

APA-1
11/96

TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION

Control 420 Alabama Department of Public Health

Rule Number 420-3-26-.06

Rule Title Radiation Safety Requirements for Users of X-Ray in Healing Arts or Servicers of X-Ray Equipment

 New XXXX Amend Repeal Adopt by Reference

Would the absence of the proposed rule significantly harm or endanger the public health, welfare or safety? Yes

Is there a reasonable relationship between the state's police power and the protection of the public health, safety or welfare? Yes

Is there another, less restrictive method of regulation available that could adequately protect the public? No

Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved and, if so, to what degree? No

Is the increase in cost, if any, more harmful to the public than the harm that might result from the absence of the proposed rule? n/a

Are all facts of the rulemaking process designed solely for the purpose of and so they have as their primary effect, the protection of the public? Yes

Does the proposed rule have an economic impact? No

If the proposed rule has an economic impact, the proposed rule is required to be accompanied by a fiscal note prepared in accordance with subsection (f) of §41-22-23, Code of Alabama, 1975.

Certification of Authorized Official

I certify that the attached proposed rule has been in full compliance with the requirements of Chapter 22, Title 41, Code of Alabama, 1975, and that it conforms to all applicable filing requirements of the Administrative Procedure Division of the Legislative Reference Service.

Signature of Certifying Officer *Fabrice Bine* Date 8/22/2014



FORM APA2
11/96

STATE BOARD OF HEALTH
NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama Department of Public Health, Radiation Control

RULE NUMBER AND TITLE: 420-3-26-.06, Radiation Safety Requirements for Users of X-Ray in Healing Arts or Servicers of X-Ray Equipment

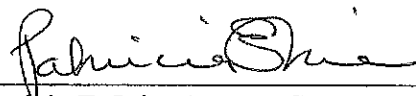
INTENDED ACTION: Revision of Rule 420-3-26-.06.

SUBSTANCE OF PROPOSED ACTION: To delete text that is now moved into 420-3-26-.01 or is covered in office policy.

TIME, PLACE, AND MANNER OF PRESENTING VIEWS: A public hearing will be held at 9:00 a.m. September 24, 2014, at the Alabama Department of Public Health, RSA Tower, Suite 1540, 201 Monroe Street, Montgomery, AL 36104.

FINAL DATE FOR COMMENTS AND COMPLETION OF NOTICE: Written or oral comments will be received until the close of the record at 5:00 p.m. on October 3, 2014. All comments and requests for copies of the proposed amendments should be addressed to the contact person listed below.

CONTACT PERSON AT AGENCY: David Walter, Director of the Office of Radiation Control, Department of Public Health, 201 Monroe Street, Suite 700, Montgomery, Alabama 36104. Telephone number (334) 206-5391.



Patricia E. Ivie, Agency Secretary

420-3-26-.06 Radiation Safety Requirements for Users of X-Ray in Healing Arts or Servicers of X-Ray Equipment

(1) **Scope.** Rule 420-3-26-.03 establishes standards for use of x-rays in the healing arts including but not limited to medicine, dentistry, osteopathy, chiropractic, podiatry, and veterinary medicine or servicers of x-ray equipment. The provisions of this Rule 420-3-26-.06 are written in addition to, and not in substitution for, other applicable provisions of these regulations. Periodic inspections will be performed of all registrants. ~~The inspection frequency will depend upon available personnel and work load, but every x-ray unit ideally should be inspected not less than once every two years.~~

(2) **Definitions.**

(a) "Agency" means the State Board of Health.

(b) "ARCR" means the Alabama Regulations for Control of Radiation.

(c) "Aluminum Equivalent" means the thickness of aluminum affording the same attenuation, under specified conditions, as the material in question.

(d) "Dead Man Switch" means a switch so constructed that a circuit closing contact can only be maintained by continuous pressure by the operator.

(e) "Diagnostic Tube Housing" means an x-ray tube housing so constructed that the leakage radiation with the port closed at a distance of one (1) meter in any direction from the target cannot exceed one hundred (100) milliroentgens in one (1) hour when the tube is operated at any of its specified ratings.

(f) "Direct Supervision" means the supervising physician shall be present in the office and immediately available for complications.

(fg) "Filter" means material placed in the useful beam to absorb preferentially the less penetrating radiations.

(h) "Fluoroscopically-Guided Procedures" means an interventional diagnostic or therapeutic procedure performed via percutaneous or other access routes, usually with local anesthesia or intravenous sedation, which uses external ionizing radiation in the form of fluoroscopy to localize or characterize a lesion, diagnostic site, or treatment site, to monitor the procedure, and to control and document therapy.

(i) "Fluoroscopy" means a technique for generating x-ray images and presenting them simultaneously and continuously as visible images.

(j) "Gonad Shield" means a primary protective barrier for the testes or ovaries.

(k) "Half-Value Layer (hvl)" means the thickness of absorber required to reduce a beam of radiation to one-half (1/2) its incident exposure rate.

(l) "Healing Arts" means the practice of medicine, dentistry, osteopathy, chiropractic, podiatry, and for non-humans, veterinary medicine.

(m) "High Radiation Area" means any area in which there exists radiation or such levels that a major portion of the body could receive in any one (1) hour a dose in excess of 100 millirems.

(n) "Image Receptor" means any device, such as a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further electronic or chemical transformations.

(o) "Inherent Filtration" means the filtration in the useful beam due to the window of the x-ray tube and any permanent tube enclosure.

(p) "Interlock" means a device for precluding access to an area of radiation hazard either by preventing entry or by automatically removing the hazard.

(q) "Kilovolts Peak (kVp)" means the crest value in kilovolts of the potential of a pulsating potential generator.

(r) "Lead Equivalent" means the thickness of lead affording the same attenuation under specified conditions as the material in question.

(s) "Leakage Radiation" means all radiation coming from within the tube housing except the useful beam.

(t) "Mobile X-Ray Unit" means a unit that is not permanently fixed to a definite location in a building or vehicle.

(u) "Personnel Monitoring Equipment" means devices designed to be worn or carried by an individual for the purpose of measuring the dose received (film badges, pocket dosimeters).

(v) "Personal Supervision" means the supervising physician is physically present in the same room with the Physician Assistant, Certified Registered Nurse Practitioner, or Radiologic Technologist.

(w) "Portable" means x-ray equipment designed to be hand-held.

~~(px)~~ "Primary Protective Barrier" means a barrier sufficient to attenuate the useful beam to the required degree.

~~(qy)~~ "Protective Apron" means a barrier of attenuating materials, used to reduce radiation exposure.

~~(rz)~~ "Protective Barrier" means a barrier of attenuating materials, used to reduce radiation exposure.

~~(saa)~~ "Protective Glove" means a glove made of attenuating materials used to reduce radiation exposure.

~~(tbb)~~ "Radiation." ~~The word radiation shall~~ means ionizing radiation, that is, any electromagnetic or particulate radiation capable of producing ions directly or indirectly in its passage through matter.

~~(ecc)~~ "Radiation Area" means any area in which there exists radiation at such levels that a major portion of the body could receive in any one (1) hour a dose in excess of 5 millirems, or in any five (5) consecutive days a dose in excess of 100 millirems.

~~(vdd)~~ "Restricted Area" means any area to which access is controlled by the registrant for purposes of protection of individuals from exposure to radiation. "Restricted area" shall not include any areas used for residential quarters, although upon authorization by the Agency a separate room or rooms in a residential building may be set apart as a restricted area.

~~(wee)~~ "Scatter Radiation" means secondary radiation or radiation that, during passage through matter has been deviated in direction.

~~(xff)~~ "Secondary Protective Barrier" means a barrier sufficient to attenuate stray radiation to the required degree.

(gg) "Services" means the installation, calibrating, repairing, maintaining or performing a radiation protection survey of an x-ray producing machine or associated x-ray component.

(yhh) "Shutter" means a device, generally of lead, fixed to an x-ray housing to intercept the useful beam.

(ii) "Stationary" means x-ray equipment which is installed in a fixed location.

(zjj) "Stray Radiation" means radiation not serving any useful purpose. It includes leakage and scattered radiation.

(aakk) "Therapeutic Type Tube Housing" means an x-ray tube housing so constructed that the leakage radiation with the port closed at a distance of one (1) meter in any direction from the target cannot exceed one (1) roentgen in one (1) hour and at a distance of five (5) centimeters from any point of the surface of the housing accessible to the patient, cannot exceed thirty (30) roentgens in one (1) hour when the tube is operated at any of its specified ratings.

(bbll) "Useful Beam" means that part of the radiation which passes through the window, aperture, cone, or other collimating device of the tube housing.

~~(ee) "Services" means the installation, calibrating, repairing, maintaining or performing a radiation protection survey of an x-ray producing machine or associated x-ray component.~~

~~(dd) "Healing Arts" means the practice of medicine, dentistry, osteopathy, chiropractic, podiatry, and for non-humans, veterinary medicine.~~

~~(ee) "Portable" means x-ray equipment designed to be hand-held.~~

~~(ff) "Stationary" means x-ray equipment which is installed in a fixed location.~~

~~(gg) "Gonad shield" means a primary protective barrier for the testes or ovaries.~~

~~(hh) "Image receptor" means any device, such as a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further electronic or chemical transformations.~~

(3) **General Safety Provisions**

(a) The Agency may waiver compliance with the specific requirements of this Rule 420-3-26-.06 by an existing machine or installation if (1) such compliance would require replacement or substantial modification of the machine or installation and (2) the registrant demonstrates, to the Agency's satisfaction, achievement through other means of radiation protection equivalent to that required by these rules.

~~(b) — Persons shall not be exposed to the useful beam except for healing arts purposes, each exposure of which shall be authorized by:~~

~~1. — A licensed practitioner of the healing arts; or~~

~~2. — A licensed physician's assistant, a certified registered nurse practitioner, or a certified nurse midwife subject to the rules of his/her licensure board.~~

(eb) A written order for each exposure shall be prepared by the a licensed practitioner of the healing arts, certified registered nurse practitioner or certified nurse midwife and provided to the individual administering the radiation. This order shall, at a minimum, include the following information:

1. Patient's name;
2. Date of birth;
3. Examination(s) requested;
4. Related diagnosis;
5. Name of the individual ordering the exposure; and
6. Date of the order.

(ec) These rules specifically prohibits deliberate exposure for the following purposes:

1. Exposure of an individual for training, demonstration, or other purposes unless (a) there are also healing arts requirements and proper prescription has been provided, (b) the radiographs are made for the student's own training, (c) the radiographs are made only once with no more than two retakes and if only a small tissue volume (e.g. less than a skull) is exposed per radiograph, and (d) the images are properly interpreted and are made a part of the dental or medical record.

2. Exposure of an individual for the purpose of healing arts screening without prior written approval of the Agency. (Screening means an exposure of a person without prior examination or a determination of a specific individual need by a licensed practitioner.)

(ed) Personnel Monitoring. Each registrant shall provide personnel monitoring devices which shall be used by:

1. Each individual who receives, or is likely to receive, whole body dose in excess of 25 milliroentgens per week;
2. Each individual who enters a high radiation area;
3. Each individual who operates mobile x-ray equipment;
4. Each individual who operates fluoroscopic equipment;
5. Each individual while he services an operable x-ray producing machine.

(fe) Use.

1. The registrant shall be responsible for assuring that all requirements of Rule 420-3-26-.03 are met.
2. The registrant shall assure that all x-ray equipment under his control is operated only by individuals adequately instructed in safe operating procedures and competent in safe use of the equipment.
3. After October 1, 1974, no registrant who services x-ray producing equipment shall permit any person to service such equipment, when operable, until such person has been appropriately instructed in the subjects outlined in Appendix A of Rule 420-3-26-.05 of these rules and shall have demonstrated an understanding thereof.
4. The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objectives of the examination.
5. Portable or mobile x-ray equipment shall be used only for examinations where it is impractical to transfer the patient to a stationary radiographic installation.

(gf) Shielding. 4.—Each installation shall be provided with such primary barriers and/or secondary barriers as are necessary to assure compliance with 420-3-26-.03(2), 420-3-26-.03(5), and 420-3-26-.03(6). This requirement shall be deemed to be met if the thickness of such barriers is equivalent to those as computed in accordance with National Council on Radiation Protection and Measurements Report No. 49.¹

(hg) Darkroom Requirements. To reduce unnecessary re-exposures of patients resulting from film processing problems:

¹ Available from NCRP Publications, 7910 Woodmont Avenue, Suite 1016 Bethesda, Md. 20814

1. The darkroom shall be light-proof.
2. The area in which undeveloped films are handled for processing shall be devoid of light, during handling and processing, with the exception of light in the wave lengths having no specific effects on the radiographic film.
3. A thermometer and timer operable and appropriate to the type of film processing shall be in use in the darkroom. The use of properly maintained automatic film processing equipment shall meet this requirement for all film so processed.

(4) **Fluoroscopic Installations**

(a) Equipment.

1. The tube housing shall be of diagnostic type.
2. The target-to-panel or target-to-table top distance of equipment installed before the effective date of these rules shall not be less than twelve (12) inches, and shall not be less than fifteen (15) inches in equipment installed thereafter.
3. The total filtration permanently in the useful beam shall not be less than 2.5 millimeters aluminum equivalent. This requirement may be assumed to have been met if the half-value layer is not less than 2.5 millimeters aluminum at normal operating voltages.
4. The equipment shall be so constructed that the entire cross section of the useful beam is attenuated by a primary barrier. This barrier is usually the viewing device, either a conventional fluoroscopic screen or an image intensification mechanism.

(i) For equipment installed before June 15, 1966, ~~the effective date of the rules,~~² the required lead equivalent of the barrier shall not be less than 1.5 millimeters for 100 kVp, shall not be less than 1.8 millimeters for 125 kVp or shall not be less than 2.0 millimeters for 150 kVp. For equipment installed or re-installed after June 15, 1966, ~~the effective date of these rules,~~ the required lead equivalent of the barrier shall not be less than 2.0 millimeters for 125 kVp, or shall not be less than 2.7 millimeters for 150 kVp. For conventional fluoroscopes the requirements of paragraph (i) may be assumed to have been met if the exposure rate measured at the viewing surface of the fluorescent screen does not exceed fifty (50) milliroentgens per hour with the screen in the primary beam of the fluoroscope without a patient, under normal operating conditions.

² ~~June 15, 1966~~

(ii) Collimators shall be provided to restrict the size of the useful beam to less than the area of the barrier. For conventional fluoroscopes this requirement is met if, when the adjustable diaphragm is opened to its fullest extent, an unilluminated margin is left on the fluorescent screen with the screen centered in the beam at a distance of fourteen (14) inches from the panel or table top. The margin requirement does not apply to installations where image intensifiers are used, but a protective shield shall be provided in these installations so that the useful beam does not produce a radiation hazard; however, the useful beam may not exceed the viewing area by more than 2% of the source to image receptor distance for any dimension.

(iii) The tube mounting and the barrier shall be so linked together that under conditions of fluoroscopic use, the barrier always intercepts the useful beam.

(iv) Collimators and adjustable diaphragms or shutters to restrict the size of the useful beam to the area of clinical interest and shall provide a minimum of 2.0 millimeters lead-equivalent protection for 100 kVp, 2.4 millimeters for 125 kVp, or 2.7 millimeters for 150 kVp.

5. The exposure switch shall be of the dead-man type.

6. A manual-reset, cumulative timing device shall be used which will either indicate elapsed time by an audible signal or turn off the apparatus when the total exposure exceeds a predetermined limit in one or a series of exposures. The device shall have a maximum time range of 5 minutes.

7. For fluoroscopy, the exposure rate measured at the panel or table top shall not exceed 10 roentgens per minute. This does not apply during cinegraphic procedures.

8. Unless measurements indicate otherwise, protective aprons of at least a quarter millimeter lead equivalent shall be worn by all persons in the fluoroscopic room except the patient.

9. Protective gloves of at least a quarter millimeter lead equivalent shall be worn by the fluoroscopist during every examination.

10. Mobile fluoroscopic equipment shall meet the requirements of this Rule where applicable, except that:

(i) In the absence of a table top, a cone or spacer frame shall limit the target-to-skin distance to not less than 20 centimeters.

(ii) Image intensification shall always be provided. Conventional fluoroscopic screens shall not be used.

(iii) It shall be impossible to operate a machine when the collimating cone or diaphragm is not in place.

(iv) The exposure rate measured at the 30 cm from image receptor shall not exceed ~~ten (10)~~ roentgens per minute.

(b) Qualifications and Responsibilities of Personnel Using or Supervising the Use of Fluoroscopic Equipment.

1. Physicians

(i) Each facility shall have a written policy for granting fluoroscopic privileges to all physicians who perform or supervise fluoroscopy. The physician performing or supervising fluoroscopically guided procedures shall have the following documented qualifications:

(I) Certification in Radiology, Diagnostic Radiology, or Radiation Oncology by the American Board of Radiology, the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or the Collège des Médecins du Québec; or,

(II) Completion of a residency/fellowship program approved by the Accreditation Council for Graduate Medical Education (ACGME), the Royal College of Physicians and Surgeons of Canada (RCPSC), the Collège des Médecins du Québec, or the American Osteopathic Association (AOA) that includes 6 months of training in fluoroscopic imaging procedures. To satisfy this requirement, the residency/fellowship program must include the successful completion of didactic course lectures and laboratory instruction in radiation physics, radiobiology, radiation safety, and radiation management applicable to the use of fluoroscopy, including passing a written examination in these areas; or,

(III) Be privileged for specific fluoroscopically guided procedures. Physicians whose residency did not include radiation physics, radiobiology, radiation safety, and radiation management may meet the qualifications if they have performed at least ten (10) procedures of each type for which they intend to use fluoroscopic guidance under the direction of a qualified physician who has met these standards and who certifies, in writing, that the trainee meets minimum clinical and fluoroscopy safety standards. These physicians must also have documented evidence of at least 4 hours of didactic lectures and laboratory instruction in radiation physics, radiobiology, radiation safety, and radiation management including imaging of pediatric patients and pregnant patients applicable to the use of fluoroscopy, and should have satisfactorily passed an examination in these areas. Physicians who perform more complex interventional procedures, such as vascular, cardiovascular, neurological, and urological procedures, shall have at least 8 hours of didactic lectures and laboratory instruction in radiation physics, radiobiology, radiation safety, and radiation management applicable to the use of

fluoroscopy, and have satisfactorily passed an examination in these areas. The physician must understand the operation of the specific types of fluoroscopic equipment that he or she operates or supervises in sufficient detail to be able to use available dose management and image quality features effectively.

2. Physician Assistants, Certified Registered Nurses Practitioners, and Radiologic Technologists

(i) A Physician Assistant, Certified Registered Nurse Practitioner, or Radiologic Technologist shall complete specific fluoroscopic coursework of not less than forty (40) hours. The coursework shall include training in:

(I) Digital image acquisition and display;

(II) Fluoroscopic unit operation and safety;

(III) Image analysis;

(IV) Radiation biology, including the effects of radiation exposure;

(V) Radiation production and characteristics of radiation, radiation units; and

(VI) Radiation protection, including methods for reducing exposures, principles of ALARA and use of personnel monitoring equipment.

(ii) In addition to the completion of forty (40) hours of fluoroscopic coursework, the Physician Assistant, Certified Registered Nurse Practitioner, or Radiologic Technologist shall complete a minimum of forty (40) hours of performance of fluoroscopy under the personal supervision of a licensed physician trained in the safe operation of fluoroscopic x-ray equipment or a qualified medical physicist. The supervisor shall document competency of the Physician Assistant, Certified Registered Nurse Practitioner, or Radiologic Technologist in performing fluoroscopy.

(iii) The Registrant of a facility shall validate the credentials of a Physician Assistant, Certified Registered Nurse Practitioner, or Radiologic Technologist and shall ensure that the Physician Assistant, Certified Registered Nurse Practitioner, or Radiologic Technologist to whom the supervising physician has delegated the performance of specified fluoroscopic procedures, has submitted the following documentation:

(I) Successful completion of the education and clinical training as specified above;

(II) A written and signed statement from the supervising physician verifying the competency of the Physician Assistant, Certified Registered Nurse Practitioner, or Radiologic Technologist to perform specified fluoroscopic procedures that have been approved by the respective boards; and

(III) A written practice agreement between the Physician Assistant or Certified Registered Nurse Practitioner and the supervising/collaborating physician.

3. Copies of all documentation required by 420-3-26-.06(4)(b)1. and 2.(ii) shall be available for review by the Agency.

4. For more complex interventional procedures, such as vascular, cardiovascular, neurological, and urological procedures, a licensed physician trained in the safe operation of fluoroscopic x-ray equipment shall provide personal supervision of Physician Assistants, Certified Registered Nurse Practitioners, and Radiologic Technologists.

5. For other procedures a licensed physician trained in the safe operation of fluoroscopic x-ray equipment shall provide direct supervision of Physician Assistants, Certified Registered Nurse Practitioners, and Radiologic Technologists.

6. Procedures done using fluoroscopy must be submitted to and approved by the Alabama Board of Medical Examiners for Physician Assistants or the Alabama Board of Nursing and the Alabama Board of Medical Examiners for Certified Registered Nurse Practitioners.

7. The training and experience specified in this rule shall be obtained and documented on or before (insert date 2 years after the effective date of this rule).

(c) Recentness of Training. The training and experience specified in this rule must have been obtained within the seven (7) years preceding the date of use, or supervision of use, of fluoroscopic equipment or the individual must have had related continuing education and experience since the required training and experience was completed.

(bd) Structural Shielding. Ordinarily, only secondary barriers are necessary except for combined fluoroscopic-radiographic installations.

(5) Radiographic Installations Other than Dental and Veterinary Medicine.

(a) Equipment.

1. The tube housing shall be of a diagnostic type.

2. (i) Diaphragms or cones shall be provided for collimating the useful beam. When round collimators are used, the diameter of the beam at the film location shall be no greater than the diagonal dimension of the film plus three (3) percent of the source to image receptor distance. For rectangular collimators, the beam size shall be no greater than the film dimension plus three percent of the source to image receptor distance. The diaphragms or cones shall provide the same degree of protection as the tube housing.

(ii) Adjustable collimators installed after March 18, 1970, ~~the effective date of this rule~~³ shall incorporate light beams to define the projected dimensions of the useful beam.

3. (i) Except when contraindicated for a particular purpose, for equipment operation at seventy (70) kVp, and below, the total filtration permanently in the useful beam shall be equivalent to at least 1.5 mm of aluminum. This requirement may be assumed to have been met if the half-value layer is not less than 1.5 mm aluminum at normal operating voltages.

(ii) Except when contraindicated for a particular medical purpose, for equipment capable of operating above seventy (70) kVp the total filtration permanently in the useful beam shall be equivalent to at least 2.5 mm of aluminum. This requirement may be assumed to have been met if the half-value layer is not less than 2.5 mm aluminum at normal operating voltages.

4. A device shall be provided to terminate the exposure after a preset time interval, preset product of current and time (mAs), a preset number of pulses, or a preset radiation exposure to the image receptor. It shall not be possible to make an exposure when the timer is set to a zero or off position, if either position is provided.

5. A dead-man type of exposure switch shall be so arranged that it cannot be conveniently operated out of a shielded area. Exposure switches for "spot-film" devices used in conjunction with fluoroscopic tables are exempted from this shielding requirement.

(b) Structural Shielding.

1. All wall, floor and ceiling areas exposed to the useful beam shall have primary barriers. Primary barriers in walls shall extend to a minimum height of eighty-four (84) inches above the floor of the area being shielded.

2. Secondary barriers shall be provided in all wall, floor, and ceiling areas not having primary barriers or where the primary barrier's requirements are lower than the secondary barrier's requirements.

³ March 18, 1970

3. The operator's station at the control shall be behind a protective barrier, either in a separate room, in a protected booth, or behind a shield which will intercept the useful beam and any radiation which has been scattered only once.

4. A window of lead-equivalent glass equal to that required by the adjacent barrier or a mirror system shall be provided large enough and so placed that the operator can see the patient without having to leave the protected area during exposure, and shall meet the requirements of 420-3-26-.05, Appendix C.3.

(c) Operating Procedures.

1. No individual exposed to occupational radiation shall hold patients during exposures except during emergencies, nor shall any individual be regularly used for this service. If the patient must be held by an individual, that individual shall be protected with appropriate shielding devices such as protective gloves and apron and he shall be so positioned that no part of his body will be struck by the useful beam.

2. Only the operators of radiographic equipment, other required individuals, and the patient shall be present during exposures. No unprotected parts of the operator's body shall be in the useful beam.

3. The useful beam shall be restricted to the area of clinical interest.

(6) **Mobile Diagnostic Radiographic Equipment.**

(a) Equipment.

1. All requirements of 420-3-26-.06(5)(a) apply except 420-3-26-.06(5)(a)5.

2. The exposure control switch shall be of the dead-man type and shall be so arranged that the operator can stand at least six (6) feet from the patient and well away from the useful beam.

(b) Structural Shielding. ~~4.——~~When a mobile unit is used routinely in one location, it shall be considered a fixed installation subject to shielding requirements specified in 420-3-26-.06(3)(d) and 420-3-26-.06(5)(b).

(c) Operating Procedures.

1. All provisions of 420-3-26-.06(5)(c) apply, except 420-3-26-.06(5)(c)2.

2. The target-to-skin distance shall not be less than twelve (12) inches.

(7) **Chest Photofluorographic Installations.**

(a) Equipment.

1. All provisions of 420-3-26-.06(5)(a) apply.

2. A collimator shall restrict the useful beam to the area of the photofluorographic screen.

(b) Structural Shielding. 1.——All provisions of 420-3-26-.06(3)(d) and 420-3-26-.05(5)(b) apply.

(c) Operating Procedures.

1. All provisions of 420-3-26-.06(5)(c) apply.

2. All individuals except the patient being examined shall be in shielded positions during exposures.

(8) **Dental Radiographic Installations.**

(a) Equipment.

1. The tube housing shall be of diagnostic type.

2. Diaphragms or cones shall be used for collimating the useful beam and shall provide the same degree of protection as the housing. The diameter of the useful beam at the cone tip shall not be more than three (3) inches.

3. A cone or spacer frame shall provide a target-to-skin distance of not less than seven (7) inches with apparatus operating above fifty (50) kVp or four (4) inches with apparatus operating at fifty (50) kVp or below.

4. (i) For equipment operating up to seventy (70) kVp, the total filtration permanently in the useful beam shall be equivalent to at least 1.5 mm of aluminum. This requirement may be assumed to have been met if the half-value layer is not less than 1.5 mm aluminum at normal operating voltages.

(ii) For equipment operating above seventy (70) kVp, the total filtration permanently in the useful beam shall be equivalent to at least 2.5 mm of aluminum. This requirement may be

assumed to have been met if the half-value layer is not less than 2.5 mm of aluminum at the normal operating voltages.

5. A device shall be provided to terminate the exposure after a preset time interval, preset product of current and time (mAs), a preset number of pulses, or a preset radiation exposure to the image receptor. It shall not be possible to make an exposure when the timer is set at a zero or off position, if either position is provided. Except for dental panoramic systems, termination of exposure shall cause automatic resetting of the time to its initial setting or to zero.

6. The exposure control switch shall be of the dead-man type.

7. Each installation shall be provided with a protective barrier for the operator or shall be so arranged that the operator can stand at least six (6) feet from the patient and well away from the useful beam.

(b) Structural Shielding.

1. Dental rooms containing x-ray machines shall be provided with primary barriers for all areas struck by the useful beam.

2. When dental x-ray units are installed, the rooms adjacent will be adequately protected.

NOTE: In most cases structural materials or ordinary walls suffice as a protective barrier without addition of special shielding material.

(c) Operating Procedures.

1. Neither the dentist nor his assistant shall be permitted to hold patients or films during exposure, nor shall any individual be regularly used for this service.

2. During each exposure, the operator shall stand at six (6) feet from the patient or behind a protective barrier.

3. Only the patient shall be in the useful beam.

4. Neither the tube housing nor the pointer cone shall be hand-held during exposure.

5. Fluoroscopy shall not be used in dental examinations.

(9) **Therapeutic X-ray Installations.**

(a) Equipment.

1. The tube housing shall be of therapeutic type.
2. Permanent diaphragms or cones used for collimating the useful beam shall afford the same degree of protection as the tube housing. Adjustable or removable beam-defining diaphragms or cones shall transmit not more than five (5) percent of the useful beam obtained at the maximum kilovoltage and with maximum treatment filter.
3. Filters shall be secured in place to prevent them from dropping out during treatment. The filter slot shall be so constructed that the radiation escaping through it does not exceed one (1) roentgen per hour at one (1) meter, or if the radiation from the slot is accessible to the patient, thirty (30) roentgens per hour at five (5) centimeters from the external opening.
4. The x-ray tube shall be so mounted that it cannot turn or slide with respect to the aperture.
5. Means shall be provided to immobilize the tube housing during stationary portal treatment.
6. A timer shall be provided to terminate the exposure after a preset time regardless of what other exposure limiting devices are present.
7. Equipment utilizing shutters to control the useful shall have a shutter position indicator on the control.
8. There shall be on the control panel an easily discernible indicator which will give positive information as to whether or not the x-ray tube is energized.

(b) Structural Shielding.

1. All wall, floor, and ceiling areas that can be struck by the useful beam, plus a border of one foot, shall be provided with primary protective barriers.
2. All wall, floor, and ceiling areas that cannot be struck by the useful beam shall be provided with secondary barriers.
3. With equipment operating above one hundred and twenty-five (125) kVp, the required barriers shall be an integral part of the building.
4. With equipment operating above one hundred and fifty (150) kVp, the control panel shall be within a protective booth equipped with an interlocked door, or outside the

treatment room.

5. Interlocks shall be provided for x-ray therapy equipment capable of operating above 150 kVp so that, when any door of the treatment room is opened, either the machine will shut off automatically or the radiation level within the room will be reduced to an average of not more than two milliroentgens per hour and a maximum of ten milliroentgens per hour at a distance of one (1) meter in any direction from the target. After such shut off or reduction in output, it shall be possible to restore the machine to full operation only from the control panel.

6. Provisions shall be made to permit continuous observation of patients during irradiation.

7. Windows, mirror systems, or closed-circuit television viewing screens used for observing the patient shall be so located that the operator may see the patient and the control panel from the same position.

(c) Operating Procedures.

1. All new installations shall have a protection survey made by, or under the direction of, a qualified expert. This shall also be done after any change in the installation which might produce a radiation hazard. The expert shall report his findings in writing to the person in charge of the installation and to the Agency (State Board of Health).

NOTE: Paragraph (c)1. of 420-3-26-.06(9), Rule 420-3-26-.06 was revised by the State Board of Health on March 19, 1979.

2. The installation shall be operated in compliance with any limitations indicated by the protection survey.

3. No individual who works with radiation, unless he is the patient, shall be in the treatment room during exposure. No other individual shall be there except when it is clinically necessary. If any individual is required to be in the treatment room with the patient during exposure, he shall be protected as much as possible from scattered radiation, and shall not be in the useful beam.

4. Records of surveys required by subparagraph (4) of this paragraph shall be maintained for two years after the facility has ceased to be used as described in the survey. If the survey was used to determine an individual's exposure, the record must be maintained until disposal is authorized by the Agency.

(d) All provisions of this Section apply to therapeutic veterinary installations.

(e) The output of each therapeutic x-ray machine shall be calibrated by, or under the direction of, a qualified expert. The calibration shall be repeated after any change in or replacement of components of the x-ray generating equipment which could cause a change in x-ray output. Check calibrations shall be made at least one a year thereafter. Records of calibration shall be maintained by the registrant.

(10) X-ray Therapy Equipment Operated at Potentials of Sixty (60) KV and Below.

(a) Equipment.

1. All provisions of 420-3-26-.06(9)(a) apply, except for equipment used for "contact therapy", 420-3- 26-.06(9)(a) in which instance the leakage radiation at the surface of the tube housing shall not exceed 0.1 roentgen per hour.

2. There shall be on the control panel some easily discernible device which will give positive indication as to whether or not the tube is energized.

(b) Operating Procedures.

1. Automatic timers shall be provided which will permit accurate presetting and determination of exposures as short as one second.

2. In the therapeutic application of apparatus constructed with beryllium or other low-filtration windows, the registrant shall insure that the unfiltered radiation reaches only the part intended and that the useful beam is blocked at all times except when actually being used.

3. Machines having an output of more than 1,000 roentgens per minute at any accessible place shall not be left unattended without the power being shut off at the primary disconnecting means.

4. If the tube is hand-held during irradiation, the operator shall wear protective gloves and apron.

(11) Veterinary Medicine Radiographic Installations.

(a) Equipment.

1. The tube housing shall be of diagnostic type.

2. Diaphragms or cones shall be provided for collimating the useful beam to the area of clinical interest and shall provide the same degree of protection as required of the housing, as

indicated in 420-3-26-.06(5)(a)2.(i) and (ii).

3. Except when contraindicated for a particular radiographic purpose, the total filtration permanently in the useful beam shall not be less than 1.5 millimeters aluminum-equivalent for equipment operating up to seventy (70) kVp and 2.0 millimeters aluminum-equivalent for machines operated in excess of seventy (70) kVp.

4. A device shall be provided to terminate the exposure after a preset time interval, preset product of current and time (mAs), a preset number of pulses, or a preset radiation exposure to the image receptor. It shall not be possible to make an exposure when the timer is set at a zero or off position, if either position is provided.

5. A dead-man type of exposure switch shall be provided, together with an electrical cord of sufficient length so that the operator can stand out of the useful beam at least six (6) feet from the animal during all x-ray exposures.

(b) Structural Shielding.

1. All wall, floor, and ceiling areas shall be provided with applicable protective barriers as required in 420-3-26-.06(5)(b).

(c) Operating Procedures.

1. The operator shall stand well away from the tube housing and the animal during radiographic exposures. Provisions shall be made so that it will not be necessary for the operator to stand in the useful beam. Hand-held fluoroscopic screens shall not be used. The tube housing shall not be held by the operator. No individual other than the persons involved in the operation shall be in the x-ray room while exposures are being made.

2. In any application in which the operator or an assistant is not located behind a protective barrier, a protective apron having a lead-equivalent of not less than 0.5 millimeter shall be worn.

3. No individual shall be regularly employed to hold or support animals or hold film during radiation exposures. Occupationally exposed individuals shall not perform this service except in cases in which no other method is available. Any individual holding or supporting an animal during radiation exposure shall wear protective gloves and apron having a lead-equivalent of not less than 0.5 millimeter.

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Statutory Authority: §§ 22-14-4, 22-14-7, 22-14-8, Code of Alabama, 1975.

History: New 6-15-66; Revised 6-17-68, 3-18-70, Repromulgated 8-21-74, Revised 15-76, 1-18-78; Recodified 6-11-78; Revised 11-21-79; Revised and Repromulgated 10-21-81; Revised and Repromulgated effective 12-31-83. Revised effective 12-31-86. Revised and Repromulgated effective 1-31-90. Revised effective 9-30-90. Amended: Filed ~~5-20-10~~; effective ~~6-24-10~~.