COLORADO DENTAL ASSOCIATION
A CONSTITUENT OF THE AMERICAN DENTAL ASSOCIATION

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VIA EMAIL: cdphe.hmxraycomments@state.co.us

September 30, 2009

Colorado Department of Public Health and Environment (CDPHE)
attn: Brian Vamvakias
4300 Cherry Creek Drive South
Denver, CO 80246

RE: Rules and Regulations Pertaining to Radiation Control

To Whom It May Concern:

The Colorado Dental Association (CDA) represents over 82% 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 healthcare services.

The CDA would like to applaud the CDPHE for reaching out to the dental profession during its revision process and for allowing the CDA to comment on proposed revisions to the "Rules and Regulations Pertaining to Regulation Control." In writing these comments, the CDA solicited input from members that 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 CDPHE. 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 concerns with the proposed revisions. Specific comments on the proposal are outlined below.

Section 2.4.5.1

> **2.4.5.1 X-RAY MACHINE OPERATOR.**
> **(2) APPLICATION FOR RENEWAL, ACCOMPANIED BY THE REQUIRED FEE(S) AND EVIDENCE OF 24 HOURS OF CONTINUING EDUCATION AS PRESCRIBED IN APPENDIX 2D, SHALL BE SUBMITTED AT LEAST 30 CALENDAR DAYS PRIOR TO EXPIRATION OF EACH TWO-YEAR REGISTRATION PERIOD.**

While we understand that Section 2.4.5.1(2) is intended to apply only to registrants licensed by the department (limited scope, bone density and computed tomography operators) who must renew their licenses, the continuing education requirements are placed under a general "machine

operator" heading where they may cause confusion among registrants. Could the subsection be moved to Appendix 2D or include a phrase that clarifies its applicability (for example, "operators licensed under Appendix 2D shall, as part of application for renewal…, submit evidence of …continuing education…")? State licensure board rules establish education and training requirements for other operators not addressed in Appendix 2D, like dental personnel.

Section 2.6.5.1

> Record Retention **AND REPORTS.**
> 2.6.~~3~~5.1 The registrant shall maintain **EACH DIAGNOSTIC IMAGE IN A MEDICAL RECORD FOR EACH PATIENT** for a period **NOT LESS THAN TEN (10) YEARS, OR ANY PERIOD OF MINORITY OR INCOMPETENCY.** ~~for a period of three years (six years for a facility or machine inspected only every three years) copies of personnel qualifications, facility and machine certification evaluations, notice of violations, complaints, investigations, and service records for the x-ray machines and processors for review by the Department.~~

Prior language in this section had dealt with documentation related to machine operation and servicing. The new addition addresses patient records, which is a substantial change in scope. Patient record requirements are usually determined by the respective healthcare licensure board. In fact, these new requirements are inconsistent with the thorough patient record keeping requirements of the Colorado State Board of Dental Examiners (SBDE). When two regulatory agencies set policy on a single issue without coordination, the duplicate effort results in great potential for legal conflicts as well as confusion for practitioners.

To ensure consistency and simplicity, it may be advisable to work with healthcare licensing boards to incorporate any necessary patient record requirements into existing rules for the respective profession. If the Agency is concerned that some entities regulated under this rule may be overlooked through the licensure board approach, it could consider an exception to Section 2.6.5.1 – requiring a registrant to maintain patient records "unless an applicable professional licensure board has established patient record keeping requirements, in which case the professional licensure board's standards shall apply."

Section 6.3.1.5

> **6.3.1.5 THE REGISTRANT OR THE REGISTRANT'S AGENT SHALL**~~, including the~~ use ~~of~~ licensed/certified/registered ~~persons or companies (~~providers~~) to provide~~ **OF** services~~, to the facility. Such services~~ include**ING BUT NOT LIMITED TO** the operation of x-ray equipment, ~~interpretation of exams,~~ inspection of ~~x-ray~~ **RADIATION** machines and facilities, **AND ASSEMBLY,** installation, service and/or calibration of ~~x-ray~~ **RADIATION** machines.

This section, as revised, requires a registrant to use licensed/certified/registered providers to operate x-ray equipment. Consistent with Rule X referenced in Section 2.6.1.10, auxiliary dental personnel are authorized to operate dental x-ray systems. These auxiliary personnel are not otherwise licensed, certified or registered. As written, this section could prevent currently authorized personnel from operating x-ray equipment, even though they are appropriately qualified under Section 2.6.1 of the x-ray rules. To address this concern, the department could consider striking the "licensed/certified/registered" terminology and replacing it with another, more inclusive term – perhaps "approved providers," "authorized providers…" or similar. As an

alternative, the machine operation element of this rule could be qualified with a reference to Section 2.6.1 ("not inconsistent with Section 2.6.1").

Sections 6.3.2.2, 6.3.2.4, 6.7.3.2

> **6.3.2.2 EVALUATION OF SHIELDING DESIGN AFTER COMMENCEMENT OF OPERATIONS.**
> **(1) A QUALIFIED EXPERT SHALL REVIEW AND MODIFY THE SHIELDING DESIGN... WHENEVER:**
> ...
> **(e) MOBILE OR PORTABLE X-RAY EQUIPMENT IS USED REGULARLY IN THE SAME ROOM;**
>
> **6.3.2.4 THE FOLLOWING CIRCUMSTANCES ARE EXEMPT FROM THE *[shielding]* REQUIREMENT OF 6.3.2.1, 6.3.2.2 AND 6.3.2.3:**
> ...
> **(3) A FACILITY USING ONLY MOBILE OR PORTABLE X-RAY EQUIPMENT NOT ROUTINELY IN THE SAME ROOM; OR**
>
> 6.7.3.2 **(2)** X-Ray Control **FOR INTRAORAL OR PANORAMIC DENTAL X-RAY SYSTEMS. (b)** Each ~~x-ray~~ control shall be located in such a way as to meet the following requirements:
> **(i) FOR** stationary x-ray systems, and mobile or portable systems used routinely in one location, ~~shall be required to have~~ the x-ray control permanently mounted in a protected **SEPARATED** area~~, so that the~~ **BEHIND A WHOLE BODY PROTECTIVE BARRIER (OF NOT LESS THAN 0.25 MILLIMETER LEAD EQUIVALENT) WHERE** operator is required to remain ~~in that protected area~~ during the entire exposure, or the exposure control shall be such that the operator can stand at least ~~21.83~~ meters (**MORE THAN** 6 feet) from the patient, the x-ray tube and the useful beam;
> **(ii)** ~~m~~**M**obile and **NON-HAND-HELD** portable x-ray systems not routinely used in one location shall be required to have an exposure switch so arranged that the operator can stand at least ~~21.83~~ meters (**MORE THAN** 6 feet) from the patient, the x-ray tube and the useful beam.**; OR**
> **(iii) PORTABLE HAND-HELD X-RAY EQUIPMENT SHALL MEET APPENDIX 6E.**

The cited sections address shielding requirements for portable x-ray equipment. Shielding requirements and the associated routine use regulations likely derive from concerns about patient and operator exposure related to previous mobile technology. However, technology has changed greatly with the introduction of portable handheld devices.

It's important to note the difference between previous mobile technology and the newer portable handheld units. Handheld devices, such as the NOMAD, have a built in leaded shield that is attached to the cone which prevents scatter radiation from being directed at the operator holding the device. That shield is not present on standard x-ray unit cones. Without the built-in shield, standard operator shielding mechanisms would be necessary. However, with the shield, studies have shown that operators can safely expose radiographs while holding the device and standing next to the patient. Indeed, studies have shown that operator exposure using portable handheld units is substantially less than operator exposure when using traditionally shielded wall-mount systems.[1] Given the low dosage levels of these machines and the built-in shielding, portable

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[1] Bailey E, Gray J, Ludlow J. Image quality and radiation dose comparison for intraoral radiography: hand-held, battery powered versus conventional x-ray systems. Accessed at http://www.aribex.com/pdfs/Dosimetry%20Study%20CRCPD.pdf. 2009 Sept 30.

handheld devices have been demonstrated as safe for routine use, even in the same area, without the more extensive shielding required in these sections.

Section 6.7.3.2(2)(iii) seems to recognize the difference between previous technology and the new portable handheld devices, with a statement that portable handheld equipment (like the NOMAD device used in dental applications) should meet the requirements of Appendix 6E. Further, dental intraoral technology, including the NOMAD handheld unit, is generally exempt from shielding requirements in Section 6.3.2.4(1). However, language in Sections 6.3.2.2(1)(e), 6.3.2.4(3) and 6.7.3.2(2)(i) seem to require shielding for portable devices (all types used routinely in a given area). The terminology in these sections is not limited in scope to non-handheld portable devices, which causes confusion. It's ultimately unclear whether dental intraoral exemptions and Appendix 6E would apply or whether handheld units would be included in the shielding requirements.

To clarify these sections and ensure consistency, the department might consider inserting the term "non-handheld" before "portable x-ray equipment" in each of in Sections 6.3.2.2(1)(e), 6.3.2.4(3) and 6.7.3.2(2)(i). Any shielding requirements for portable handheld equipment should be addressed in a consistent location, likely Appendix 6E.

In addition, we have been informed that the requirements of Section 6.3.2.4 are intended to be tiered, where an exemption under a preceding subsection would exempt a facility from any of the subsequent subsections requirements (for example, if exempt under subsection (1), the subsequent requirements in subsections (2), (3) and (4) would be inapplicable). The fact that Section 6.3.2.4 is tiered could use some additional clarification in the rules.

Section 6.3.2.4

> **6.3.2.4 THE FOLLOWING CIRCUMSTANCES ARE EXEMPT FROM THE *[shielding]* REQUIREMENT OF 6.3.2.1, 6.3.2.2 AND 6.3.2.3:**
>
> **(2) AN OPEN BAY USED ONLY FOR DENTAL INTRAORAL EQUIPMENT, PROVIDED THAT AT LEAST A 2-METER DISTANCE (MORE THAN 6 FEET) SEPARATES ANY TWO CHAIRS;**

The intent of this section appears to be to ensure that bystanders are not exposed to radiation when an exposure is taken. It may helpful to clarify which "two chairs" are being referenced in the provision. As written, the provision could be misinterpreted to disallow the presence of any chair within 6 feet, including chairs of dental personnel. The assumption is that this stipulation refers to patient chairs, treatment chairs, operating chairs (which is the terminology used in dental board regulations), or a similar qualifying term. As an alternative, this section could take the approach of Appendix 6E, which states that "the operator shall ensure there are no bystanders within a radius of at least 2 meters (six feet) from the patient being examined… ."

Section 6.3.3.10

> **6.3.3.10 PORTABLE OR MOBILE 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 PRACTITIONER DETERMINES THAT PORTABLE EQUIPMENT IS MOST SUITABLE FOR THE DIAGNOSTIC PROCEDURE.**

See also, 6.3.3.9 (2) – duplicate text

These use requirements appear to be written to address concerns associated with patient and operator exposure related to previous mobile technology. However, technology has changed greatly with the introduction of portable handheld devices. Portable handheld devices have been demonstrated as safe for routine use. It is not necessary to limit their use to situations where it is "impractical to move a patient" or when the equipment is demonstrated to be the "most suitable for the diagnostic procedure." To ensure appropriate flexibility for use of new technology, the term "non handheld" should be inserted before "portable..." in this section. As an alternate approach, the department could use a qualifier like "unless otherwise authorized by the Agency" to exempt specific devices.

Section 6.7.1.1

6.7.1.1 (1) Requirements for extra-oral dental radiographic systems are covered in ~~RH~~ **GOVERNED BY** 6.6.

Section 6.7 has supposedly been expanded to incorporate all dental requirements for all dental devices, including both intraoral and extra-oral systems. However, Section 6.7.1.1 (1), addressing machine operator training requirements, cites back to Section 6.6 for extra-oral radiograph systems. Section 6.6 (6.6.1.1 specifically) then refers to other sections, including Section 6.5 for fluoroscopy, 6.9 for computed tomography and back to Section 6.7 for dental. This structure creates some circular references that create confusion about exactly which standards apply to dental operators. For clarity, it would be ideal to strike the reference to Section 6.6 in 6.7.1.1(1) and instead incorporate any needed requirements for extra-oral dental radiograph systems directly into Section 6.7. The expanded title for Section 6.7 should allow such requirements to be included directly in the section.

Section 6.7.3.4

6.7.3.4 A THYROID SHIELD SHALL BE USED TO REDUCE PATIENT EXPOSURE TO SCATTERED RADIATION.

Thyroid shielding is addressed in two sections of the proposed revisions, Section 6.3.3.6 (2) and Section 6.7.3.4. Section 6.3.3.6 (2) notes the following exception to the thyroid shielding requirement: [shielding shall be provided] "except for a case in which shielding would interfere with the diagnostic procedure." This exception is not provided in Section 6.7.3.4.

In panoramic, cephalometric and volumetric imaging, the thyroid shield can sometimes be an obstruction. For example, a dentist or oral surgeon may need to examine the jaw for bone loss prior to performing certain procedures, like implants. In certain cases like these, thyroid shielding could interfere with the desired image.

As with general imaging in Section 6.3.3.6, dental imaging should be granted the flexibility to forego the thyroid shielding requirement if it hinders the desired image. The exception language, "except for a case in which shielding would interfere with the diagnostic procedure," should be also added to Section 6.7.3.4.

Appendix 6E.1.1.4

> **6E.1.1.4 A TRIPOD OR STAND SHALL BE UTILIZED TO IMMOBILIZE A HAND-HELD DEVICE DURING PATIENT EXAMINATION IN ORDER TO PREVENT INSTRUMENT MOTION.**

Appendix 6E appears to be modeled from the Suggested State Regulations for Control of Radiation (SSRCR). However, this particular provision, 6E.1.1.4, is not consistent with the SSRCR. The most current revision of the SSRCR reads:

> "A hand-held intraoral dental radiographic unit shall be held without any motion during a patient examination. A tube stand **may be** utilized to immobilize a hand-held intraoral dental radiographic unit during patient examination."

There is a substantial difference between allowing or encouraging the use of a stand and requiring such use. Handheld devices are designed to be highly portable. This requirement would severely restrict the portability and usefulness of the machines.

Handheld portable devices are often used to provide care to patients who are may not otherwise receive radiographs. Handheld devices are used to improve access to care for special needs populations, like those with mental disabilities and those with limited mobility. Unless there is a compelling scientific rationale that indicates that the technology is unsafe or ineffective, it is important not to overly restrict use of this technology such that these vulnerable populations are adversely impacted.

We understand that the proposed requirement in 6E.1.1.4 may be rooted in concerns about poor image quality due to motion of the machine during exposure. However, multiple studies have found blur due to movement on portable handheld devices to be clinically negligible. A February 2009 clinical trial found the image quality for radiographs taken with the handheld NOMAD-brand device and a wall-mounted X-ray machine to be similar in a variety of clinical situations. The study found that motion artifact is not a significant issue with the handheld unit.[2] A May 2009 study presented at the conference of Radiation Control Program Detectors found that the resolution and contrast for a handheld device (that was explicitly handheld and not mounted on a tripod or similar device) were superior to that of a conventional x-ray system.[3] Dental offices using handheld technology repeatedly state that they have had no problems with image quality from using the device in a handheld manner. Operator safety and patient safety have been validated as well, with studies finding that doses with the handheld device are well below recommended levels.

Most data cited above is connected to a particular device, as handheld technology in the market place is currently limited. If there are concerns about future devices coming to market that may

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2 Brooks SL, McMinn WE, Benavides E. A clinical trial of the Nomad portable X-ray unit. J Mich Dent Assoc. 2009 Feb; 91(2):54-8.

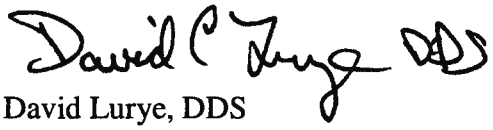
3 Bailey E, Gray J, Ludlow J. Image quality and radiation dose comparison for intraoral radiography: hand-held, battery powered versus conventional x-ray systems. Accessed at http://www.aribex.com/pdfs/Dosimetry%20Study%20CRCPD.pdf. 2009 Sept 30.

not meet current standards, there should, at minimum, be provision allowing unrestricted handheld use for devices that can perform acceptably when operated in a handheld manner.

As a final note on handheld devices, each year, the CDA conducts a charitable dental clinic at different locations around the state. Portable handheld x-ray technology is routinely utilized at this event. A portable handheld device allows quick and efficient imaging for the procedures that benefit from the guidance a radiograph offers. For example, having quality x-rays allows some patients the option of having root canals (thus saving their tooth) instead of extractions. Too many patients in Colorado lack access to dental care. This charitable event helps to address a small portion of a tremendous need. However, the restriction on portable handheld technology has the potential to greatly slow the efficiency of the x-ray process and substantially reduce the number of procedures that can be performed at the event. It would be a disservice if this 6E.1.1.4 was implemented without a strong scientific justification and resulted in diminished access to care.

The CDA appreciates the CDPHE's proactive approach in working to ensure appropriate regulation for x-ray technology. 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,



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