COLORADO

Hazardous Materials & Waste Management Division

Department of Public Health & Environment

This document highlights the impacts of the more significant changes being proposed for Part 6 and Part 2 for Chiropractic Practices. All facilities using radiation machines for healing arts purposes must comply with Part 2 and Part 6, Section 6.3 and 6.4 unless exempted. Almost all chiropractic facilities use general purpose x-ray machines, and so must comply with the machine performance requirements in Section 6.6. Chiropractic facilities using fluoroscopic must comply with the requirements in Section 6.5.

I. Chiropractic – proposed rule potential impacts
   a. Credential requirement changes
      i. Proposed requirements of Section 6.3.3.5 allow a person to supervise and authorize an x-ray exam who is 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 or is otherwise within the standard and acceptable scope of practice for the licensed individual. Current regulations restrict supervising and authorizing individuals for human imaging to Colorado-licensed Physicians, Dentists, Chiropractors or Podiatrists. The proposed change will allow Physician Assistants and Nurse Practitioners, for example, to supervise x-ray exams as long as their professional Colorado Board authorizes it. The credential requirements for a chiropractic practice is set by the Colorado State Board of Chiropractic Examiners.
   b. Proposed CT Regulations
      i. In 6.9.1.3, the proposed regulations will require facilities using CT machines to be accredited by an organization recognized by Medicare or the Department. CBCT machines are exempt from the accreditation requirement. There are no Chiropractic facilities with registered CT machines in Colorado. These proposed rules for CT machines should not affect Chiropractic facilities at this present time.
   c. Proposed Fluoroscopy Regulations
      i. In the proposed rule, the language of Section 6.5 is replaced in its entirety with the language of Part F. Many of the current Part 6 requirements exist in the proposed regulations, but may appear in different sections or with different wording that is more consistent with Part F. Some Chiropractic facilities have registered fluoroscopic machines. The proposed requirements below will apply to any chiropractic facility using any fluoroscopic machine, as applicable.
      ii. Part 6, Section 6.5.12 and Part 2, Section 2.6.1.4 now refer to Appendix 2G in Part 2 for credential requirements for Fluoroscopy operators. New requirements to maintain at least 2 hours of fluoroscopic “continuing education” every two years are proposed.
      iii. Part 6, Sections 6.5.13.3 to 6.5.13.7 contain proposed new requirements that involve operator competence on the machine being used, procedure planning for pregnant women

and pediatric patients, dose monitoring and written policies for fluoroscopically guided procedures.

iv. Section 6.5.15 contains new proposed requirements for facilities performing fluoroscopically-guided interventional (FGI) procedures which would require:
    1. A Case Review Committee (CRC) be formed consisting of a supervising physician, a medical physicist, and the lead technologist as a minimum.
    2. The CRC would be responsible for:
        a. Developing written policies on who is authorized to operate a fluoroscope for interventional procedures.
        b. Develop written policies on how the facility will record patient dose.
        c. Develop written policies for levels of dose that require physician notification and additional response for patient safety.
        d. Develop written policies for setting a "Substantial Radiation Dose Level" that will trigger additional dose-management actions.
    3. Record-keeping requirements will include documenting the operator, the patient, the date and type of examination, the machine model, and dose to the patient.

v. Fluoroscopic machine performance requirements were not changed from current regulations.

d. Equipment Design and Configuration Changes

i. Section 6.6.1.2 of the proposed rule requires that digital systems be evaluated initially by a Colorado Registered Medical Physicist (RMP). Subsequent routine inspections may be done by a QI who has appropriate approval for the machine. Display monitor testing must be done by a Registered Medical Physicist. This is a slight modification of the current requirements for machine evaluation, but essentially the requirement will not change. Many chiropractic facilities are using digital image receptors and therefore will be affected by the requirements in Section 6.3.5.5 and 6.3.5.6 for digital systems and display monitors.

ii. In Section 6.6.2.2(2) when a system uses a light localizer to visualize the useful beam area, the proposed regulations require that the light has a luminance of 160 lux. The current regulations require 500 lux, so the proposed regulations allow a light localizer with less luminance.

iii. Section 6.6.2.2(3) of the proposed rule requires a contrast ratio of at least 4 for stationary machines and at least 3 for mobile or portable systems. This test ensures the light localizer is visible to the operator. The current regulations do not require a contrast ratio test.

iv. Section 6.6.2.4(4) – The testing of field indication and alignment must be measured at SID's in common clinical use.

v. Facilities using general purpose diagnostic, CT and fluoroscopic systems are required to have a shield design calculated by a Colorado-registered Qualified Expert for each area adjacent to the x-ray area. The shielding design must show the calculated radiation levels in each adjacent area and the amount of shielding required to keep the adjacent areas within the limits for public exposure or radiation worker exposure as appropriate.
    1. Areas using only bone densitometry machines are exempt from this requirement.
    2. Areas where mobile or portable machines are used less than 5 days per month are exempt.

e. Mobile and Portable Systems

i. In Section 6.6.3.4(1)(b), the proposed regulations require a control booth to meet Appendix 6B requirements if the machine is used at one location more than five days each month. If the machine is used less than five days a month, the operator may be protected by a leaded apron or a leaded barrier or by standing 2.7 meters from the tube head. The current regulations require a facility to follow Appendix 6B requirements for any area the machine is used routinely, regardless of how many times it is used. The proposed regulations allow the facility to use temporary protection when the area is used very infrequently and provides some additional clarity to the requirement.

f. Radiation Exposure Monitoring Requirements
   i. No changes were made to the requirements for limiting radiation exposure to the public or the requirement to monitor radiation exposure for workers.
   ii. Every facility must have a documented program to monitor the radiation exposure of all machine operators and any other staff that may be exposed to radiation as part of their job duties.

g. Registration
   i. No changes have been made to the registration requirements in Part 2, Section 2.4.1. All facilities that use radiation machines must register annually and also pay a $50 X-Ray Facility Registration fee.