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Colorado Department
of Public Health
and Environment

October 7, 2009

Dr. David Lurye, DDS
Colorado Dental Association
3960 South Yosemite, Suite 100
Denver, Colorado 80237-1808

RE: Revised Proposed Rules and Regulations Pertaining to Radiation Control, Parts 2 and 6

Dr. Lurye,

This letter is in response to your letter dated September 30, 2009 in which you provided comment on the proposed regulatory changes presented to the Colorado Board of Health on August 19, 2009. The Department appreciates the effort made to review recent proposed changes to the Colorado Rules and Regulations to Radiation Control, specifically Parts 2 and 6. Your suggestions and comments were extremely valuable and helped to improve both of these documents. Based on your suggestions, we have revised the proposed regulatory changes. The revision language listed below follows the format used in your letter, along with a short description of our regulatory intent. I believe you will find that these revised regulations answer your concerns and will maintain a necessary level of safety without unduly limiting the practice of dentistry in Colorado.

Section 2.4.5.1 is revised.

2.4.5 Approval of an Operator.

2.4.5.1 X-ray Machine Operator Subject to Appendix 2D.

- (1) Consistent with and governed by 2.6.1, prior to operating an x-ray system on living humans in the State of Colorado, each individual shall meet the x-ray machine operator adequate radiation safety training and experience criteria established in Appendix 2D, in particular 2D.2.4 for a limited scope x-ray machine operator.
- (2) Application for renewal as a limited scope x-ray machine operator, accompanied by the required fee(s) and evidence of 24 hours of continuing education as prescribed in Appendix 2D and not inconsistent with 2.6.1, shall be submitted at least thirty (30) calendar days prior to the expiration of each two-year registration period.

The revised language makes it more clear that this section pertains to “approval” of an x-ray machine operator subject to Appendix 2D. In paragraph 2.4.5.1 (1), section 2.6.1 is cited so that it is clear that approval conditions

also include the Colorado professional licensure board conditions, if any. Also note that the continuing education requirements refer to limited scope operators specifically.

Section 2.6.5.1 is revised.

- 2.6.5.1 The registrant shall maintain each diagnostic image in a medical record for each patient as specified by the applicable State of Colorado professional licensure board; absent an applicable board specification, record retention shall be for a period not less than ten (10) years or any period of minority or incompetency.

The revised language now includes your suggestion that the requirement for record retention follow applicable Colorado professional licensure board requirements.

Section 6.3.1.5 is revised.

- 6.3.1.5 The registrant or the registrant's agent shall use approved providers of services, consistent with 2.6.1, including but not limited to operation of equipment, inspection of radiation machines and facilities, and assembly, installation, service and/or calibration of radiation machines.

Please note that the revised regulation refers to approval consistent with Section 2.6.1. This maintains the requirement for use of operators that are considered adequately trained without limiting a facility to “registered” operators.

Sections 6.3.2.2(1)(e) and 6.7.3.2(2)(b)(i) are revised.

As requested, “non-handheld” is added before “portable x-ray equipment...”

Section 6.3.2.2 sets requirements for a shielding design after installation of an x-ray machine. The requirement has always been to have shielding designs done prior to installation of an x-ray machine with certain exceptions. The proposed regulations included conditions that would require a shield design after installation. By changing the requirement in 6.3.2.2(1)(e) to “Mobile or non-hand-held portable x-ray equipment...”, use of a hand-held x-ray machine would not trigger a need to have a Qualified Expert perform a shield design. Also, please note that the word “non-hand-held” is not added to 6.3.2.4(3), since the exemption is inclusive of all mobile or portable x-ray equipment. Section 6.3.2.4(1)(a) exempts all dental intraoral x-ray machines from shield design requirements, provided that only one machine is used in a room at one time. To add “non-hand-held” to section 6.3.2.4(3) would mean that other portable x-ray machines would not be exempt and would thus potentially limit diagnostic imaging for other healing arts professions. It should also be noted that dental panoramic units are now included in section 6.3.2.4 without the complication of requiring a “single occupancy room” for the exemption. As the revised regulations state, if a panoramic unit is in an enclosed area, a shield design is not required. An example of an enclosed area would be an alcove that is constructed such that any direct scatter radiation from a patient exposure is intercepted by a wall before reaching staff or other members of the public. This change was made in response to past comments from dentists and is supported by national standards.

Section 6.7.3.2 sets several requirements exclusively to x-ray machines used in the dental profession. The x-ray control requirements in section 6.7.3.2(2)(b) are tiered to apply to systems used routinely in one room, then systems not routinely used in one room, then to portable hand-held systems. This structure, with the revised changes clearly separates the portable hand-held machines from other mobile or portable systems.

Section 6.3.2.4 is revised.

6.3.2.4 The following circumstances are exempt from the requirements of 6.3.2.1 and consequently are exempt from the requirements of 6.3.2.2 and 6.3.2.3:

- (1) An enclosed area (room) used only for a single radiation machine or system limited to one of the following:
 - (a) Dental intraoral;
 - (b) Dental panoramic;
 - (c) Mini-c-arm; or
 - (d) Bone densitometry;
- (2) An open area (bay) used only for dental intraoral equipment, provided that any patient operating chair and any bystander are separated by at least a 2-meter distance (more than 6 feet); ...

As suggested, the regulation in this section has been improved by distinguishing the type of chair meant. Now the requirement clearly reflects our intention of allowing an exemption from the shield design requirements for dental intraoral systems used when the patient chairs are separated by greater than six feet. This revised wording also improves the regulations by stipulating that the open bay configuration must allow for bystanders, such as parents, to be greater than six feet away from the patient chair. Otherwise, a shield design must be done by a Qualified Expert.

Proposed Section 6.3.3.10 is deleted.

~~6.3.3.10 Mobile or portable x ray equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary x ray installation, or when the mobile or portable equipment is most suitable for the diagnostic~~

This section exists in the current regulations and was carried over to the proposed regulations because the Department required increased control over the use of mobile or portable x-ray equipment. The main concern about the use of mobile or portable x-ray equipment is the potential for exposure to staff and other members of the public from use of the equipment in areas not evaluated for shielding. Section 6.3.2 addresses that concern for use of mobile or portable equipment used routinely in an area. The Department understands that infrequent use of a mobile or portable x-ray system in an area not evaluated for shielding is sometimes necessary for patient care. The Department believes that the licensed professional should be allowed to determine what type of machine is appropriate for the healthcare of their patient.

In Section 6.7.1.1, the cross-reference from prior Part 6 is deleted.

~~Requirements for extra-oral dental radiographic systems are covered in RH 6.6.~~

As noted in your letter, this section is deleted in the revised proposed regulations. This section was missed when moving requirements for dental practice into one section. Current regulations have intraoral systems in section 6.7, but do not cover extraoral systems such as panoramic, cephalometric or cone beam volumetric. Those systems are currently regulated by section 6.6. The proposed regulations changed section 6.7 to cover all dental x-ray systems so that it will be easier for both inspectors and dental facility registrants to find the regulations that apply to the dental practice.

Section 6.3.3.9(2), the duplicate text has been deleted

This change will show up in the revised proposed regulations.

Section 6.7.3.4 is revised.

6.7.3.4 A thyroid shield shall be used to reduce patient exposure to scattered radiation (except for a case in which shielding would interfere with the diagnostic procedure).

Per your suggestion, the revised proposed regulations for this section will be similar to section 6.3.3.6, which has been revised as well.

Appendix 6E, Section 6E.1.1.4 is revised.

6E.1.1.4 The device shall be held without any motion, in order to prevent repeat imaging due to motion that reduces image quality. If the operator has difficulty in holding the device stationary, the operator shall use a stand or tripod to immobilize the device.

Per your suggestion, the revised proposed regulations for Appendix 6E will allow the use of a hand-held system without requiring a mechanical stand as long as the unit can be held motionless. The Department has heard from several dentists on this point and has been provided with information that supports the use of the hand-held unit as it was intended. The Department agrees that this revision will allow the use of a hand-held device and still maintain good image quality.

We believe that these revised proposed regulations will answer your concerns. These revisions will be given to the Colorado Board of Health on October 8, 2009 and will be provided to the public on our website soon after. Please review these changes to ensure that they are appropriate for your members. I personally wish to extend my sincere appreciation to your staff, notably Jennifer Goodrum, for their attention to detail and dedication to providing reasonable, yet safe, regulations over the use of x-ray machines in the dental profession. If you have further concerns or questions, please do not hesitate to contact me at (303)692-3427 or Brian.Vamvakias@state.co.us.

Sincerely,

Brian N. Vamvakias, M.S.
Lead, X-Ray Certification