Proposes Changes on Radiological Health Program Registration, Inspection, & Fee for Medical & Dental Devices in the Regulations of the Department of Health (DOH); Law File Number 2023200299; PUBLIC COMMENT RECEIVED & DOH RESPONSE.

1. **Comments seeking a response regarding the Department of Health's (DOH) obligation to consult with the Board of Dental Examiners (BODE) on registration fees for x-ray devices.**

   To address public comments regarding SB 173 AS 08.01.065(C), lines 06-08, the Department of Health believes that reference in AS 08.01.065(C) to "the department" does not refer to the Department of Health (DOH) but rather to the Department of Commerce, Community, and Economic Development (DCCED). There is no directive for the DOH to consult the Alaska Board of Dental Examiners (BODE) in the bill. In general, all of Title 8 of Alaska Administrative Code is directed to the responsibilities of the DCCED. Additionally, the new subsection adopted by SB 173 in AS 08.01.065(k) instructs:

   - *(k) [Effective July 1, 2023.] Notwithstanding (c) of this section, the department shall establish fee levels under (a) of this section so that the total amount of fees collected by the Board of Dental Examiners approximately equals the total regulatory costs of the department, the board, and the Department of Health for all occupations regulated by the board. For purposes of this subsection, the regulatory costs of the Department of Health for the occupations regulated by the board include the cost of inspecting dental radiological equipment under AS 44.29.020(d).*

2. **Public comments questioning the regulatory purpose and benefit of routine radiological health inspections. One commentor stated: "There is seemingly no benefit to patients or dental practices."**

   To address public concern regarding the regulatory purpose of registering, certifying, and inspecting dental radiological devices, DOH points to the fact these regulations are not new and they have existed in 12 AAC § 28.965. In the existing and proposed regulation, state inspection of radiologic equipment is supported by suggested state regulations described below by the Conference of Radiation Control Program Directors (CRCPD) (Table 1). Additionally, the role of partnerships to strengthen dental practice (Tables 2 and 3) and information on safe practices (Table 4) are also included in this response to address these concerns.

   Moving the current regulations to the DOH oversight serves two primary purposes:
   1. To ensure the medical device is operating properly to maximize its functionality to produce quality images for accurate diagnosis.
   2. To ensure all medical devices undergo third-party oversight to ensure proper use, function, maintenance, and compliance with federal regulations. All medical equipment sustains this level of stringency which has been shown to improve the quality of patient care.

   As stated above, the State of Alaska (SOA) regulations surrounding dental equipment have not changed but were simply transferred to DOH's authority. To meet all the Alaska Statute requirements surrounding dental x-ray devices, a four-way partnership is required between the practicing dentists, the vendors of dental x-ray devices, the BODE, and the SOA's Radiological Health Program. The roles of each partner are described in Table 2.

Table 1: Suggested State Regulatory language from the Conference of Radiation Control Program Directors (CRCPD) concerning dental x-ray devices - SSRCR Volume I – July 2021[3]

Part	Selected Content for Dental Practices
Part F: Medical Diagnostic & Interventional X-ray & Imaging	Sections F.1 through F.7 in the 1982 SSRCR have been changed from the 1978 version with the insertion of SI units, changes resulting from amendments to the Federal diagnostic x-ray standard, changes in x-ray log requirements, and changes in dental x-ray beam quality. Section F.3 General and Administrative Requirements. The registrant shall be responsible for directing the operation of the x-ray system(s) under his or her administrative control and shall assure that the requirements of these regulations are met in the operation of the x-ray system(s). a. Radiation Safety Requirements b. Quality Assurance (QA) c. Exemptions for Dental: Sec.F.3a.viii (information available to referring physician) and Sec.F.3b.i.(5) (repeat analysis). All other sections in F.3 apply to dental practices including annual documentation of maintenance, calibration, and review of QA processes. Section.F.7 Dental Facilities. In addition to the applicable provisions of Sec.F.3, the requirements of Sec.F.7 apply to dental facilities using intraoral, panoramic, and cephalometric x-ray equipment. Dental facilities using cone beam computed tomography (CBCT) technology shall follow applicable provisions of Sec.F.11h. Section F.11h applies to dental facilities using cone beam computed tomography (CBCT). These regulations set forth requirements of quality assurance, warning labels on devices, evidence of radiation exposure control, exposure control location and operator protection, administrative controls, as well as specific standards related to hand-held intraoral equipment, beam-on indicators, devices with multiple tubes, mechanical support of tube heads, battery charge indicators, locks, technique indicators, exposure reproducibility, timers, kilovolt peak, x-ray beam alignment, and beam quality. The standards also set forth requirements for measuring leakage radiation from the diagnostic source assembly, radiation from components other than the diagnostic source assembly, and maintaining compliance with the federal X-Ray Equipment Performance Standard 21 CFR Part 1020.

Table 2: Roles and Responsibilities Surrounding Dental X-ray Partners in Alaska

Partner	Role and Responsibility
Dentists	Comply with federal and state laws and regulations surrounding dental equipment[1]. Dental practices must document a minimum of one maintenance visit by a service provider annually as outlined in Part F of the CRCPD suggested state regulatory language[2], 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 and may implement service contracts with clients to perform preventive maintenance and calibration on x-ray equipment at least **annually** or at a frequency required by the manufacturer. NOTE: 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 3). Registered service providers (i.e., vendors) must provide service to devices in accordance with state and federal regulations including by completing the vendor form adopted by reference by DOH.
Alaska's Board of Dental Examiners	Provide assistance with 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 **a 6-year period**, 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 3. Dental X-ray Device Regulatory and Activities Timeline

	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]	Service and repair devices [price varies]	Service and repair devices [price varies]	Service and repair devices [price varies]	Service and repair devices [price varies]	Service and repair devices [price varies]	Service and repair devices [price varies]
SOA Rad Health Program	Register devices [$100/intraoral or $200/extraoral]	Register devices [$100/intraoral or $200/extraoral]	Register devices [$100/intraoral or $200/extraoral]	Register devices [$100/intraoral or $200/extraoral]	Register devices [$100/intraoral or $200/extraoral]	Register devices [$100/intraoral or $200/extraoral]	Register devices [$100/intraoral or $200/extraoral]
	Initial State Inspection and Certification						State Inspection and Certification #2

Table 4: SOA position on safety surrounding dental radiological equipment

Public Comments	DOH's Response
1. Despite the proposed changes, it is unclear how patient or employee safety will be enhanced. If this regulation is to be implemented, there should be a demonstrated and substantial improvement in safety standards that justify the additional burden on dental professionals.	DOH stands behind regulatory oversight of radiological devices for medical purposes to ensure compliance with national standards to minimize risk to patients and employees. Radiological devices are required to be registered for several reasons which includes accountability, regulatory requirements, and safety.[3,4] Radiological devices used for dentistry are considered a low-risk radiological practice, however, this use is not risk-free.[5, 6, 7] Regular inspection of these devices helps ensure that the devices are functioning properly, that staff are operating them safely, and radiological exposure of patients and staff is minimized, thereby minimizing the risk of malfunction as well as risk of over-exposure. To that end, the CRCPD guidelines and these regulations are designed to protect the public from hazardous and unnecessary exposure to devices capable of emitting x-rays.[2] Accountability in meeting the expectations of the regulatory bodies is essential to measure device thresholds to ensure staff and patient safety around such practices.[7] Assessing the functionality and safety surrounding x-ray medical equipment is essential for delivering quality patient care.
2. These changes: • WILL NOT increase patient safety • WILL NOT increase employee safety • WILL NOT improve quality of patient care	
3. The regulations are simply not required for patient or employee safety. We do that on our own.	
4. I do not see how this will improve safety to any involved, or increase the quality of care we provide.	

3. <u>Public comments requested DOH to address the need for increased bureaucracy and its perceived negative impact on dental practices.</u>

To address public comments on the negative impact of increased bureaucracy surrounding dental devices, DOH reminds the public that regulations incorporating dental x-ray devices are not new but have been simply transferred to DOH's authority to ensure regulatory compliance.

The medical industry is regulated by various federal partners stemming from the U.S. Department of Health and Human Services, such as FDA and CMS. The American Dental Association (ADA) as part of a recommended quality assurance plan recommends following inspections by qualified experts as specified by government regulations and manufacturers recommendations[1]. In terms of radiological health, the FDA relies on the experts that make up the CRCPD to provide suitable guidelines of regulatory activities to ensure proper safety and functionality is upheld across all medical practices using x-ray devices on patients. The cost of annual maintenance and registration of x-ray devices represent required overhead expenses to allow medical practices to demonstrate evidence of federal compliance to better validate equipment functionality. Like any quality system, upfront costs can save a lot of money in terms of misdiagnosis, patient mismanagement, and possible litigation.

Previously, 12 AAC 28.965, "Inspection of dental radiological equipment," provided for regulation under the authority of DCCED through the BODE. It stated 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 BODE 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. The equipment must meet or exceed testing requirements and standards applicable to radiological equipment in the Suggested State Regulations for the Control of Radiation, Part F, published by the CRCPD, Inc. May 2009 edition, adopted by reference. The CRCPD suggests state regulations include a section stating all devices must be calibrated, serviced and/or evaluated annually to ensure proper operation and accuracy.[2] DOH provides emphasis on the annual calibration in 7 AAC 19.030(b) to distinguish vendor or service provider maintenance evaluations from the six-year routine state inspection (Table 3).

The SOA has been overseeing the registration, certification, and inspection of radiological equipment for non-dental medical providers for decades. The Radiological Health Program operated by the Division of Public Health has been successfully operating for many years, and as such is well versed in the needs of Alaskan providers when it comes to radiological health services of x-ray devices. The Radiological Health Program is grateful to have received legislative approval to hire another Radiological Health Physicist that can contribute to the successfully implementation of a dental x-ray program. The DOH is doing its best to reduce administrative overhead and keep costs as low as possible. Cost advantages are clear when combining non-dental and dental inspections geographically to reduce travel expenses associated with inspections for the overall program in conjunction with keeping all our medical providers in compliance with federal and state regulations. We also believe that automation of our registry system will remove barriers and reduce costs.

4. <u>Fee setting disclosure for dental devices.</u>

The DOH is operating the Radiological Health Program in a manner that supports itself and does not require additional funds from the public. Essentially, business owners operating radiological devices pay for registering those devices with the State of Alaska, and these fees cover the State's cost of certification and inspection.

All fees for x-ray devices, dental and otherwise, require annual review to account for the cost of the registration, certification, and inspection program hosted by the State of Alaska. The formula proposed in the current AAC regulatory language allows for sufficient program coverage without the added administrative burden of updating the AAC language regularly. We understand that this leaves all medical and dental offices unsure of future costs. However, in our experience, the benefit of stabilizing a registration system lends itself to stable fee structures.

For instance, the dental program increment projected by the State of Alaska is $240,000 per year to cover the accumulated costs of personnel, contracts for equipment, and travel expenses to reach all medical and dental providers in our vast state. We estimate that there are approximately 2,400 dental devices to add to our registry, which would cost the state **$100 per intra oral and $200 per extra oral devices per year to inspect**. The difference in fees for these device types is due to extra oral devices requiring more time and testing to evaluate. Each new state fiscal year, fees will be slightly adjusted to accommodate costs based on the past fiscal year and the number of registered devices. Once annual fees are set, the fee will be posted on our website and will not change for an entire fiscal year.

The proposed fee amount for FY24 ($100 intraoral and $200 extraoral/device/year) aligns with costs of dental x-ray device inspections in other states and covers certification and inspections that occur every 6 years in Alaska. To be clear, registration fees are the only fee from the State of Alaska's Radiological Health Program which allows our Radiological Health Physicists to track, inspect, and certify dental radiological devices on a routine schedule.

References:

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