

**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 material<sup>1</sup> 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,

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

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).
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.**<sup>2</sup> 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;

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

- (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:
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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