DEPARTMENT OF CONSUMER AND INDUSTRY SERVICES

RADIATION SAFETY SECTION

(By authority conferred on the department of public health by section 13521 of Act No. 368 of the Public Acts of 1978, as amended, and section 48 of Act No. 306 of the Public Acts of 1969, as amended, being SS333.13521 and 24.248 of the Michigan Compiled Laws)

PART 10. VETERINARY X-RAY INSTALLATIONS

R 325.5401. Purpose and scope.

Rule 401. (1) This part establishes requirements governing the use of x-radiation in veterinary medicine.

(2) This part applies to all registrants who use x-radiation in veterinary medicine or research for the intentional exposure of animals.

(3) In addition to the requirements of this part all registrants are subject to parts 1, 4 and 5 and all applicable provisions of the other parts.

(4) The veterinarian should be aware of the requirements of the Michigan department of labor with regard to the employment of persons under 18 in occupations involving x-ray equipment.

History: 1979 AC.

THERAPEUTIC MACHINES USED FOR VETERINARY X-RAY TREATMENT

R 325.5402. X-ray equipment.

Rule 402. The x-ray equipment shall comply with the general requirements of rules 312 and 321.

History: 1979 AC.

R 325.5403. Enclosures.

Rule 403. The enclosure shall comply with the general requirements of rules 315 and 322.

History: 1979 AC.

R 325.5404. Conditions of operation.

Rule 404. (1) Operation shall comply with the general requirements of rule 317 excluding (2), (5), (6), and (11).

(2) The output of the x-ray generator should be calibrated initially before use for the treatment of animals. It should also be recalibrated after each tube replacement and after any changes or replacement in the generating apparatus which could effect a change in the x-ray output. Check calibrations should be made on an annual basis and records of all calibration maintained for not less than 5 years.

(3) Patients shall not be hand-held in position for radiation therapy. Mechanical supporting or restraining devices shall be used if restraint is required.

(4) A person shall not be permitted in the treatment room when the tube is operated at any potential.

(5) The x-ray tube of a contact therapy machine as defined in rule 321 (3) shall not be hand-held during irradiation. When practical, a cap of at least 0.5 millimeter lead equivalence should cover the aperture window of the tube housing of such apparatus when the apparatus is not being used. Because the exposure rate at the surface of the window of contact therapy and beryllium window machines may be more than 10,000 R per minute, extreme precautions are necessary to prevent accidental exposure to the useful beam.

(6) Lead, lead rubber, lead foil and similar materials used for limiting the field, should not transmit more than 5% of the useful beam under the conditions at which the machine is operated for therapy.

History: 1979 AC.

FIXED RADIOGRAPHIC INSTALLATIONS

R 325.5405. X-ray equipment.

Rule 405. (1) All x-ray tube housings in fixed radiographic installations shall be of the diagnostic type.

(2) The aluminum equivalent of the total filtration in the useful beam shall not be less than the values shown in table 1.

TABLE 1

Operating kVp (Inherent plus added)	Minimum Total Filter
Below 50 kVp	0.5 mm aluminum
50-70 kVp	1.5 mm aluminum
Above 70 kVp	2.5 mm aluminum

(3) Beam-limiting devices (diaphragms, cones, adjustable collimators) capable of restricting the useful beam to the area radiographically recorded shall be provided to define the beam and shall provide the same degree of attenuation as that required of the tube housing.

(4) Beam-limiting devices shall be calibrated in terms of the size of the projected useful beam at specified source-image distances (SID). This calibration shall be clearly and permanently recorded on the beam-limiting device. Calibration of adjustable beam-limiting devices shall permit reproducible settings.

(5) X-ray systems designed for only 1 image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions not greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within 2% of the SID.

(6) General purpose radiographic x-ray systems should be equipped with adjustable beam-limiting devices containing light localizers that define the entire field. Rectangular beam-limiting devices are usually preferable.

(7) The size of the x-ray beam projected by fixed aperture beam-limiting devices, except those used for stereoradiography, shall not exceed the dimensions of the image receptor by more than 2% of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

(8) The calibrated field size indicator on adjustable beam-limiting devices shall be accurate to within 2% of the SID. The light field shall be aligned with the x-ray field with the same degree of accuracy. The field size projected by automatic adjustable beam-limiting devices shall provide the same precision.

(9) For radiographic procedures resulting in multiple views on a single x-ray film the beam-limiting device shall limit the x-ray field size to the recorded radiographic image size within 2% of the SID. Covering a portion of the radiographic film with radio-opaque material is not a substitute for proper x-ray field limitation. This subrule does not apply to spotfilm devices manufactured before the effective date of these rules.

(10) A device shall be provided which terminates the exposure at a preset time interval or exposure limit. The operator shall be able to terminate the exposure at any time by discontinuing pressure upon the exposure switch except that during serial radiography means may be provided to permit completion of any single exposure of the series in progress.

(11) A primary radiographic exposure switch shall be provided which shall be securely fixed such that the operator is required to be behind a fixed shield which will intercept the useful beam and any radiation which has been scattered only once.

(12) An auxiliary foot switch may be provided to activate the radiographic tube in addition to but not in substitution of the requirement of subrule (11). This auxiliary switch need not be fastened behind a fixed shield.

(13) The control panel shall provide positive visual identification of the production of x-rays whenever the x-ray tube is energized. A milliammeter may comply with this subrule.

(14) On diagnostic x-ray systems manufactured after the effective date of these rules, a signal audible to the operator shall indicate that the exposure has ended.

(15) The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls are used, in which case the technique factors which are set before the exposure shall be indicated. On equipment having fixed technique factors, this requirement may be met by permanent markings. Indication of technique factors shall be visible from the operator's position.

(16) X-ray equipment installed after the effective date of these rules shall be installed and used in accord with the appropriate portions of the 1975 national electrical code (NFPA No. 70-1975) reproduced or referenced in rule 359. X-ray equipment installed before the effective date of these rules shall conform with the appropriate national electrical code in effect at the time of installation.

History: 1979 AC.

R 325.5407. Enclosures.

Rule 407 (1) An enclosure shall be a permanent part of the building or equipment. Portable shields shall not be used for permanent installations.

(2) The degree of protection required for an enclosure shall be determined by the workload, use and occupancy factors and the kilovoltage, milliamperage, mechanical movement, and distance factor, and shall be subject to design approval by the department.

(3) Radiographic-room wall and floor areas exposed to the useful beam plus an additional area extending at least 30 centimeters (1 foot) beyond shall be provided with a primary protective barrier where necessary as determined by workload, use, occupancy and distance factors. All vertical primary protective barriers specified in this rule shall extend continuously from the floor to a minimum height of 2.1 meters (7 feet).

(4) Secondary protective barriers shall be provided in the radiographic room ceiling and in those walls not requiring primary barriers.

(5) Control apparatus for the radiographic equipment shall be shielded by a primary protective barrier which cannot be removed from a protective position between the operator and the radiation source during machine operation.

(6) Movable barriers with electrical interlocks shall not be approved in lieu of compliance with subrule (5).

(7) The primary exposure switch location and control shield shall be oriented so that, at arm's length from the exposure switch, the operator shall not be exposed to the useful beam, leakage radiation or any radiation which has been scattered only once.

(8) The operator shall be able to see and communicate with personnel within the room from a shielded position at the control panel. When an observation window is provided, it shall have a lead equivalence at least equal to that required of the control barrier and shall be installed so that the attenuation effectiveness of the barrier is not impaired.

(9) At times it may be necessary for personnel to remain within operating room or special procedure installations during radiographic exposures. A primary protective barrier shall be provided for personnel protection under these circumstances unless necessary technique prevents use of such protection. This barrier may be movable if necessary. Movable barriers shall not be permitted in lieu of the provisions of subrules (3) and (5).

History: 1979 AC.

R 325.5409. Conditions of operation.

Rule 409. (1) An operator shall properly utilize the beam-limiting devices provided to restrict the useful beam to the smallest area consistent with clinical requirements. Particular care shall be taken to align accurately the x-ray beam with the patient and film.

(2) The operator shall insure the presence of adequate filtration before any radiographic procedure. See rule 405 (2).

(3) When a patient or film must be held in position for radiography, mechanical supporting or restraining devices shall be available and shall be used unless contraindicated. Proper use of these devices shall permit the operator to stand behind the primary control shield during most radiographic procedures.

(4) If the patient or film must be held by 1 or more individuals, each individual shall wear protective gloves and body aprons of 0.5 millimeter minimum lead equivalence as well as head and neck protection of 0.25 millimeter minimum lead equivalence. Each person shall be so positioned that no part of his body will be struck by the useful beam and that his body is as far as possible from the edge of the useful beam.

(5) Only individuals whose presence is necessary shall be permitted in the radiographic room during exposure. These individuals shall be protected as specified in subrule (4) unless protected by an approved primary barrier.

(6) If an auxiliary foot switch is provided as specified in rule 405 (12), it shall be used only be a licensed veterinarian and only at times when sufficient personnel are not available to permit use of the primary exposureswitch specified in rule 405 (11).

(7) To protect the feet of the veterinarian or his assistant from the primary beam while restraining patients, the underside of the radiographic table shall be protected by at least 1.6 millimeter (1/16 inch) lead or equivalent protection approved by the department.

(8) Personnel monitoring shall be performed in controlled areas for each individual occupationally exposed to ionizing radiation from diagnostic x-ray equipment. Personnel monitoring devices such as film badge dosimeters or thermoluminescent dosimeters shall be permanently assigned to each occupationally exposed individual. This monitoring shall be continuous during employment as a radiation worker.

(9) Personnel exposure records shall be kept on permanent available file at the facility where the exposure occurs.

(10) Monitoring devices used to estimate whole body exposure shall normally be worn on the chest or abdomen. Monitoring of any other body part shall comply with rule 222.

(11) Monitoring devices worn to estimate personnel occupational exposure shall not be worn by the individual when he is exposed as a patient for any medical or dental reason.

(12) Medical x-ray screen type films and intensifying screens shall be employed to reduce patient exposure except in cases where a noticeable decrease in image definition resulting from increased sensitivity may reduce the clinical value of the examination.

(13) Film processing materials and techniques shall be those recommended by the x-ray film and processing materials manufacturers unless otherwise tested to insure maximum information content of the developed film. Sight developing is not

permitted except under extreme emergency conditions. Correct temperature control and development time are necessary to minimize radiation dose to the patient.

(14) A radiographic x-ray system shall not be left unattended without locking the apparatus, room or building in some manner which will prevent use of the apparatus by unauthorized persons.

History: 1979 AC.

FIXED FLUOROSCOPIC INSTALLATIONS

R 325.5411. X-ray equipment.

Rule 411. (1) All x-ray tube housings in fixed fluoroscopic installations shall be of the diagnostic type.

(2) The aluminum equivalent of the total filtration permanently in the useful beam shall not be less than 2.5 millimeters aluminum.

(3) The source-patient distance on fluoroscopic machines manufactured before the effective date of these rules should not be less than 45 centimeters (18 inches) and shall not be less than 30 centimeters (12 inches).

(4) Provision shall be made to intercept the scattered x-rays from the undersurface of the table top and other structures under the fluoroscopic table if the tube is mounted under the table. A cone or shield shall provide the same degree of attenuation as is required of the tube housing.

(5) On fluoroscopic machines manufactured after the effective date of these rules a shielding device of at least 0.25 millimeter lead equivalence for covering the bucky slot during fluoroscopy shall be provided.

(6) On fluoroscopic machines manufactured after the effective date of these rules a shielding device of at least 0.25 millimeter lead equivalence, such as overlapping protective drapes or hinged or sliding panels, shall be used to intercept scattered radiation which would otherwise reach the fluoroscopist and others near the machine.

(7) The equipment shall be so constructed that, under conditions of normal use, the entire cross-section of the useful beam is attenuated by a primary protective barrier, permanently incorporated into the equipment. The exposure shall automatically terminate when the barrier is removed from the useful beam.

(8) On fluoroscopic machines manufactured after the effective date of these rules:

(a) The entire cross section of the useful beam shall be intercepted by the primary protective barrier of the fluoroscopic image assembly at any SID. The fluoroscopic tube shall not produce x-rays unless the barrier is in position to intercept the entire useful beam. The exposure rate due to transmission through the barrier with the attenuation block in the useful beam combined with radiation from the image intensifier, if provided, shall not exceed 2 milliroentgens per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.

(b) The entrance exposure rate shall be measured in accordance with subrule (18). The exposure rate due to transmission through the primary barrier combined with radiation from the image intensifier shall be determined by

measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, if it is not closer than 30 centimeters. Movable grids and compression devices shall be removed from the useful beam during the measurement. For all measurements, the attenuation block shall be positioned in the useful beam 10 centimeters from the point of measurement of the entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly.

(9) The lead equivalence of the barrier of conventional fluoroscopes shall be not less than 1.5 millimeters at 100 kVp, 1.8 millimeters at 125 kVp, and 2.0 millimeters at potentials greater than 125 kVp.

(10) A beam-limiting device shall be provided to restrict the size of the useful beam to less than the area of the barrier. The x-ray tube and beam- limiting system shall be linked with the fluorescent screen assembly so that the useful beam at the fluorescent screen is confined within the barrier irrespective of the panel-screen distance. For image intensifiers, the useful beam shall be centered on the input phosphor. It should not exceed the diameter of the input phosphor during fluoroscopy or cine- recording. Ideally, for spot film radiography with image intensifier equipment, the shutters should automatically open to the required field size before such exposure.

(11) Beam-limiting devices (collimators, adjustable diaphragms or shutters) shall provide the same degree of attenuation as is required of the tube housing.

(12) When the beam-limiting device is opened to its fullest extent, a minimum 1/4 inch unilluminated margin shall exist at all edges of the fluorescent screen when the screen is 35 centimeters (14 inches) from the panel surface or table top, or at the fixed screen position in equipment such

as an orthodiascope. In equipment used solely for image intensified fluoroscopy, the x-ray beam shall not have dimensions greater than the diameter of the input phosphor.

(13) On fluoroscopic machines manufactured after the effective date of these rules:

(a) The x-ray field produced by nonimage-intensified fluoroscopic equipment shall not extend beyond the entire visible area of the image receptor. Means shall be provided to permit further limitation of the field. The minimum field size at the greatest SID shall be equal to or less than 5 by 5

centimeters.

(b) For image-intensified fluoroscopic equipment, the total misalignment of the edges of the x-ray field with the respective edges of the visible area of the image receptor along any dimension of the visually defined field in the plane of the image receptor shall not exceed 3% of the SID.The sum, without regard to sign, of the misalignment along any 2 orthogonal dimensions intersecting at the center of the visible area of the image

receptor shall not exceed 4% of the SID. For rectangular x-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor. Means shall be provided to permit further limitation of the field. The minimum field size, at the greatest SID, shall be equal to or less than 5 by 5 centimeters.

(14) X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the operator for the entire time of any exposure. When recording serial fluoroscopic images, the operator shall be able to terminate the x-ray exposures at any time, but means may be provided to permit completion of any single exposure of the series in progress.

(15) When the fluoroscope is operated at 80 kVp, the exposure rate at the position where the beam enters the patient shall not exceed 3.2 R/mA-min and should not exceed 2.1 R/mA-min.

(16) The entrance exposure rate at the position where the center of the useful beam enters the patient should be as low as is consistent with the fluoroscopic requirements and shall not normally exceed 10 R/min. With modern equipment, most fluoroscopy can be carried out with entrance exposure rates of less than 5 R/min.

(17) Entrance exposure rate limits for fluoroscopic machines manufactured after the effective date of these rules shall be as follows:

(a) Machines with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 10 roentgens per minute at the point where the center of the useful beam enters the patient, except during recording of fluoroscopic images or when an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. Special means of activation of high level controls, such as additional pressure applied continuously by the operator, shall be required to avoid accidental use. A

continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(b) Machines without automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens per minute at the point where the center of the useful beam enters the patient, except during recording of fluoroscopic images or when an optional high level control is activated. Special means of activation of high level controls, such as additional pressure applied continuously by the operator, shall be provided to avoid accidental use. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(18) Compliance with subrules (16) and (17) shall be determined as follows:

(a) If the source is below the table, the exposure rate shall be measured 1 centimeter above the tabletop or cradle.

(b) If the source is above the table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

(c) In a C-arm type of fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly.

(19) A cumulative timing device, activated by the fluoroscope exposure switch, shall be provided. It shall indicate the passage of a predetermined period of irradiation either by an audible signal or by temporary interruption of the irradiation when the increment of exposure time exceeds a predetermined limit not exceeding 5 minutes.

(20) On fluoroscopic machines manufactured after the effective date of these rules means shall be provided to preset the cumulative on-time of the fluoroscopic tube. The maximum cumulative time of the timing device shall not exceed 5 minutes without resetting. A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on- time. This signal shall continue to sound while x-rays are produced until the timing device is reset.

(21) Devices which indicate the x-ray tube potential and current shall be provided. On image intensified fluoroscopic equipment, these devices should be located in such a manner that the operator may monitor the tube potential and current during fluoroscopy.

(22) All x-ray equipment shall be installed and used in accord with article 660 of the national electrical code which is reproduced in rule 359.

History: 1979 AC.

R 325.5417. Enclosures.

Rule 417. (1) An enclosure shall be a permanent part of the building or equipment. Portable shields shall not be used for permanent installations.

(2) The degree of protection required for an enclosure shall be determined by the workload, use and occupancy factors and the kilovoltage, milliamperage, mechanical movement and distance factor, and shall be subject

to design approval by the department.

(3) For conventional fluoroscopy extraneous light that interferes with the fluoroscopic examination shall be eliminated. Dark adaptation normally is not necessary when using image intensifiers.

History: 1979 AC.

R 325.5418. Conditions of operation.

Rule 418. (1) Each individual present in a fluoroscopic room shall wear a protective apron of at least 0.5 millimeter lead equivalence.

(2) Only individuals whose presence is needed to conduct the examination, to conduct radiation protection surveys or undergoing specific training shall be permitted in the fluoroscopy room during x-ray exposures.

(3) Personnel monitoring shall be performed in controlled areas for each individual occupationally exposed to ionizing radiation from diagnostic x-ray equipment. Personnel monitoring devices such as film badge dosimeters or thermoluminescent dosimeters, shall be permanently assigned to each

occupationally exposed individual. This monitoring shall be continuous during employment as a radiation worker.

(4) Personnel exposure records shall be kept on permanent available file at the facility where the exposure occurs.

(5) Monitoring devices used to estimate whole body exposure shall normally be worn on the chest or abdomen. Monitoring of any other body part shall comply with rule 222. Since employees involved in fluoroscopic procedures are required to wear protective aprons and may be subjected to non-uniform radiation fields, a dosimeter assigned to monitor whole body exposure will not necessarily record the dose most representative of exposure to the lens of the eye. To monitor this critical area for which the exposure limit is the same as for whole body, active blood-forming organs, or gonads, an auxiliary dosimeter shall be provided in accord with rule 222.

(6) Monitoring devices worn to estimate personnel occupational exposure shall not be worn by the individual when he is exposed as a patient for any medical or dental reason.

(7) The fluoroscopist's eyes should be sufficiently dark-adapted for the visual task required before commencing conventional fluoroscopy. Under no circumstances shall he attempt to compensate for inadequate adaptation by increasing exposure factors employed or by prolonging the fluoroscopic examination.

(8) A fluoroscopic x-ray system shall not be left unattended without locking the apparatus, room or building in some manner which will prevent use of the apparatus by unauthorized persons.

History: 1979 AC.

MOBILE OR PORTABLE DIAGNOSTIC X-RAY EQUIPMENT

R 325.5421. X-ray equipment.

Rule 421. (1) Radiographic x-ray equipment shall comply with the general requirements of rule 405 excluding subrules (5) and (11).

(2) Fluoroscopic x-ray equipment shall comply with the general requirements of rule 411 excluding subrules (4), (5), (6) and (9).

(3) The radiographic exposure control switch shall be located on the machine where adequate personnel protection is provided to attenuate the direct and scatter radiation, or the length of switch cord shall be such that the operator shall be able to stand at least 1.8 meters (6 feet) from the patient, the x-ray tube, and out of the useful beam. A coil type extension switch cord capable of providing more than 1.8 meters (6 feet) of distance protection is recommended.

(4) Hand-held fluoroscopic screens and others not attached to a diagnostic source assembly with stable mounting shall not be used.

(5) Image intensification shall always be provided on mobile fluoroscopic equipment. It shall be impossible to operate mobile fluoroscopic equipment unless the useful beam is intercepted by the image intensifier. Means shall be provided to limit the source-skin distance to not less than 30 centimeters (12 inches). For fluoroscopes intended for specific surgical application that would be prohibited at the source-skin distances specified in this subrule, provisions may be made for operation at shorter source- skin distances but in no case less than 20 centimeters.

History: 1979 AC.

R 325.5422. Shielding.

Rule 422. (1) Portable shielding shall be used by the operator and others nearby when possible, 1.6 millimeter (1/16 inch) lead equivalent.

(2) Mobile or portable diagnostic x-ray equipment used routinely in 1 location shall be considered a fixed installation and shall comply with the general requirements of rules 405 and 407 or rules 411 and 417 or both.

History: 1979 AC.

R 325.5423. Conditions of operation.

Rule 423. (1) Operation shall comply with the general requirements of rules 409 and 418.

(2) Individuals operating mobile or portable diagnostic x-ray equipment shall wear a protective apron of minimum 0.5 millimeter lead equivalence unless portable shielding is provided as specified in subrule (1) of rule 422.

History: 1979 AC.

MISCELLANEOUS AND SPECIAL INSTALLATIONS

R 325.5425. General provisions.

Rule 425. (1) Types of x-ray sources and uses not specifically covered by this part and not exempted in rule 182, shall comply with parts 1, 4 and 5.

(2) For the purpose of registering and approving veterinary x-ray producing equipment and devices not specifically covered by this part the protective design, the workload, the use factor and the occupancy factor shall be considered.

History: 1979 AC.