will issue a certificate of registration to the owner or lessee for each device. The owner or lessee of the equipment device shall ensure that the certificate of registration is retained and made available upon request. A certificate of registration is valid for one year from the date of issuance.
- (c) The owner or lessee of dental radiological equipment that is registered under this section shall notify the department in writing not later than 30 days after the equipment is sold, relocated, or no longer in use.

#### 7 AAC 19.020. Inspection of dental radiological equipment.

- (a) An owner or lessee of dental radiological equipment must comply with federal regulations by documenting annual evaluations of device performance and repair by vendors or service providers. A vendor or service provider of dental radiological equipment must meet or exceed the routine standards applicable to dental radiological equipment in the Suggested State Regulations for the Control of Radiation, Part F, published by the Conference of Radiation Control Program Directors, Inc., April 2015 edition, adopted by reference. Instances of vendor involvement must be recorded on the form titled *Evaluation of Dental Radiological Equipment*, dated January 5, 2024, adopted by reference in 7 AAC 19.030. Completed forms must be available for review during state inspections.
- (b) The owner or lessee of dental radiological equipment must have that equipment inspected by the department not later than six years from the date that the equipment was first registered with the department under 7 AAC 19.010. The owner or lessee of dental radiological equipment must have that equipment inspected by the department again at least once during every six-year period following the initial inspection.
- (c) An owner or lessee of dental radiological equipment shall maintain records that document compliance with the requirements of AS 44.29.020(d), 7 AAC 19.010, and this section. The records shall be made available to the department or its designee for inspection.
- (d) The department, upon completion of an inspection, will issue the owner or lessee of equipment an inspection result letter that identifies any deficiencies and discloses the timeframe for the next inspection.

#### 7 AAC 19.030. Registration and inspection forms; review of completed forms.

- (a) A registration certificate will not be issued unless the information gathered during a department-led inspection meets the requirements of AS 44.29.020(d), and of 7 AAC 19.010 and 7 AAC 19.020, as applicable.
- (b) The form titled Evaluation of Dental Radiological Equipment, dated January 5, 2024, is adopted by reference. This form is established by the department for completion by the vendor or service provider that performs annual service on dental radiological equipment under 7 AAC 19.020.



## **EVALUATION OF DENTAL RADIOLOGICAL EQUIPMENT**

### RADIOLOGICAL HEALTH PROGRAM (907) 334-2107 doh.radiation.control@alaska.gov

FORM MUST BE COMPLETED AFTER ANY EQUIPMENT SERVICE OR ASSESSMENT WHICH EFFECTS
THE TUBE OR IMAGE QUALITY OF THE DEVICE. Note: This form is intended to document initial installs, annual service, or repairs to a device which involves the tube head. Minor repairs to devices, such as switch replacements, are not to be listed on this form.

PART I. DEVICE STATUS:  INITIAL INSTALL	ANNUAL SERVICE REPAIR OTHER			
PART II. FACILITY INFORMATION:  REGISTRATION NUMBER:  NAME OF BUSINESS:  OR Doing-Business-As:  MAILING ADDRESS:  CITY/STATE/ZIP:  TELEPHONE NUMBER:  POINT OF CONTACT:  FAX/E-MAIL ADDRESS:				
PART II. ALL DEVICE(S) MUST BE EVALUATED IN ACCORDANCE TO REGULATIONS (PART F) & MANUFACTURER  RECOMMENDATIONS: The following minimum conditions must be checked for the appropriate device used at a facility (refer to the regulations and/or request a DOH Equipment Inspection Guide). All device parameters must be recorded on a separate document showing each measurement for each device evaluated. Refer to Part III below.  ✓ Device is FDA registered/permitted				

PART III. RADIATION PRODUCING EQUIPMENT: Devices requiring installation, evaluation, or preventative maintenance must include the following device identification information and all applicable measurements described in Part II above: Manufacture, Model, Serial Number, and Device Type (such as CT, CBCT, PANO, intraoral, etc.) Device parameters must be recorded on a seperate document showing each measurement for each device EVALUATED. EACH DEVICE MUST STATE A PASS OR FAIL RATING AND ANY CORRECTIVE ACTIONS, IF FAILED. ATTACH ALL DOCUMENTS RECORDING MEASUREMENTS TO THIS FORM.

PART IV. CERTIFICATION OF QUALIFIED SERVICE PROVIDER/VENDOR/OR INSPECTOR: THIS IS TO CERTIFY THAT, I, THE			
DELEGATED AUTHORITY, TO THE BEST OF MY KNOWLEDGE AND BELIEF, ALL INFORMATION CONTAINED HEREIN, INCLUDING ANY SUPPLEMENTS ATTACHED			
HERETO, IS CORRECT AND MEETS THE REQUIREMENTS OF THE SUGGESTED STATE REGULATIONS-PART F- PUBLISHED BY THE CONFERENCE OF RADIATION			
CONTROL PROGRAM DIRECTORS (CRCPD).			
PRINT NAME:	SIGNATURE:		
COMPANY NAME	Date:		
COMPANY EMAIL ADDRESS & PHONE #			

## Appendix F: Key differences between DCCED and DOH dental x-ray device program execution

	DCCED - repealed	DOH – new legislation			
1	Register x-ray producing device(s).	Register x-ray producing device(s).			
2	Registration seal was provided after registration was completed.	A Certificate of Registration is provided after registration is completed. Certificates are valid for 1 year.			
3	Inspection of the device must occur within six years of installation by the Board or its representative.	Inspection of the device must occur within six years of transition of authority from the DCCED* Dental Examiners Board (i.e., 7/1/2023).			
4	Service providers are required to do annual inspections of devices and document inspection results.	Vendors who perform the required annual service and repairs of devices meeting the requirements of Part F will fill and attach findings to the DOH** "Evaluation of Radiological Health Equipment" form, adopted by reference.			
5	Inspection by the Board-approved service provider required the inspection be documented on the DCCED* form adopted by reference.	Inspections by the DOH** Radiological Health Physicist requires the inspection be documented as an entire facility inspection according to regulation (Part F and associated referenced regulations in Part F).			
6	Inspection by the Board-approved service provider must meet or exceed the requirements of Part F and referenced regulations in Part F. Part F required annual inspection of devices and required compliance with Part D & Food and Drug Administration, 21 CFR* regulatory sections.	Inspections by the DOH** Radiological Health Physicist must meet or exceed the requirements of Part F. Part F requires annual inspection of devices and requires compliance with Part D & Food and Drug Administration, 21 CFR† regulatory sections. Part of the inspection will be a review of vendor-completed documentation that disclose annual services and repairs on the "Evaluation of Radiological Health Equipment" form, adopted by reference.			
7	Board-approved inspectors who performed an inspection of dental radiological equipment within the six-year time period would place a seal on the device to indicate when the next inspection was due and the inspector would provide a copy of the inspection form to the facility and the Board.	DOH** inspector who checked operating parameters during the state inspection of dental radiological equipment will place a label on the device to indicate the inspection date and the inspector will provide an outcome letter to the facility identifying any deficiencies of non-compliance identified during the inspection.			

<sup>\*</sup> DCCED: Department of Commerce, Community, and Economic Development

<sup>\*\*</sup> DOH: Department of Health
† CFR: Code of Federal Regulations

#### Appendix G. Additional resources for dental registrants

#### Contacting the Radiological Health Program at DOH

Email (preferred method): <u>DOH.Radiation.Control@alaska.gov</u> Phone: 907-334-2101 (preferred), 907-334-2107 Fax: 907-334-2161

Hours: Monday – Friday, 8:00am - 4:30pm

Website: <a href="https://health.alaska.gov/dph/Labs/Pages/radiological/default.aspx">https://health.alaska.gov/dph/Labs/Pages/radiological/default.aspx</a>

5455 Dr. Martin Luther King Jr. Avenue

Anchorage, AK 99507

Registrants can request assistance from DOH's Radiological Health Program at any time. Please request the following documents which have been prepared to assist facilities in becoming more familiar with the regulatory requirements:

Guidance documents to further explain requirements and SOA due process procedures.
Examples of properly filled forms.
Inspection checklists which will be used in all facility-wide state inspections.
Smartsheet assistance to access facility and device information and make changes as necessary.

Our commitment to dental clients: DOH is committed to carrying out the authority that was transferred to register and inspect dental radiological devices in Alaska to the best of our ability. DOH is also committed to listening to your comments and concerns as we initiate and continue to maintain this program over the years to come. Feedback will help us find ways to make this process as easy and efficient as possible. DOH acknowledges that facilities may require time to comply with regulations and will not invoke penalties unless the facility demonstrates hostility or harm to the public and/or state inspectors who are hired to complete the duties of the position. For instance, DOH will allow ample time for dental facilities to update their related policies and operating procedures, as well as acquire service on radiological devices.

What registrants can expect: Registrations will be followed by inspections, invoicing, payment processing and delivery of certificates of registration. Notices of inspection will be coordinated with a facility representative before an inspection occurs. On-time inspections of all registered facilities will be dependent upon facility accessibility, physical location, travel delays, weather, etc. DOH inspections, like those for non-dental devices, will be conducted in a manner that reduces cost to the program and associated registrants. Notifications affecting the dental x-ray device program will be sent through the automated Smartsheet registration email system. If you aren't receiving notifications as expected, please contact the Radiological Health Program. It is recommended to also check spam or junk folders for misrouted emails.

**Non-compliant facilities:** Any facility intentionally rejecting compliance with state and federal regulations within DOH's due process policy timeframes will be forwarded to the Office of Law and DCCED Dental Examiners Board for further possible actions. The DOH's penalty policy states:

AS Sec. 18.60.535. Penalty. A person who violates a regulation, standard, or order of the department adopted or issued under AS 18.60.475 – 18.60.545 is guilty of a misdemeanor and, upon conviction, is punishable by a fine of not more than \$500, or by imprisonment for not more than one year, or by both. Each day upon which a violation occurs constitutes a separate offense.

Table G1: Roles and Responsibilities of Dental X-ray Partners in Alaska

Partner	Role and Responsibility
Dentists	Comply with federal and state regulations surrounding dental equipment to ensure 1) devices are operating correctly for proper diagnosis of dental conditions and 2) devices are not delivering higher than necessary levels of exposure to radiation. Dental practices must document a minimum of one maintenance visit by a service provider annually as outlined in Part F, as well as all in-house maintenance and quality control activities on x-ray devices in-use as indicated by the manufacturer.
Vendors	Provide service to devices. This may involve implementing service contracts with clients to perform preventive maintenance and calibration on x-ray equipment at least <b>annually</b> or at a frequency required by the manufacturer.  NOTE: Service on instruments is not equivalent to an inspection under DOH definitions. DOH will register all service providers as a vendor; however, DOH will not be licensing vendors as did the DCCED previously. The previously licensed inspectors from DCCED can continue to provide service such as preventive maintenance, calibrations, or repairs on x-ray devices operated by dental facilities but this will not be considered a state inspection (Table G2). Registered service providers (i.e., vendors) must provide service to devices in accordance with state and federal regulations as evidenced by completing the Evaluation of Dental Radiological Equipment form adopted by reference by DOH.
Alaska's Board of Dental Examiners	Provide assistance when communicating between the dentists and the SOA's Radiological Health Program. Review documents generated by SOA's Radiological Health Program when requested.
SOA's Radiological Health Program	Register, certify, and provide state inspection to radiological devices to ensure that all maintenance has been performed and documented over <b>a 6-year period</b> , and to ensure proper functionality by evaluating certain parameters of radiological devices. The state inspection will evaluate that the facility remains in compliance with all applicable regulations regarding radiological devices and usage.

Table G2. <u>Dental X-ray Device Regulatory and Activities Timeline</u>

	Cycle 1				Cycle 2		
	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 1
Vendors	Service and repair devices [price varies] Vendor	Service and repair devices [price varies] Vendor	Service and repair devices [price varies] Vendor	Service and repair devices [price varies]	Service and repair devices [price varies] Vendor	Service and repair devices [price varies] Vendor	Service and repair devices [price varies]  Vendor
	completes form v1.5.24)	completes form v1.5.24)					
SOA Rad Health Program	Register device and distribute Certificate of Registration [\$100/intraoral or \$200/extraoral]	Register device and distribute Certificate of Registration [\$100/intraoral or \$200/extraoral]					
	Initial State Inspection and Outcome Letter						Initial State Inspection and Outcome Letter #2

## Appendix H: Definitions and Acronyms

Term/Acronym	Definition			
Certificate of Registration	A document issued to each facility by DOH after successful registration and inspection of the device(s) by the State of Alaska's Radiological Health Program. This certificate is valid for one year and must be renewed each year the device is in use.			
CRCPD	Conference of Radiation Control Program Directors			
DCCED	State of Alaska's Department of Commerce, Community, and Economic Development			
DOH	State of Alaska's Department of Health			
Evaluation	Any equipment service or assessment which effects the tube or image quality of the device. This may include initial installations, annual service or repairs to a device which involves the tube head. Once a vendor has performed any service or repair on dental x-ray devices, they must document all activities and attach findings to the "Evaluation of Radiological Health Equipment" form, adopted by reference. Dental offices must keep a file of completed forms and other documentation for review during a state inspection.			
Inspection	On-site assessment of compliance conducted by the State of Alaska's Radiological Health Physicists. The purpose of the inspection is to determine that facility, equipment, and procedures follow state regulations to minimize or eliminate any condition(s) which cause 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 fetus, or the general public. Inspections occur every 6 years and include a facility assessment, review of completed documentation over the survey period, and measurement of device linearity, accuracy, and precision. Inspection outcomes will come in the form of a letter from the State of Alaska describing strengths and deficiencies in the facility's handling of radiological devices. Recommendations will be made to enforce federal regulations.			
Vendor	A person representing a company that makes and/or distributes dental x-ray devices and serves as a field service engineer, or equivalent, to service and make repairs on proprietary equipment. These individuals are responsible for repairing damaged or non-working devices and providing maintenance to the instrument at the frequency dictated by the manufacturer. Vendors may be referred to as service providers or "Qualified Experts", but not state inspectors. DOH will register vendors to maintain oversight of their competency.			
Qualified Expert	A person who is granted professional privileges based on education and experience to provide clinical services in diagnostic medical physics by the DOH. This is a term used in CRCPD suggested state regulations Part F and refers to qualified vendors that can support facilities by providing service and repairs to dental x-ray devices.			
Radiological Health Physicist	A state employee that has met the educational and experience qualifications to inspect facilities operating x-ray devices and evaluate their compliance with regulations. Two Radiological Health Physicists and one Office Assistant make up the Division of Public Health's Radiological Health Program which resides at the Anchorage State Public Health Laboratory.			
Registration	The process of disclosing details such as location, make, and model of a dental x-ray device to the Radiological Health Program for cataloging and tracking purposes. Registrations are required annually to maintain accurate records and to accommodate updates to accumulated or discontinued devices over the 6-year survey period.			
Service	The process of a vendor installing and confirming proper operation of a device prior to use in patient care. Annual (or more frequent) service in the form of calibrations and/or maintenance may be required, as indicated by the manufacturer. Dental offices must be aware of the services required on their chosen devices and maintain service activities at the frequency dictated by the vendor. Maintenance costs are the responsibility of the dental facility.			
Survey Period	<b>Time since last inspection that will be subject for review.</b> For instance, if your last inspection date was 11/15/24, your next inspection will be scheduled 11/15/30. The survey period during your next inspection will cover all documentation and activities between 11/15/24 through 11/15/30.			