APA-1
11/96

TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION

Control 420 Alabama Department of Public Health

Rule Number 420-3-26-.05

Rule Title Registration of X-Ray Producing Machines

_____ 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 Patricia Shinn Date 8/20/2014

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-.05, Registration of X-Ray Producing Machines

INTENDED ACTION: Revision of Rule 420-3-26-.05.

SUBSTANCE OF PROPOSED ACTION: To change the rule to close a gap in regulated x-ray energies.

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, 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-.05 Registration of X-Ray Producing Machines

(1) **Registration Requirement.**

(a) This Rule 420-3-26-.05 provides for the registration of radiation machines capable of producing x-rays of less than or equal to ~~0.9~~1.0 meV. Every person possessing an x-ray producing machine shall register in accordance with the provisions of this rule. Except as specifically exempted in Section 420-3-26-.05(4), each person who receives, possesses, uses, or services a radiation machine shall register such machines with the Agency in accordance with the requirements of this Rule 420-3-26-.05. [1]

(b) In addition to the requirements of this Rule 420-3-26-.05, all registrants are subject to the requirements of Rules 420-3-26-.01, 420-3-26-.10, and 420-3-26-.11. Registrants using radiation machines for the performance of industrial radiography are also subject to the requirements of Rule 420-3-26-.04 and registrants using radiation machines in the healing arts are also subject to the requirements of Rule 420-3-26-.06 of these rules.

(2) **General Definitions.**

(a) "Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing, other than the U.S. Nuclear Regulatory Commission and other Federal Government agencies.

(b) "Possessing an x-ray producing machine" means using, operating, storing manufacturing, or otherwise having control of an x-ray producing machine in the State of Alabama.

(c) "Radiation producing machine" means any machine or device capable of producing radiation, but excluding devices which produce radiation only by the use of radioactive material.

(d) "Registrant" means any person who is registering or who has registered with the Agency pursuant to this rule.

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

(3) **Registration Procedure.**

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[1] See Rule 420-3-26-.08 for the registration requirements for particle accelerators.

(a) ~~**Initial Registration**~~ Every person who possesses an x-ray producing machine shall register the machine with the Agency by June 1, 1965. Every person not already registered who acquires possession of an x-ray producing machine subsequent to June 1, 1965, shall register with the Agency prior to acquiring an x-ray machine.

(b) ~~**Renewal of Registration**~~ Every person possessing an x-ray producing machine shall renew such registration with the agency at such times as the Agency shall deem necessary.

(c) ~~**Registration Form**~~ Registration and renewal of registration shall be made on a form furnished by the Agency (Alabama State Board of Health). The registration shall set forth all information called for by the form.

(d) ~~**Report of Change**~~ Within thirty (30) days of change, the registrant shall report to the Agency of any change in the name or address of the registrant or location of the installation; receipt, sale, or disposal of any reportable source of radiation.

(e) ~~**Report of Discontinuance**~~ Every registrant who permanently discontinues the use of, or permanently disposes of all his x-ray producing machines at an installation, shall notify the Agency within thirty (30) days of such action.

(f) ~~**Registration Shall Not Imply Approval**~~ No person, in any advertisement, shall refer to the fact that an x-ray producing machine is registered with the Agency and no person shall state or imply that any activity so registered has been approved by the Agency.

(g) ~~**Registration of Services**~~ Each person who commercially services an x-ray producing machine in this s~~S~~State, to an Agency registrant, shall apply for the registration of such services with the Agency not later than October 1, 1974, thereafter prior to furnishing or offering to furnish any such services. Such registration shall indicate the training of each individual in the subjects listed in Appendix A. Such registration is also subject to the requirements of paragraphs (b), (c), (d), (e), and (f) of this section.

(4) **Exclusion from Registration**. The following materials and devices do not require registration:

(a) Electrical equipment that is not primarily intended to produce radiation and that does not produce a radiation level greater than 0.5 mr/hr at any readily accessible point 5 centimeters from the surface. Such equipment shall not be exempt if it is used or handled in such a manner that any individual might receive a radiation dose exceeding the limits specified in these rules.

(b) All radioactive material.

(c) Radiation producing machines while in transit or storage incident thereto.

(5) **Vendor Obligations.**

(a) Any person who sells, leases, transfers, or lends x-ray producing machines in this sState shall notify the Agency (Alabama State Board of Health) within thirty (30) days after the end of each calendar quarter of:

1. (i) The name and address of persons who have received these machines.

(ii) The manufacturer and model of each machine transferred;

(iii) The date of transfer of each x-ray machine.

2. Negative reports shall be furnished to the Agency (Alabama State Board of Health) within thirty (30) days after the end of each calendar quarter.

(b) No person shall sell, lease, transfer, or install x-ray equipment or the accessories used in connection with such equipment unless such accessories and equipment, when properly placed in operation and properly used, will meet the requirements of these rules. This includes responsibility for the delivery of cones or collimators, filters, adequate timers, and fluoroscopic shutters. Further, no person shall sell, lease, deliver, install, or place in operation any x-ray equipment at any facility or for any person not registered with the Agency.

(6) **Out-of-State X-ray Producing Machines.** Whenever any x-ray machine is brought into the State for any temporary use the person proposing to bring such machine into the state shall give written notice to the Agency (Alabama State Board of Health) at least two (2) days before such machine enters the State. The notice shall include the type of X-ray producing machine; the nature, duration, and scope of use; and the exact location where the x-ray producing machine is to be used. If for a specific case the two (2) day period would impose an undue hardship on the person, he may upon application to the Agency (Alabama State Board of Health) obtain permission to proceed sooner. In addition, the out-of-state person must:

(a) Comply with all applicable rules of the Agency (Alabama State Board of Health); and,

(b) Supply the Agency (Alabama State Board of Health) with such other information as the Agency (Alabama State Board of Health) may reasonable request.

(7) **Plan Review.**

(a) Prior to construction, the floor plans and equipment of all installations (new modification of existing installations after January 1, 1977) utilizing x-rays for diagnostic or therapeutic purposes shall be submitted to the Agency for review and approval. The required information is denoted in Appendices B and C of this Rule.

(b) The Agency may require the applicant to utilize the services of a qualified expert to determine the shielding requirements prior to the plan review and approval.

(c) The approval of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in 420-3-26-.03(2), 420-3-26-.03(5), and 420-3-26-.03(6).

(8) **Modification, Suspension, and Termination of a Registration or Activities Registered.**

(a) A registration or activity registered shall be subject to amendment, revision, or modification or such activities may be suspended or terminated by reason of amendment to the Act, or by reason of rule, regulations, and orders issued by the Agency.

(b) Any registration or activity registered may be terminated, suspended, or modified in whole, or part, for any material false statement in the application, or because of conditions revealed by such application or statement of fact or any report, records, or inspection or other means which would warrant the Agency to refuse to grant a registration on an original application, or for violation of, or failure to observe any of the terms and conditions of the Act, or the regulations, or of any rule, regulation, or order of the Agency.

(c) Except in case of willfulness or those in which the public health interest or safety requires otherwise, no registration or activity registered shall be modified, suspended, or terminated, unless prior to the institution of proceedings therefore, facts or conduct which may warrant such action shall have been called to the attention of the registrant in writing and the registrant shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

Author: Karl David Walter, Office of Radiation Control, Alabama Department of Public Health.

Authority: §§22-14-4, 22-14-6, 22-14-7, 22-14-8, 22-14-9, 22-14-11, 22-14-12, 22-14-13, and 22-14-14, also 22-2-1, 22-2-2-, 22-2-5, and 22-2-6, Code of Alabama, 1975.

History: New, 6-15-66; Revised, 3-18-70, 3-17-71; Repromulgated 8-21-74; Revised 9-15-76; Recodified 6-11-78; Revised and Repromulgated 10-21-81; Repromulgated effective 12-31-83. Revised effective 12-31-86. Revised and Repromulgated effective 1-31-90.

APPENDIX A

INSTRUCTION OF SERVICERS OF X-RAY EQUIPMENT

I. Fundamentals of radiation safety

A. Characteristics of x-radiation

B. Units of radiation dose (mrem)

C. Hazards of excessive exposure to radiation

D. Levels of radiation from sources of radiation

E. Methods of controlling radiation dose

1. Working time

2. Working distances

3. Shielding

II. Radiation detection instrumentation to be used

A. Use of radiation survey instruments

1. Operations

2. Calibration

3. Limitations

B. Survey techniques

C. Use of personnel monitoring equipment

1. Film Badges and/or Thermoluminescence Dosimeters (TLD's)

2. Pocket Dosimeters

3. Pocket Chambers

III. Operation and control of x-ray equipment

A. Effects of collimation and filtration

B. Film processing techniques

IV. The requirements of pertinent Federal and State regulations

APPENDIX B

INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS

In order for the Agency to provide an evaluation, technical advice and official approval on shielding requirements for a radiation installation, the following information is needed.

1. The plans should show, as a minimum, the following:

a. The normal location of the radiation producing equipment's radiation port; the port's travel and traverse limits; general direction(s) of the radiation beam; locations of any windows; the location of the operator's booth; the location of the equipment's control console.

b. Structural composition and thickness of all walls, doors, partitions, floor, and ceiling of the rooms(s) concerned.

c. Height, floor to floor, of the room(s) concerned.

d. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest existing occupied area(s).

e. The make and model of the radiation producing equipment including the maximum energy output (for x-ray machines this is the kilovolt peak potential).

f. The type of examination(s) or treatment(s) which will be performed with the equipment (e.g., dental, orthodontal, chest, gastrointestinal, fluoroscopic, podiatry, fixed therapy, rotational therapy, etc.).

2. Information on the anticipated workload used in shielding calculations will be provided by the registrant.

3. If the services of a qualified radiation expert have been utilized, a copy of his report shall be submitted with the plans. This report must show all basic assumptions (i.e., workload, occupancy and use factors, distance, etc.) used to determine the shielding requirements.

APPENDIX C

MINIMUM DESIGN REQUIREMENTS FOR AN X-RAY MACHINE OPERATOR'S BOOTH

1. **Space Requirements.**

The operator shall be allotted not less than 7.5 square feet of unobstructed floor space in the booth.

(1) The minimum space as indicated above may be any geometric configuration with no dimension of less than 2 feet.

(2) The space shall be allotted excluding any encumbrance by the console, such as overhang or cables, or other similar encroachments.

(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) The booth walls shall be at least 7 feet high and shall be permanently fixed to the floor or other structure as may be necessary.

(5) When a door or movable panel is used as an integral part of the booth structure, it must have a permissive device which will prevent an exposure when the door or panel is not closed (this type of booth structure is not recommended).

2. **Switch Placement.**

The operator's switch for the radiographic machine shall be fixed within the booth and:

(1) Shall be at least 30 inches from any open edge of the booth wall which is proximal to the examining table.

(2) Shall allow the operator to use the majority of the available viewing windows.

3. **Viewing System Requirements.**

Each booth shall have at least one viewing device which will:

(1) Be so placed that the operator can view the patient during any exposure, and

(2) The device shall be so placed that he can have full view of any occupant of the room and should be so placed that he can view any entry into the room. If any door, which

allows access to the room, cannot be seen from the booth, then that door must have a permissive device controlling the exposure which will prevent the exposure if the door is not closed.

(3) When the viewing system is a window, the following requirements also apply:

(a) It shall have a visible area of at least 1 square foot the base of which is at least 4.5 feet above the floor.

(b) The distance between the proximal edge of the window and the open edge of the booth shall not be less than 13 inches.

(c) The glass shall have the same lead equivalence as that required in the booth's wall in which it is to be mounted.

(4) When viewing system is by mirrors, the mirror(s) shall be located as to accomplish the general requirements as in (1) above.

(5) When the viewing system is by electronic means (e.g., TV, etc.):

(a) The camera shall be so located as to accomplish the general requirements in (1) above, and

(b) There shall be an alternate viewing system as a back up for electronic failure.