

APA-1
11/96

TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION

Control 420 Alabama Department of Public Health

Rule Number 420-3-26-.08

Rule Title The Registration of Particle Accelerators

XXXX New Amend XXXX 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 B. Bie 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-.08, The Registration of Particle Accelerators

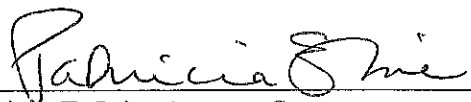
INTENDED ACTION: Repeal and New

SUBSTANCE OF PROPOSED ACTION: To repeal and replace rules that did not adequately address new technologies and modalities involving particle accelerators that have occurred since the last rules revision.

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-.08 The Registration of Particle Accelerators

(1) **Purpose.** This Rule, 420-3-26-.08, provides for the registration of particle accelerators.

(2) **Scope.** No person shall receive, possess, use, transfer, own, operate, or acquire a particle accelerator except as authorized in a Notice of Registration or as otherwise provided for in this Rule, 420-3-26-.08.

(3) **Definitions.** As used in this Rule, 420-3-26-.08:

(a) "Act" means Act No. 582, Alabama Law, Regular Session, 1963, codified as 22-14-1, Code of Alabama, 1975.

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

(c) "Authorized medical physicist" means an individual who:

1. Meets the requirements in 420-3-26-.08(10)(a)3. and 4. or, is identified as an authorized medical physicist on an Agreement State or Licensing State accelerator registration that authorizes the medical use of accelerators; and

2. Is identified as an authorized medical physicist on a medical use accelerator registration issued by the Agency.

(d) "Authorized user" means a physician who:

1. Meets the requirements in 420-3-26-.08(10)(a)2. and 4. or is identified as an authorized user on an Agreement State or Licensing State registration that authorizes the medical use of accelerators; and

2. Is identified as an authorized user on a medical use accelerator registration issued by the Agency.

(e) "Industrial Radiography" means the examination of the macroscopic structure of materials by nondestructive methods utilizing a particle accelerator.

(4) **Registration Procedures.** No registration shall be complete or valid until the person applying for registration has received a written Notice of Registration which shall be issued by the Agency in accordance with this Rule, 420-3-26-.08, or is exempted from such requirement by this Rule, 420- 3-26-.08.

(5) **Notice of Registration-Exemptions.** A Notice of Registration is not required:

(a) To transfer, own, receive, acquire, or possess a particle accelerator when such devices are in storage or disassembled, or otherwise incapable of intentional or accidental operation. Each person receiving such particle accelerator shall, within thirty (30) days after the receipt of the particle accelerator, notify the Agency of the type of particle accelerator and the name and address of the person supplying the particle accelerator.

(b) For electrical equipment that is not primarily intended to produce radiation and does not produce a radiation level greater than 0.5 mrem per hour 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.

(6) **Transfer of Particle Accelerators.** Any person transferring a particle accelerator shall, within thirty (30) days after the end of the calendar quarter in which any particle accelerator is transferred, notify the Agency of the type of particle accelerator and the name and address of the person to whom the particle accelerator was supplied.

(7) **Filing of Application for Notice of Registration.**

(a) Application for a Notice of Registration shall be filed on a form prescribed by the Agency.

(b) The Agency may at any time after the filing of the original application, and before the expiration of the Notice of Registration, require further statements in order to enable the Agency to determine whether the application should be granted or denied, or whether the Notice of Registration should be modified or revoked.

(c) Each application shall be signed by the applicant or registrant or a person duly authorized to act for and on his behalf.

(d) An application for a Notice of Registration may include a request for the registration of one or more activities.

(e) Applications and documents submitted to the Agency may be made available for public inspection except that the Agency may withhold any document or part thereof from public inspection if disclosure of its contents is not required in the public interest and would adversely affect the interest of a person concerned.

(8) **Application for Amendments to Notices of Registration.** In addition to the requirements specified in 420-3-26-.08(15), a registrant shall apply for, and shall receive, an amendment before:

- (a) Making any change in the accelerator room shielding;
- (b) Making any change in the location of the Particle Accelerator within the accelerator room;
- (c) Using the Particle Accelerator in a manner that could result in increased radiation levels in areas outside the accelerator room;
- (d) Relocating the Particle Accelerator;
- (e) Allowing an individual who is not a visiting medical physicist pursuant to 420-3-26-.09(8)(h) or is not listed on the Notice of Registration to perform the duties of a medical physicist; or
- (f) Allowing any physician who is not a visiting authorized user pursuant to 420-3-26-.09(8)(k) or is not listed on the Notice of Registration to prescribe radiation treatments for humans.

(9) **General Requirements for the Issuance of a Notice of Registration.** A registration application will be approved if the Agency determines that:

- (a) The applicant is qualified by reason of training and experience to use the particle accelerator and any associated radioactive material¹ for the purpose requested, in accordance with these rules, in such a manner as to minimize danger to public health and safety or property;
- (b) The applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety or property;
- (c) The issuance of the Notice of Registration will not be harmful to the health and safety of the public;
- (d) The applicant has appointed a radiation safety officer who will advise and assist on radiological safety problems;
- (e) The applicant and the applicant's staff have substantial experience in the use of particle accelerators;
- (f) The applicant has an adequate training program for operators of particle accelerators;
- (g) The applicant has established and submits to the Agency satisfactory written operating and emergency procedures; and

¹ See Rule 420-3-26-.02 for the licensing of such radioactive material.

(h) The applicant satisfies any applicable special requirements in this Rule, 420-3-26-.08.

(10) Special Requirements for Issuance of a Notice of Registration for Particle Accelerators.

(a) Human Use. In addition to the requirements set forth in 420-3-26-.08(9) above, a Notice of Registration for human use of a particle accelerator in the practice of medicine will be issued only if:

1. The applicant has access to adequate facilities for the clinical care of patients.
2. The registrant requires the authorized user to be a physician who:

(i) Is certified in:

(I) Radiation oncology or therapeutic radiology by the American Board of Radiology or Radiology (combined diagnostic and therapeutic radiology program) by the American Board of Radiology prior to 1976; or

(II) Radiation oncology by the American Osteopathic Board of Radiology; or

(III) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology;" or

(IV) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(ii) Is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit, five-hundred (500) hours of supervised work experience, and a minimum of three (3) years of supervised clinical experience.

(I) To satisfy the requirement for instruction, the classroom and laboratory training shall include:

- I. Radiation physics and instrumentation;
- II. Radiation protection;
- III. Mathematics pertaining to the use and measurement of ionization radiation; and
- IV. Radiation biology.

(II) To satisfy the requirement for supervised work experience, training shall be under the supervision of an authorized user and shall include:

- I. Review of the full calibration measurements and periodic quality assurance checks;
- II. Evaluation of prepared treatment plans and calculation of treatment times/patient treatment settings;
- III. Using administrative controls to prevent misadministrations;
- IV. Implementing emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit or console; and
- V. Checking and using radiation survey meters.

(III) To satisfy the requirement for a period of supervised clinical experience, training shall include one (1) year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two (2) years of clinical experience in therapeutic radiology under the supervision of an authorized user. The supervised clinical experience shall include:

- I. Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations/contraindications;
- II. Selecting proper dose and how it is to be administered;
- III. Calculating the therapeutic radiation machine doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses and/or treatment plans as warranted by patients' reaction to radiation; and
- IV. Post-administration follow-up and review of case histories.

(iii) A physician shall not act as an authorized user for any therapeutic radiation machine until such time as said physician's training has been reviewed and approved by the Agency.

3. The applicant has designated a medical physicist on the application. The registrant for any therapeutic radiation machine subject to 420-3-26-.08(10) shall require the Medical Physicist to:

- (i) Be certified by the American Board of Radiology in:
 - (I) Therapeutic radiological physics; or
 - (II) Roentgen-ray and gamma-ray physics; or
 - (III) X-ray and radium physics; or
 - (IV) Radiological physics; or
- (ii) Be certified by the American Board of Medical Physics in Radiation Oncology Physics; or
- (iii) Be certified by the Canadian College of Medical Physics; or
- (iv) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university, and have completed one (1) year of full time training in medical physics and an additional year of full-time work experience under the supervision of an Authorized Medical Physicist. This training and work experience shall be conducted in clinical radiation facilities that provide high-energy external beam radiation therapy (photons and electrons with energies greater than or equal to one MV/one MeV). To meet this requirement, the individual shall have performed the tasks listed in 420-3-26-.09(8)(d)(g) and (i) under the supervision of an Authorized Medical Physicist during the year of work experience.

4. The training and experience specified in this rule must have been obtained within the seven (7) years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

5. Visiting Authorized User.

(i) A registrant may permit a physician to act as a visiting authorized user of a particle accelerator in the practice of medicine under the terms and conditions of the registrant's registration for 60 days each calendar year if:

(I) The visiting authorized user has the prior written permission of the registrant's management, and the Radiation Safety Committee if a committee is required;

(II) The registrant has a copy of an Agency registration that identifies the visiting authorized user, by name, as an authorized user of a particle accelerator in the practice of medicine; and

(III) The visiting authorized user performs only those procedures:

I. For which they are specifically authorized to perform on an Agency registration;
and,

II. Which are specifically approved on the registrant's registration.

(ii) A registrant need not apply for a registration amendment in order to permit a visiting authorized user to use a particle accelerator in the practice of medicine.

(iii) A registrant shall retain copies of the records specified in 420-3-26-.08(10)(a)5.(i) for 3 years from the date of the last visit.

6. Visiting Authorized Medical Physicist.

(i) A registrant may permit a medical physicist to act as a visiting authorized medical physicist and perform the duties of a medical physicist under the terms and conditions of the registrant's registration for 60 days each calendar year if:

(I). The visiting authorized medical physicist has the prior written permission of the registrant's management, and the radiation safety committee if a committee is required; and,

(II) The registrant has a copy of an Agency registration that identifies the visiting authorized medical physicist, by name, as an authorized medical physicist.

(ii) A registrant need not apply for a registration amendment in order to permit a visiting authorized medical physicist to perform registered duties as described in 420-3-26-.09.

(iii) A registrant shall retain copies of the records specified in 420-3-26-.08(10)(a)6.(i) for 3 years from the date of the last visit.

(b) Research and Development. In addition to the requirements of 420-3-26-.08(9) above, a Notice of Registration for the use of a particle accelerator in research and development will be issued only if:

1. The applicant's staff has substantial experience in the use of particle accelerators for a variety of research and development uses;

2. The applicant has established a radiation safety committee (composed of such persons as a radiation safety officer, one or more persons trained or experienced in the safe use of particle accelerators, and a representative of management or the administration) which will review and approve, in advance, proposals for research, diagnostic, and therapeutic uses.

(c) Industrial Radiography. In addition to the requirements set forth in 420-3-26-.08(9) above, a Notice of Registration for use of a particle accelerator in industrial radiography will be issued only if;

1. The licensee or registrant does not permit any individual to act as a radiographer using a particle accelerator until the individual has received at least 40 hours of training in the subjects outlined in 420-3-26-.08(10)(e)7., in addition to on the job training consisting of hands-on experience under the supervision of a radiographer, is certified through a radiographer certification program by a certifying entity in accordance with the criteria specified in Appendix A of Rule 420-3-26-.04, and has on their person a valid certification ID card issued by a certifying entity. The on the job training shall include a minimum of 160 hours of active participation in the performance of industrial radiography utilizing radiation machines.

2. In addition, the registrant may not permit any individual to act as a radiographer until the individual:

(i) Has received copies of and instruction in the requirements described in the applicable sections of Rules 420-3-26-.01, 420-3-26-.02, 420-3-26-.03, 420-3-26-.04, 420-3-26-.08, 420-3-26-.09 and 420-3-26-.10, in the registration under which the radiographer will perform industrial radiography, and the registrant's operating and emergency procedures;

(ii) Has demonstrated an understanding of items in 420-3-26-.08(10)(e)2.(i) by successful completion of a written or oral examination;

(iii) Has received training in the use of the registrant's radiation machines, in the daily inspection of devices and associated equipment, and in the use of radiation survey instruments; and

(iv) Has demonstrated understanding of the use of the equipment described in 420-3-26-.08(10)(e)2.(iii) by successful completion of a practical examination.

3. The registrant may not permit any individual to act as a radiographer's assistant until the individual:

(i) Has received copies of and instruction in the applicable sections of Rules 420-3-26-.01, 420-3-26-.02, 420-3-26-.03, 420-3-26-.04, 420-3-26-.08, 420-3-26-.09 and 420-3-26-.10, in the registration under which the radiographer's assistant will perform industrial radiography, and the registrant's operating and emergency procedures;

(ii) Has demonstrated an understanding of items in 420-3-26-.08(10)(e)3.(i) by successful completion of a written or oral examination;

(iii) Under the personal supervision of a radiographer, has received training in the use of the registrant's radiation machines, in the daily inspection of devices and associated equipment, and in the use of radiation survey instruments; and

(iv). Has demonstrated understanding of the use of the equipment described in 420-3-26-.08(10)(e)3.(iii) by successful completion of a practical examination.

4. The registrant shall provide annual refresher safety training for each radiographer and radiographer's assistant at intervals not to exceed 12 months.

5. Except as provided in 420-3-26-.08(10)(c)5.(iv), the radiation safety officer or designee shall conduct an inspection program of the job performance of each radiographer and radiographer's assistant to ensure that the Agency rules, registration requirements, and operating and emergency procedures are followed. The inspection program must:

(i) Include observation of the performance of each radiographer and radiographer's assistant during an actual industrial radiographic operation, at intervals not to exceed 6 months; and

(ii) Provide that, if a radiographer or a radiographer's assistant has not participated in an industrial radiographic operation for more than 6 months since the last inspection, the radiographer must demonstrate knowledge of the training requirements of 420-3-26-.08(10)(e)2.(i) and the radiographer's assistant must demonstrate knowledge of the training requirements of 420-3-26-.08(10)(e)3.(i) by a practical examination before these individuals can next participate in a radiographic operation.

(iii) The Agency may consider alternatives in those situations where the individual serves as both radiographer and radiation safety officer.

(iv) In those operations where a single individual serves as both radiographer and radiation safety officer, and performs all radiography operations, an inspection program is not required.

6. The registrant shall maintain records of the required training to include certification documents, written, oral and practical examinations, refresher safety training and inspections of job performance for three (3) years following termination of employment.

7. The registrant shall include the following subjects in their forty (40) hour training program:

(i) Fundamentals of radiation safety including:

(I) Characteristics of gamma and x-radiation;

(II) Units of radiation dose;

(III) Hazards of exposure to radiation;

- (IV) Levels of radiation from sources of radiation; and
- (V) Methods of controlling radiation dose (time, distance, and shielding);
- (ii) Radiation detection instruments including:
 - (I) Use, operation, calibration, and limitations of radiation survey instruments;
 - (II) Survey techniques; and
 - (III) Use of personnel monitoring equipment;
- (iii) Equipment to be used including:
 - (I) Operation and control of radiation machines; and
 - (II) Inspection and maintenance of equipment.
- (iv) The requirements of pertinent state and federal regulations; and
- (v) Case histories of accidents in radiography.

8. The applicant has established and submits to the Agency satisfactory written operating and emergency procedures as described in 420-3-26-.04(17); and,

9. The applicant submits to the Agency a description of his overall organizational structure pertaining to the industrial radiography program, including specified delegations of authority and responsibility for operation of the program.

(d) Production of Radioactive Materials.² In addition to the requirements set forth in 420-3-26-.08(9) above, a Notice of Registration for the production of multiple quantities or types of radioactive materials by a particle accelerator will be issued only if:

1. The applicant's staff has substantial experience in the use of particle accelerators to produce a variety of radioactive materials;

2. The applicant has an adequate training program for particle accelerator operators consisting of;

- (i) Initial training;

² See Rule 420-3-26-.02 for the licensing requirements for the possession of such radioactive materials.

- (ii) Periodic training;
- (iii) On-the-job training; and
- (iv) A means to be used by the applicant to determine the operator's knowledge and understanding of and ability to comply with or use:

- I. Agency rules;
- II. Applicant's operating and emergency procedures;
- III. Survey instruments as required by these rules; and,
- IV. Personnel monitoring equipment:

3. The applicant has an adequate training program for staff personnel for possession and use of radioactive materials produced by the accelerator.

(e) Modification of the Structure, Chemical Composition, or Bacterial Composition of Materials. In addition to the requirements set forth in 420-3-26-.08(9) above, a Notice of Registration for the modification of the structure, chemical composition, or bacterial composition of materials by a particle accelerator will be issued only if:

- 1. The applicant's staff has substantial experience in the modification of materials;
- 2. The applicant has an adequate training program for the training of the particle accelerator operators consisting of:

- (i) Initial training;
- (ii) Periodic training;
- (iii) On-the-job training;
- (iv) A means of determining the operator's knowledge and understanding of and ability to comply with or use:

- I. Agency rules;
- II. The applicant's operating and emergency procedures;
- III. Survey instruments as required by these rules; and

IV. Personnel monitoring equipment.

(10) **Issuance of a Notification of Registration.**

(a) Upon a determination that an application meets the requirements of the Act and the rules of the Agency, the Agency will issue a Notice of Registration authorizing the proposed activity.

(b) The Agency may incorporate in any Notice of Registration at the time of issuance, or thereafter by appropriate rule, regulation, or order, such additional requirements with respect to the registrant's particle accelerator subject to the Rule 420-3-26-.08 as it deems appropriate or necessary in order to:

1. Minimize danger to public health and safety or property;
2. Require the maintenance of specific records and the reporting of specific information to the Agency; and
3. Require necessary inspections, calibrations and output checks.

(12) **Specific Terms and Conditions of the Notice of Registration.**

(a) Each Notice of Registration issued pursuant to this Rule 420-3-26-.08 shall be subject to all the provisions of the Act, now or hereafter in effect, and to all rules, regulations, and orders of the Agency.

(b) Each person registered by the Agency pursuant to this Rule 420-3-26-.08 shall confine his use and possession of the particle accelerator registered to the locations and purposes authorized in the Notice of Registration.

(13) **Expiration of Registration.** Except as provided in 420-3-26-.08(14)(b), each Notice of Registration shall expire at the end of the day, in the month and year stated therein.

(14) **Renewal of Registration.**

(a) Applications for renewal of a Notice of Registration shall be filed in accordance with 420-3-26-.08(7).

(b) In any case in which a registrant, not less than thirty (30) days prior to expiration of his existing Notice of Registration, has filed an application in proper form for renewal or for a new Notice of Registration authorizing the same activities, such existing Notice of Registration shall not expire until the application has been finally determined by the Agency.

(15) **Amendment of Notice of Registration at Request of Registrant.** Applications for amendment of a Notice of Registration shall be filed in accordance with 420-3-26-.08(8) and shall specify the respects in which the registrant desires his Notice of Registration to be amended and the grounds for such amendment.

(16) **Agency Action on Application to Renew or Amend.** In considering an application by a registrant to renew or amend his Notice of Registration, the Agency will apply the criteria set forth in 420-3-26-.08(9), and 420-3-26-.08(10) as applicable.

(17) **Inalienability of Notice of Registration.** No Notice of Registration issued or granted under this Rule and no right to utilize a particle accelerator granted by any Notice of Registration issued pursuant to this Rule shall be transferred, assigned, or in any manner disposed of, either voluntarily, directly, or indirectly, through transfer of control of any Notice of Registration to any persons unless the agency shall, after securing full information find that the transfer is in accordance with the provisions of the act, and shall give its consent in writing.

(18) **Modification, Revocation, and Termination of a Notice of Registration.**

(a) A Notice of Registration shall be subject to amendment, revision, or modification or the Notice of Registration may be suspended or revoked by reason of amendments to the Act, or by reason of rule, regulations, or orders issued by the Agency.

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

(c) Except in cases of willfulness, or those in which the public health, interest or safety requires otherwise, no Notice of Registration shall be modified, suspended, or revoked unless, prior to the institution of proceedings, 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.

(d) The Agency may terminate a Notice of Registration upon request submitted by the registrant to the Agency in writing.

Author: Karl David Walter, Assistant Director, 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 3-18-70; Repromulgated 8-21-74; Revised 1-18-78; Recodified 6-11-78; Revised and Repromulgated 10-21-81; Repromulgated effective 12-31-83. Revised and Repromulgated effective 1-31-90. Revised and Repromulgated effective 12-18-96.

Repeal

420-3-26-.08

THE REGISTRATION OF PARTICLE ACCELERATORS

- (1) **Purpose.** This Rule 420-3-26-.08 provides for the registration of particle accelerators.
- (2) **Scope.** No person shall receive, possess, use, transfer, own, operate, or acquire a particle accelerator except as authorized in a Notice of Registration or as otherwise provided for in this Rule 420-3-26-.08.
- (3) **Definitions.** As used in this Rule 420-3-26-.08:
 - (a) "Act" means Act No. 582, Alabama Law, Regular Session, 1963, codified as 22-14-1, Code of Alabama.
 - (b) "Agency" means the State Board of Health.
 - (c) "Industrial Radiography" means the examination of the macroscopic structure of materials by nondestructive methods utilizing a particle accelerator.

REGISTRATION

- (4) **Registration Procedures.** No registration shall be complete or valid until the person applying for registration has received a written Notice of Registration which shall be issued by the Agency in accordance with this Rule 420-3-26-.08, or is exempted from such requirement by this Rule 420- 3-26-.08.
- (5) **Notice of Registration-Exemptions.** A Notice of Registration is not required:
 - (a) To transfer, own, receive, acquire, or possess a particle accelerator when such devices are in storage or disassembled, or otherwise incapable of intentional or accidental operation. Each person receiving such particle accelerator shall, within thirty (30) days after the receipt of the particle accelerator, notify the Agency of the type of particle accelerator and the name and address of the person supplying the particle accelerator.
 - (b) For electrical equipment that is not primarily intended to produce radiation and does not produce a radiation level greater than 0.5 mrem per hour 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.

(6) **Transfer of Particle Accelerators.** Any person transferring a particle accelerator shall, within thirty (30) days after the end of the calendar quarter in which any particle accelerator is transferred, notify the Agency of the type of particle accelerator and the name and address of the person to whom the particle accelerator was supplied.

(7) **Filing of Application for Notice of Registration.**

(a) Application for a Notice of Registration shall be filed on a form prescribed by the Agency.

(b) The Agency may at any time after the filing of the original application, and before the expiration of the Notice of Registration, require further statements in order to enable the Agency to determine whether the application should be granted or denied, or whether the Notice of Registration should be modified or revoked.

(c) Each application shall be signed by the applicant or registrant or a person duly authorized to act for and on his behalf.

(d) An application for a Notice of Registration may include a request for the registration of one or more activities.

(e) Applications and documents submitted to the Agency may be made available for public inspection except that the Agency may withhold any document or part thereof from public inspection if disclosure of its contents is not required in the public interest and would adversely affect the interest of a person concerned.

(8) **Application for Amendments to Notices of Registration.** In addition to the requirements specified in 420-3-26-.08(14), a registrant shall apply for, and shall receive, an amendment before:

(a) Making any change in the accelerator room shielding;

(b) Making any change in the location of the Particle Accelerator within the accelerator room;

(c) Using the Particle Accelerator in a manner that could result in increased radiation levels in areas outside the accelerator room;

(d) Relocating the Particle Accelerator;

(e) Allowing an individual who is not a visiting teletherapy physicist pursuant to 420-3-26-.09(8)(f) or is not listed on the Notice of Registration to perform the duties of a teletherapy

physicist; or

(f) Allowing any physician who is not a visiting authorized user pursuant to 420-3-26-.09(8)(i) or is not listed on the Notice of Registration to prescribe radiation treatments for humans.

(9) **General Requirements for the Issuance of a Notice of Registration.** A registration application will be approved if the Agency determines that:

(a) The applicant is qualified by reason of training and experience to use the particle accelerator and any associated radioactive material¹ for the purpose requested, in accordance with these rules, in such a manner as to minimize danger to public health and safety or property;

(b) The applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety or property;

(c) The issuance of the Notice of Registration will not be harmful to the health and safety of the public;

(d) The applicant has appointed a radiological safety officer who will advise and assist on radiological safety problems;

(e) The applicant has established and submits to the Agency satisfactory written operating and emergency procedures; and

(f) The applicant satisfies any applicable special requirements in this Rule 420-3-26-.08.

(10) **Special Requirements for Issuance of a Notice of Registration for Particle Accelerators.**

(a) **Human Use.** In addition to the requirements set forth in 420-3-26-.08(9) above, a Notice of Registration for human use of a particle accelerator in the practice of medicine will be issued only if:

1. The applicant has access to adequate facilities for the clinical care of patients.

2. Each physician designated on the application as an individual user has the training and experience delineated in 420-3-26-.07(75).

¹ See Rule 420-3-26-.02 for the licensing of such radioactive material.

3. The applicant has designated a teletherapy physicist on the application who has the training and experience delineated in 420-3-26-.07(76).

(b) **Research and Development.** In addition to the requirements of 420-3-26-.08(9) above, a Notice of Registration for the use of a particle accelerator in research and development will be issued only if:

1. The applicant's staff has substantial experience in the use of particle accelerators for a variety of research and development uses;

2. The applicant has established a radiation safety committee (composed of such persons as a radiological safety officer, one or more persons trained or experienced in the safe use of particle accelerators, and a representative of management or the administration) which will review and approve, in advance, proposals for such use.

(c) **Industrial Radiography.** In addition to the requirements set forth in 420-3-26-.08(8) above, a Notice of Registration for use of a particle accelerator in industrial radiography will be issued only if;

1. The applicant has an adequate program for training radiographers and radiographer's assistants and submits to the Agency a schedule or description of such program which specifies the:

(i) Initial training;

(ii) Periodic training;

(iii) On-the-job training;

(iv) Means to be used by the registrant to determine the radiographer's knowledge and understanding of and ability to comply with Agency rules and the operating and emergency procedures of the applicant; and,

(v) Means to be used by the registrant to determine the radiographer's knowledge and understanding of and ability to comply with Agency rules and the operating and emergency procedures of the applicant;

2. The applicant submits a completed Form ARC-20 for each person who is to perform the duties of a radiographer.

3. The applicant has established and submits to the Agency satisfactory written operating and emergency procedures as described in 420-3-26-.04(15);

4. The applicant has an adequate internal inspection system, or other management control, to assure that regulations, and the applicant's operating and emergency procedures are followed by radiographers and radiographers assistants; and,

5. The applicant submits to the Agency a description of his overall organizational structure pertaining to the industrial radiography program, including specified delegations of authority and responsibility for operation of the program.

(d) **Production of Radioactive Materials.**² In addition to the requirements set forth in 420-3-26-.08(9) above, a Notice of Registration for the production of multiple quantities or types of radioactive materials by a particle accelerator will be issued only if:

1. The applicant's staff has substantial experience in the use of particle accelerators to produce a variety of radioactive materials;

2. The applicant has an adequate training program for particle accelerator operators consisting of;

(i) Initial training;

(ii) Periodic training;

(iii) On-the-job training; and

(iv) A means to be used by the applicant to determine the operator's knowledge and understanding of and ability to comply with or use:

I. Agency rules;

II. Applicant's operating and emergency procedures;

III. Survey instruments as required by these rules; and,

IV. Personnel monitoring equipment;

² See Rule 420-3-26-.02 for the licensing requirements for the possession of such radioactive materials.

3. The applicant has an adequate training program for staff personnel for possession and use of radioactive materials produced by the accelerator.

(e) **Modification of the Structure, Chemical Composition, or Bacterial Composition of Materials.** In addition to the requirements set forth in 420-3-26-.08(9) above, a Notice of Registration for the modification of the structure, chemical composition, or bacterial composition of materials by a particle accelerator will be issued only if:

1. The applicant's staff has substantial experience in the modification of materials;

2. The applicant has an adequate training program for the training of the particle accelerator operators consisting of:

(i) Initial training;

(ii) Periodic training;

(iii) On-the-job training;

(iv) A means of determining the operator's knowledge and understanding of and ability to comply with or use:

I. Agency rules;

II. The applicant's operating and emergency procedures;

III. Survey instruments as required by these rules; and,

IV. Personnel monitoring equipment.

(10) **Issuance of a Notification of Registration.**

(a) Upon a determination that an application meets the requirements of the Act and the rules of the Agency, the Agency will issue a Notice of Registration authorizing the proposed activity.

(b) The Agency may incorporate in any Notice of Registration at the time of issuance, or thereafter by appropriate rule, regulation, or order, such additional requirements with respect to the registrant's particle accelerator subject to the Rule 420-3-26-.08 as it deems appropriate or necessary in order to:

1. Minimize danger to public health and safety or property;
2. Require the maintenance of specific records and the reporting of specific information to the Agency; and
3. Require necessary inspections, calibrations and output checks.

(12) **Specific Terms and Conditions of the Notice of Registration.**

(a) Each Notice of Registration issued pursuant to this Rule 420-3-26-.08 shall be subject to all the provisions of the Act, now or hereafter in effect, and to all rules, regulations, and orders of the Agency.

(b) Each person registered by the Agency pursuant to this Rule 420-3-26-.08 shall confine his use and possession of the particle accelerator registered to the locations and purposes authorized in the Notice of Registration.

(13) **Expiration of Registration.** Except as provided in 420-3-26-.08(14)(b), each Notice of Registration shall expire at the end of the day, in the month and year stated therein.

(14) **Renewal of Registration.**

(a) Applications for renewal of a Notice of Registration shall be filed in accordance with 420-3-26-.08(7).

(b) In any case in which a registrant, not less than thirty (30) days prior to expiration of his existing Notice of Registration, has filed an application in proper form for renewal or for a new Notice of Registration authorizing the same activities, such existing Notice of Registration shall not expire until the application has been finally determined by the Agency.

(15) **Amendment of Notice of Registration at Request of Registrant.** Applications for amendment of a Notice of Registration shall be filed in accordance with 420-3-26-.08(7) and shall specify the respects in which the registrant desires his Notice of Registration to be amended and the grounds for such amendment.

(16) **Agency Action on Application to Renew or Amend.** In considering an application by a registrant to renew or amend his Notice of Registration, the Agency will apply the criteria set forth in 420-3-26-.08(9), and 420-3-26-.08(10) as applicable.

(17) **Inalienability of Notice of Registration.** No Notice of Registration issued or granted under this Rule and no right to utilize a particle accelerator granted by any Notice of

Registration issued pursuant to this Rule shall be transferred, assigned, or in any manner disposed of, either voluntarily, directly, or indirectly, through transfer of control of any Notice of Registration to any persons unless the agency shall, after securing full information find that the transfer is in accordance with the provisions of the act, and shall give its consent in writing.

(18) Modification, Revocation, and Termination of a Notice of Registration.

(a) A Notice of Registration shall be subject to amendment, revision, or modification or the Notice of Registration may be suspended or revoked by reason of amendments to the Act, or by reason of rule, regulations, or orders issued by the Agency.

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

(c) Except in cases of willfulness, or those in which the public health, interest or safety requires otherwise, no Notice of Registration shall be modified, suspended, or revoked unless, prior to the institution of proceedings, 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.

(d) The Agency may terminate a Notice of Registration upon request submitted by the registrant to the Agency in writing.

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.

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