VIA EMAIL: james.jarvis@state.co.us

August 29, 2018

Colorado Department of Public Health and Environment (CDPHE)
Radiation Control Program
HMWMD-RM-B2
attn: James Jarvis
4300 Cherry Creek Drive South
Denver, CO 80246

RE: Revisions to Rules and Regulations Pertaining to Radiation Control – 6 CCR 1007-1 Part 2, Registration of X-Ray Machines, Facilities and Services and 6 CCR 1007-1 Part 6, X-Ray Imaging in the Healing Arts

To Whom It May Concern:

The Colorado Dental Association (CDA) represents over 70% of Colorado's licensed dentists with a membership of over 3,000 dental professionals. The CDA is dedicated to improving the quality, availability, affordability and utilization of oral health services.

The CDA would like to thank CDPHE's Radiation Control Program for reaching out to stakeholders, including the dental profession, during its rule revision process and for allowing the CDA to comment on proposed revisions to rules governing x-ray imaging. These comments reflect input from CDA members who utilize varying forms of x-ray technology both for preventative screening and diagnostic purposes in dental offices. The CDA has also encouraged our members to submit comments directly to the Department. We are confident that such input will result in productive ideas and improved standards.

On behalf of the dental profession, the CDA wishes to address a few outstanding concerns with the proposed changes to x-ray imaging regulations.

2.6.1.10 Dental Operator Training Requirements (p. 19, Lines 709-714)
As revised, Part 2.6.1.10 is no longer consistent with training requirements for other healthcare professions. The reference to the Colorado Dental Board's Rule X was removed in the published rule markup. A reference to both "licensed and unlicensed" personnel was also added to 2.6.1.10, a reference that appears for no other profession and would likely be interpreted to require additional training for licensed personnel. In the past, training standards in Part 2.6.1.8-2.6.1.12 have been directed to only unlicensed personnel, as licensed personnel were credited with receiving adequate training as part of degree and credentialing programs (consistent with Part 2.6.1.2). The rules for all other healthcare operators addressed in Part 2.6.1.8-2.6.1.12 (e.g., the Medical Board's Rule 800, Podiatry Board's Rule 700, Chiropractic Board's Rule 19) outline standards for only unlicensed personnel (only the Veterinary Board's 4 CCR 727-1 does not appear to have any rules at all regarding radiographs

or imaging). It is unclear why dental is singled out with additional operator requirements for both "licensed and unlicensed" personnel. The Colorado Dental Board does not currently have radiology training requirements for licensed personnel and this provision would require the development of new rules in this area. If there are concerns with licensed personnel (dentists and dental hygienists) needing additional training, this rationale should be provided to justify the public safety benefit of this increase to regulatory requirements. Until that occurs, we suggest that the drafting of Part 2.6.1.10 should continue to mirror that of the other professions:

> "…'adequately trained' shall mean that the individual operator meets all applicable requirements of the Colorado Dental Board **consistent with Rule X of 3 CCR 700.1**."

6.3.1.6 Operation of Radiation Machines (p.17, Lines 634-646)
New language regarding the operation of radiation machines should be clarified as follows so that it cannot be misinterpreted that only licensed individuals may operate radiation machines.

> *Operation … shall be:* "(1) Under the general supervision of an individual authorized by and licensed in accordance with State of Colorado statutes to engage in the healing arts and whose license, licensing body, or licensing regulations and requirements authorize such activity *and* such supervision is otherwise *within the standard and acceptable scope of practice for the licensed individual."*

Unlicensed personnel that meet standard regulatory board training requirements across all healthcare professions have historically been authorized to operate radiation machines under appropriate supervision of a licensee. As Part 6.3.1.6 currently reads (see italics), it could be misinterpreted to restrict operation of machines to only licensed individuals. By either changing the "and" in this section to an "or" or revising the section using the underlined language, it will clarify that unlicensed personnel can continue to expose radiographs with appropriate supervision.

6.3.2.4 Shielding Design Exemptions (p. 20, Lines 752-753)
Hand-held dental devices are not included in the list of equipment exempt from shielding design requirements. Is the Department's intention to require a shielding design for hand-held dental devices? A compliant shielding design may be impractical, and potentially impossible, to attain due to the portable nature of this equipment and many possible utilization sites. We believe that an exemption should be added in Part 6.3.2.4 or Part 6.7.2.3 (4) (or potentially both locations) for hand-held devices used for dental applications with any necessary parameters required to prevent unwanted peripheral exposure added to Appendix 6E. An alternative solution to this concern would be to add "device" to Part 6.3.2.4 (3), allowing the Department to grant exemptions for specific pieces of equipment (e.g., a manufacturer of a particular hand-held unit could apply to the Department for a universal shielding design exemption for its equipment).

6.3.3.4 Anatomic Programming Controls (p. 22, Lines 836-840)
The requirement for anatomic programming controls (or detailed written protocols) on equipment may be unnecessary and duplicative for certain specialty areas like dentistry and podiatry where the applications and protocols are readily apparent and commonly built into the equipment design (though a specific anatomic control may not be available on the machine). There is question as to whether this requirement adds any additional public protection in specialty areas like dental given the nature of practice and limited use of machines. Could the regulation be revised to exclude machines that are

calibrated to a specific purpose (e.g., intra-oral dental machines, panoramic dental, etc.) or to exclude certain applications (e.g. dental)?

6.3.3.8 Evaluation of Protective Apparel (p. 26, Lines 965-974)
While we can appreciate the intention and potential benefits of the new requirement for annual evaluation of protective apparel and auxiliary shields, providers have raised some concerns about the expectations for facilities that do not have an on-site means to perform x-ray imaging on any areas of question in the protective apparel. Are visual and tactile test considered fully sufficient in that case? We understand that fluoroscopy is the recommended technique for inspection of suspect apparel, and this technology is not typically available on-site at dental offices. Screening using fluoroscopy would routinely require engaging consultants or contracting with external business entities or facilities, which could present a significant burden for offices (and raises the question as to whether there is current market and equipment capacity to accommodate all the requests). Adding a qualifier that capacity for the additional screening must exist "on-site" might help alleviate some provider concerns (e.g., "At facilities where the capability exists on-site). In addition, how broadly is "facility" defined? Especially for larger business entities that may have multiple physical locations, is "facility" considered an entity with the same x-ray program registration, same address, same building, etc.? Finally, any documentation expectations for meeting this new requirement should also be outlined in rule.

6.7.1.5 Annual Evaluations for Dental Operators (p. 74-75, Lines 3021-3034)
While we can support the intention of a reasonable and universally-applied ongoing learning process for machine operators, the dental profession has significant concern that dental registrants are singled out among all other registrants in the medical professions to provide "annual evaluations of x-ray operators." We have asked the Department on several occasions whether there has been an incident or data that justifies the increased regulatory burden of annual evaluations for just a single profession (dental) as recommended in the SSRCR Part F model regulation and have not received any evidence to substantiate an increased requirement for solely dental personnel. We understand that fluoroscopy operators (equipment that carries a much higher exposure threshold and risk of patient harm) have an existing retraining requirement of two hours of periodic training that applies every two years (6.5.12.6). However, other operators – and particularly those in comparable fields like podiatry, chiropractic, and veterinary – do not appear to have recertification, retraining or evaluation requirements at this time. Operators that currently carry ongoing learning requirements are engaged in radiology applications that carry a much higher potential patient exposure and safety risk. No data has been presented to demonstrate that annual evaluation of dental operators would meaningfully improve public safety, especially in a manner that offsets the regulatory burden and cost to dental offices to implement.

In addition, the term 'evaluation' is not defined and could carry a high cost and implementation burden (even if this is not currently intended by the Department). Competency evaluations in academic or compliance contexts could require the use of psychometrically valid, calibrated and standardized tools to measure knowledge and performance. The burden of developing and implementing such 'evaluations' could be substantial, especially since the registrant is responsible for the training and no opportunity is currently provided for delegation of the evaluation to qualified outside experts. Even for fluoroscopy operators, the requirement is for periodic training (2 hours) every 2 years, not 'evaluation.' The frequency for dental evaluations is also higher than existing retraining standards (every two years for fluoroscopy operators) and not aligned with other inspection or compliance requirements for dental offices (most equipment inspections are every 3 years). No reason or justification has been provided for the need to provide evaluations at this frequency. Dental technology is not rapidly evolving and there is not a lot of equipment turnover in dental offices. Any image quality issues are readily observed and

should be corrected (retrained) in real-time under existing standards. Quality assurance best practices indicate that testing frequency should be aligned to the problem that the evaluator is trying to catch. However, the 'problem' we are trying to resolve through training has not been defined, which makes it extremely challenging to define an appropriate evaluation or retraining timeline. If we can define the 'problem' we are trying to address and identify an appropriate timeline for addressing it, the CDA would be open to working with the Colorado Dental Board to implement continuing education requirements as a more appropriate means to address ongoing learning and recalibration for operators. However, we continue to believe that these type of continuing education standards should also apply to operators in other medical fields if applied to dentistry.

6.7.2.3 or 6.7.2.4 Rectangular Collimation (p. 75-76, Lines 3048-3089)
At the dental stakeholder meeting on August 16, there was substantial discussion about adding an explicit requirement for use of rectangular collimation in Part 6.7.2.3 or Part 6.7.2.4. If this requirement is added, we would request at least a two-year implementation timeline to give manufacturers sufficient time to adapt software and equipment to the new requirements (e.g., NOMAD equipment would require specific adaptations), as well as to give dental offices reasonable notice to plan for purchase and training on any new equipment. Perhaps implementation could be aligned with the phase out of machines operated at less than 51 kvp in 2021.

Certain exemptions would also need to be made this type of requirement to accommodate circumstances where rectangular collimation would not be feasible due to the nature of the procedure. An example is in endodontics (root canal therapy), where a patient has a rubber dam in place for the procedure that prevents ideal alignment of the beam. A broader exposure field is actually helpful in this case and should be allowed. If rectangular collimation is required, either a general exception for cases "where rectangular collimation is not indicated due to the nature of the procedure" or a specific exception for endodontic procedures should be included.

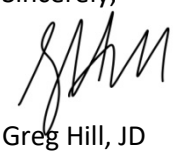
6.7.3.4 Thyroid Shielding (p. 79, Lines 3187-3193)
Part 6.7.3.4 (3) needs to be deleted, as thyroid shielding is always contraindicated in panoramic imaging. Thyroid shielding consistently interferes with the image due to the angle of the beam. In panoramic imaging, the thyroid is essentially protected by the equipment design and beam angle. The EPA Federal Guidance Report No. 14 (Nov. 2014) cited as the basis for the Department's thyroid shielding recommendation also reports that "the positive projection-angle of the panoramic x-ray beam of $+4^{o}$ to $+7^{o}$ essentially eliminates the thyroid from the primary x-ray beam during panoramic imaging" (p. 73). The thyroid can still be exposed to scatter radiation, though a thyroid shield would do little to prevent this since most scatter radiation comes from within the body. Requiring use of a thyroid shield in panoramic imaging would result in many unusable images and increased reimaging. These outcomes are not in the best interest of patients and could ultimately increase patient exposure, in contrast to the intent of this requirement. In fact, panoramic imaging should instead be listed as an exception at the beginning of Part 6.7.3.4: "Excluding <u>panoramic imaging and other</u> cases in which shielding would interfere with the diagnostic procedure, thyroid shielding… ."

6.9.1.3 CT Accreditation (p. 83, Lines 3356-3360)
The CDA fully supports the current exemption from facility accreditation requirements for dental offices using CBCT equipment, as the utilization and exposure associated with this equipment does not justify the cost and burden of accreditation at this time. Since the definition of "volumetric dental imaging systems" was segregated from the general CT definition in the draft revisions, it seems that perhaps "volumetric dental imaging systems" should be listed as an exclusion in this section for clarity as follows:

"6.9.1.3 Excluding CBCT and volumetric dental imaging systems, veterinary systems, …"

The CDA appreciates the Department's proactive approach in working to ensure appropriate regulation for radiation machines. We hope that our comments are productive and beneficial and will help the Department further improve its standards. We appreciate your consideration of these comments.

Sincerely,



Greg Hill, JD
Executive Director, Colorado Dental Association