



ADMINISTRATIVE RULES OF MONTANA



37.14.1003 GENERAL SAFETY PROVISIONS

- (1) Diagnostic x-ray systems, for use on humans, and their associated components certified pursuant to the federal diagnostic x-ray standard shall be maintained in compliance with applicable requirements of such standard as set forth in 21 CFR, chapter I, subchapter J, as revised on April 1, 2003. The department may waive compliance with the specific requirements of this subchapter by an existing machine or installation if the registrant demonstrates, to the department's satisfaction, achievement through other means of radiation protection equivalent to that required by this chapter.
- (2) No person shall make, sell, lease, transfer, lend or install x-ray equipment or the supplies used in connection with such equipment unless such supplies and equipment, when properly placed in operation and properly used, will meet the requirements of this chapter. This includes responsibility for the delivery of cones or collimators, diaphragms and adjustable diaphragms, filters, adequate timers, and fluoroscopic shutters, where applicable.
- (3) Personnel monitoring shall be performed in controlled areas for each occupationally exposed individual for a minimum of a 13-week period starting each January. When a protective apron is worn, the monitoring device shall be worn at the collar outside of the apron.
- (4) Safety requirements concerning the use of radiation sources are that:
 - (a) The registrant shall be responsible for radiation safety. He is responsible for assuring that radiation sources under his jurisdiction are used only by persons competent to use them. He is responsible for providing the instruction of personnel in safe operating procedures.
 - (b) A radiation safety officer, who may be the registrant himself, shall be designated for every installation and shall be approved by the department as per ARM 37.14.307 (1) (b) , if other than a licensed member of the healing arts.
 - (c) The radiation safety officer shall:
 - (i) establish and supervise operating procedures and review them periodically to assure their conformity with this chapter;
 - (ii) provide personnel with instruction on proper radiation protection practices;
 - (iii) conduct radiation surveys and source leak tests where indicated and keep records of such surveys and tests, including summaries of corrective measures recommended and/or instituted;
 - (iv) assure that personal monitoring devices are used where indicated and that records are kept of the results of such monitoring;

- (v) assure that interlock switches and warning signals are functioning and that signs are properly located; and
 - (vi) investigate each known or suspected case of excessive or abnormal exposure to determine the cause and to take steps to prevent its recurrence.
 - (d) The registrant shall provide safety rules to each individual operating x-ray equipment under his control, including any restrictions of the operating technique required for the safe operation of the particular x-ray apparatus, and require that the operators demonstrate familiarity with these safety rules.
 - (e) Deliberate exposure of an individual to the useful beam for training or demonstration purposes shall not be permitted unless there is also a medical or dental indication for the exposure and the exposure is prescribed by a practitioner of the healing arts.
- (5) The general shielding safety requirements are as follows:
- (a) Before construction, the floor plans and equipment arrangement of medical installations (new or modifications of existing installations) utilizing x-rays for diagnostic or therapeutic purposes shall be submitted to a qualified expert for determination of shielding requirements consistent with National Council on Radiation Protection (NCRP) and Measurements Reports No. 49 and 51, and 10 CFR part 20, as revised on January 1, 2003.
 - (b) A letter shall be submitted by the qualified expert to the department within 30 days of the project completion. The letter must contain at least the following information:
 - (i) name, address and credentials of the qualified expert;
 - (ii) facility site name, address and telephone number;
 - (iii) facility owner's name, address and telephone number;
 - (iv) date of installation;
 - (v) name and address of the manufacturer; or
 - (vi) if a used or reconditioned device is installed, the name and address of the previous facility or the owner of origin.
 - (c) Each installation shall be provided with such primary protective barriers and/or secondary protective barriers as are necessary to assure compliance with ARM 37.14.705 , 37.14.708 and 37.14.709 . This requirement shall be deemed to be met if the thickness of such barriers are equivalent to those as computed by a qualified expert and are consistent with the NCRP Reports No. 49 and 51 and 10 CFR part 20, as revised on January 1, 2003.
 - (d) Lead barriers shall be bonded to panels of rigid supporting material in such a manner that they will not sag or cold-flow because of their own weight and shall be protected against mechanical damage. Lead shielding less than one mm thick shall be bonded to panels of some rigid supporting material. The minimum allowable thickness of lead is 0.79mm (1/32 inches or two pounds per square foot) .
 - (e) Joints between different kinds of protective materials shall be so designed that the overall protection afforded by the barrier is not impaired.
 - (f) Joints at the floor and ceiling shall be so designed that the overall protection is not impaired.

- (g) Windows, window frames, doors, and door frames shall have the same lead equivalent as that required of the adjacent wall.
- (h) Holes in protective barriers shall be covered so that overall protection is not impaired.
- (6) For new and modified installations only, the following are minimum design requirements for medical x-ray machine operator booths in conjunction with ARM 37.14.1006 , 37.14.1010 , 37.14.1011 , 37.14.1012 , 37.14.1020 , 37.14.1021 and 37.14.1022 . The requirements specified under (6) , (7) , (8) and their subsections do not apply to podiatry and veterinary installations. The requirements specified under (6) through (6) (b) (iii) , (6) (d) through (6) (f) (ii) do not apply to dental installations. See (7) and (8) for dental panoramic and cephalometric requirements.
 - (a) The operator shall be allotted 0.7 sq. meters (7.5 sq. ft.) or more of unobstructed floor space in the x-ray booths.
 - (i) The 0.7 sq. meters (7.5 sq. ft.) of minimum space specified under (6) (a) shall be a geometric configuration where no dimension is less than 61.0 centimeters (2.0 ft.) .
 - (ii) The allotted space shall exclude an encumbrance by the console, such as an overhang, cables or other similar encroachment.
 - (iii) An extension of straight line drawn between any point on the edge of the booth shielding and the nearest vertical edge of a vertical cassette holder, corner of the examination table or any part of the tube housing assembly shall not impinge on the unobstructed space.
 - (iv) The booth walls shall be 2.1 meters high (7.0 ft.) or more and shall be permanently fixed.
 - (v) When a door or moveable panel is used as the integral part of the booth structure, it must have a permissive device, which will prevent an exposure when the door panel is not closed.
 - (b) The operator's switch for the radiographic machine shall be fixed within the booth. The switch shall:
 - (i) be located so that it is impossible to make an exposure when the operator is outside of the protected area;
 - (ii) allow the operator to use the available viewing windows; and
 - (iii) be constructed so that a single depression by the operator will provide a single exposure and that continuous pressure by the operator does not provide a continuous or multiple exposure.
 - (c) Each booth shall have at least one viewing device, which shall:
 - (i) be placed so the operator can have full view of the entries into the room; and
 - (ii) be placed so that the operator can view the patient during exposure.
 - (d) When the viewing system is a window, the following requirements also apply:
 - (i) the window shall have a visible area of 930 square centimeters (1.0 square foot) or more; and

- (ii) the glass shall have the same lead equivalence or more as that required in the booth's wall where the glass is mounted.
- (e) When the viewing system is by mirrors, the mirrors shall be located to accomplish the general requirements under (6) (c) .
- (f) When the viewing system is by electronic means (for example, tv) :
 - (i) the camera shall be located to accomplish the general requirements under (6) (c) ; and
 - (ii) there shall be an alternative viewing system as a backup for electronic failure.
- (7) Dimensions of primary beam shielding shall exceed the largest possible beam size by 30.5 centimeters (1.0 foot) or more in every direction. Cephalometric primary beam shielding shall be deemed adequate if, for a maximum workload of 20 films a week, two-pound lead is installed (for occupied areas) .
- (8) A viewing device shall be present in dental panoramic and cephalometric x-ray installations, so that the requirements of (6) (c) are met.
- (9) National Council on Radiation Protection and Measurements Reports No. 49 and 51, 10 CFR part 20, as revised on January 1, 2003 and 21 CFR, chapter I, subchapter J, as revised on April 1, 2003, are incorporated into this chapter by this reference. The reports and CFR pertain to requirements for radiation protection and measurements. Copies of National Council on Radiation Protection and Measurements Reports No. 49 and 51, 10 CFR part 20 and 21 CFR, chapter I, subchapter J are available for viewing at the Department of Public Health and Human Services, Quality Assurance Division, Licensure Bureau, 2401 Colonial Drive, Helena, MT.

Authorizing statute(s): Sec. 50-79-201, 50-79-202, 50-79-204, 75-3-201 and 75-3-204, MCA

Implementing statute(s): Sec. 50-79-101, 50-79-102, 50-79-103, 50-79-104, 50-79-105, 50-79-106, 50-79-107, 50-79-108, 50-79-201, 50-79-202, 50-79-203, 50-79-204 and 75-3-201, MCA

History: NEW, 1980 MAR p. 1069, Eff. 3/28/80; TRANS, from DHES, 1996 MAR p. 433; TRANS, from DEQ, 2000 MAR p. 189; AMD, 2003 MAR p. 1291, Eff. 7/1/03; AMD, 2003 MAR p. 2443, Eff. 10/31/03.