

APA-1
11/96

TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION

Control 420 Alabama Department of Public Health

Rule Number 420-3-26-.11

Rule Title Radiation Safety Requirements for Analytical 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 Patricia Shie Date 8/20/2014

FORM APA2
11/96

STATE BOARD OF HEALTH
NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama Department of Public Health

RULE NUMBER AND TITLE: 420-3-26-.11, Radiation Safety Requirements for Analytical X-Ray Equipment

INTENDED ACTION: Revision to Rule 420-3-26.11

SUBSTANCE OF PROPOSED ACTION: To amend the rule to exempt quarterly radiation surveys for analytical x-ray producing machines that have very low energies and pose no health risk.

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-.11 Radiation Safety Requirements for Analytical X-Ray Equipment

(1) **Purpose and Scope.** This rule 420-3-26-.11 provides special requirements for analytical x-ray equipment; provided, however, that nothing in this Rule shall apply to x-ray equipment used to detect, measure, gauge, or control the density, level, interface location, thickness of materials, or equipment used for industrial radiography as defined in Rule 420-3-26-.04, or sources of radiation used in the healing arts. The requirements of this Rule are in addition to, and not in substitution for, applicable requirements in other Rules. Note that Rules 420-3-26-.01, 420-3-26-.03, 420-3-26-.05, and 420-3-26-.10 also apply to analytical x-ray users.

(2) **Definitions.**

(a) “Analytical x-ray equipment” means any device which utilizes x-rays for the purpose of examining the microstructure of materials. This includes all types of x-ray diffraction, fluorescence, and spectrographic analysis equipment.

(b) “Analytical x-ray system” means a group of local and remote components utilizing x-rays to determine the elemental composition or to examine the microstructure of materials. Local components include those that are struck by x-rays such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors, and shielding. Remote components include power supplies, transformers, amplifiers, readout devices, and control panels.

(c) “Fail-safe characteristics” means a design feature which causes port beam shutters to close, or otherwise prevents emergence of the primary beam, upon a failure of a safety or warning device.

(d) “Normal operating procedures” means operating procedures for conditions suitable for analytical purposes with shielding and barriers in place. These do not include maintenance but do include routine alignment procedures. Routine and emergency radiation safety considerations are part of these procedures.

(e) “Open-beam configuration” means an analytical x-ray system in which an individual could accidentally place some part of his body in the primary beam path during normal operation.

(f) “Positive visual warning light” means a warning light which has redundant lights so that a single failure will not prevent the warning light from functioning.

(g) “Primary beam” means ionizing radiation which passes through the aperture of the source housing by a direct path from the x-ray tube or a radioactive source located in the radiation source housing.

(h) "Unattended operation" means any operation in which the analytical x-ray system is generating x-rays and an operator trained in accordance with 420-3-26-.11(6) of this Rule 420-3-26-.11 is not physically present in the area sufficiently near the local components to prevent any operation which could cause an individual to exceed the limits given in 420-3-26-.03(6) of these Rules.

(3) **Equipment Requirements.**

(a) ~~Safety Device.~~ A device such as a guard or interlock which prevents the entry of any portion of an individual's body into the primary x-ray beam path or which causes the beam to be shut off upon entry into its path shall be provided on all open-beam configurations. Prior to operation a registrant may apply to the Agency for an exemption from the requirements of a safety device. Such application shall include a description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices.

(b) **Warning Devices.**

1. A positive visible warning light labeled with the words "X-RAY ON," or words having a similar intent, shall be located;

(i) ~~n~~Near any switch that energizes an x-ray tube and shall be illuminated only when the tube is energized; and

(ii) ~~a~~At a conspicuous location that may be visible at all local components; and

2. Open-beam configurations shall be provided with a readily discernible indication of;

(i) x-ray tube status (ON-OFF) located near the radiation source housing, if the primary beam is controlled in this manner; and/or

(ii) shutter status (OPEN-CLOSED) located near each port on the radiation source housing, if the primary beam is controlled in this manner.

Warning devices shall be labeled so that their purpose is easily identified. On equipment transferred after January 1, 1977, warning devices shall have fail-safe characteristics.

(c) ~~Ports.~~—Unused ports on radiation source housings shall be secured in the closed position in the manner which will prevent casual opening.

(d) ~~Labeling.~~ All analytical x-ray equipment shall be labeled with a readily discernible sign or signs bearing the radiation symbol and the words:

1. "CAUTION-HIGH INTENSITY X-RAY BEAM," or words having a similar intent on the x-ray source housing; and

2. "CAUTION RADIATION-THIS EQUIPMENT PRODUCES X-RAYS WHEN ENERGIZED," or words having a similar intent, near any switch that energizes an x-ray tube and at a conspicuous location if the radiation source is an z-ray tube.

(e) ~~Shutters.~~ On open-beam configurations transferred after January 1, 1977, each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or a shielding coupling has been connected to the port.

(f) ~~Radiation Source Housing.~~ Each x-ray tube housing shall be constructed so that with all shutters closed the leakage radiation measured at a distance of 5 cm from its surface is not capable of producing a dose in excess of 2.5 mRem in one hour at any specified tube rating.

(g) ~~Generator Cabinet.~~ Each x-ray generator, including high voltage rectifiers, transformers, and amplifiers, shall be supplied with a protective cabinet which limits leakage radiation measured at a distance of 5 cm from its surface such that it is not capable of producing a dose in excess of 0.25 mrem in one hour.

(h) ~~Unattended Operation.~~ Each entrance to a room containing analytical x-ray equipment in unattended operations shall have a warning light with the words "X-RAY ON" or words having a similar intent. In addition, for an open-beam configuration unattended operation, there shall be a device to shut off analytical x-ray equipment upon the entrance of any person not trained in accordance with 420-3-26-.11(6) of this Rule.

(4) **Area Requirements.**

(a) ~~Radiation Levels.~~ The local components of an analytical x-ray system shall be located and arranged and shall include sufficient shielding or access control such that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the dose limits given in 420-3-26-.03(6) of these rules. These levels shall be met at any specified tube rating.

(b) ~~Surveys.~~ Radiation surveys with appropriate radiation detection devices as required by 420-3-26-.03(9), of all operable analytical x-ray systems sufficient to show compliance with paragraph 420-3-2-26.11(4)(a) shall be performed quarterly and;

1. Upon installation of the equipment;
2. Following any change in the initial arrangement, number, or type of local components in the system;
3. Following any maintenance requiring the disassembly or removal of a local component in the system;
4. During the performance of maintenance and alignment procedures require the presence of the primary x-ray beam when any local component in the system is disassembled or

removed;

5. Any time a visual inspection of the local components in the system reveals an abnormal condition; and

6. Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the limits specified in 420-3-26-.03(2).

7. Notwithstanding the radiation survey requirements in 420-3-26-.11(4)(b), quarterly radiation surveys are not required for devices with a maximum energy of 70 kVp or less.

(c) ~~Posting.~~ Each area or room containing analytical x-ray equipment that is not under constant surveillance shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words "CAUTION-X-RAY EQUIPMENT," or words having a similar intent.

(5) Operating Requirements.

(a) ~~Procedures.~~ Normal operating procedures shall be written and available to all analytical x-ray equipment workers. No person shall be permitted to operate analytical x-ray equipment in any manner other than that specified in the procedures unless such person has obtained written approval of the individual designated to the Agency as the Radiation Safety Officer.

(b) ~~Bypassing.~~ No person shall bypass a safety device unless such person has obtained the approval of the designated Radiation Safety Officer. When a safety device has been bypassed, a readily discernible sign bearing the words "SAFETY DEVICE NOT WORKING," or words having a similar intent, shall be placed on the radiation source housing.

(6) Personnel Requirements.

(a) **Instruction.** No person shall be permitted to operate or maintain analytical x-ray equipment unless such person has received instructions in and demonstrated competence as to:

1. Identification of radiation hazards associated with the use of the equipment.

2. Significance of the various radiation warning and safety devices incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases.

3. Proper operating procedures for the equipment.

4. Biological effects of radiation, including symptoms of acute localized exposure;

and

5. Proper procedures for reporting an actual or suspected exposure.

(b) Personnel Monitoring. Finger or wrist dosimetry devices shall be provided to and shall be used by:

1. Analytical x-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device, and

2. Personnel maintaining analytical x-ray equipment, if the maintenance procedures require the presence of the primary x-ray beam when any local component in the analytical x-ray system is disassembled or removed.

In reporting dose values, due consideration should be given to the energy of the x-ray beam and the size of the x-ray beam.

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

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

History: New 9-15-76; Recodified 6-11-78; Revised and Repromulgated 10-21-81; Repromulgated effective 12-31-83. Revised and Repromulgated effective 1-31-90.